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AN OVERVIEW: GASTRORETENTIVE DRUG DELIVERY SYSTEM

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ABSTRACT

Gastroretentive drug delivery systems (GRDDS) are an important area of oral controlled-release research, targeting prolonged gastric residence time (GRT) to enhance the bioavailability and therapeutic performance of drugs with narrow absorption windows, instability in alkaline pH, or requiring local gastric action. Human gastric physiology with gastric emptying increasing from 1–2 h in fasted to over 4 h in fed state, pH ranging 1.2–3.5, and migrating motor complex cycles of 90–120 min provides the basis for GRDDS development. Major approaches include floating systems (density <1.004 g/cm³), mucoadhesive systems (chitosan, alginate, carbomers), high/low-density dosage forms, expandable systems exceeding 1.5–2 cm, raft-forming formulations, and magnetic retention methods. Key formulation aspects involve polymer selection (HPMC, xanthan gum), swelling behavior, porosity control, and buoyancy-enhancing excipients. Essential in vitro tests include floating lag time, total floating duration, swelling, mucoadhesion, and dissolution in biorelevant gastric media. Challenges include gastric variability, stability issues, obstruction risks, and scale-up difficulties. Innovations such as nanotechnology-based systems, hybrid mechanisms, personalized 3D/4D-printed forms, and stimuli-responsive polymers offer improved retention. Regulatory priorities emphasize IVIVC, consistent performance, and validated protocols. Overall, this review provides a

comprehensive understanding of GRDDS and highlights research needs for their successful commercial translation.

KEYWORDS: Gastroretentive drug delivery system, floating system, controlled release.

INTRODUCTION

Among the various delivery routes, oral drug delivery is the most favorable route for systemic purposes due to its user-friendly route, cost-effectiveness, patient compliance, and overall formulation convenience.[3] However, traditional oral dosage forms are ineffective at maintaining drug concentrations for an extended period of time due to pre- and post-dose physiological difficulties experienced in the GI tract, including variability in gastric emptying, mixed pH, drug degradation from enzymatic degradation, or rapid gastrointestinal transit.[4]

Particularly, drugs that are naturally absorbed in the stomach or proximal small intestine, or degraded in higher pH, and drugs that require a local gastric drug action are particularly favorable for prolonged gastric retention approaches.[5] Gastroretentive drug delivery systems (GRDDS) aim to prolong gastric retention time for a dosage form to allow for sustained or controlled drug release from the upper gastrointestinal region.[6] GRDDS dosage forms increase the bioavailability of drugs, reduce the frequency of a patient's dose, and improve therapeutic effectiveness and patient compliance.[3] To develop successful GRDDS, one must explore physiological, formulation, and evaluation factors to produce comparable dosage forms with similar performance consistency.[2]

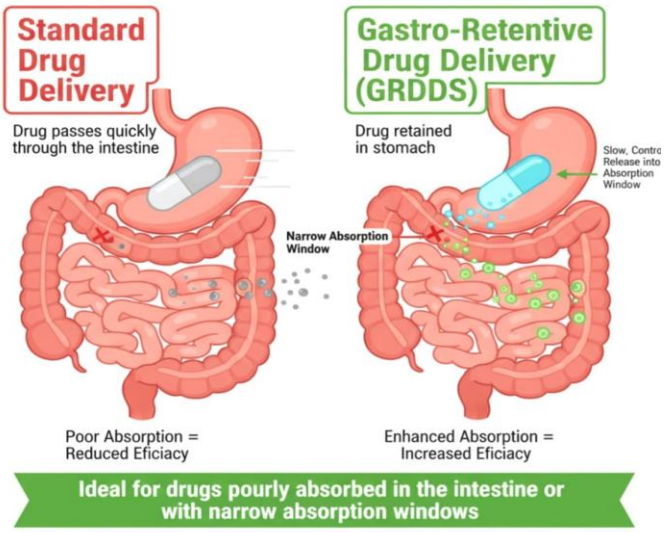

Fig. 1: Standard vs. Gastroretentive Drug Delivery.

Physiological Considerations for Gastric Retention

Understanding the gastric environment and factors influencing gastric emptying and motility is critical to designing effective GRDDS.[7]

1. Gastric Anatomy and Motility

The stomach acts as a reservoir, mixing chamber, and delivery system to the small intestine.[5] In the fasted state, the stomach exhibits the migrating motor complex (MMC) characterized by cyclic phases: quiescence (phase I), small-intensity contractions (phase II), and a housekeeping wave (phase III) that clears residual material.[8] After a meal (fed state), gastric motility changes: delayed emptying, reduced housekeeper wave frequency, and increased gastric volume and pH. These factors influence how long a dosage form remains within the stomach.[7]

2. Factors Affecting Gastric Residence Time (GRT)

Several physiological and formulation-related variables influence the GRT of an oral dosage form[9]:

- **Gastric emptying rate:** influenced by meal volume, composition, caloric density, posture, age, gender, and disease states.[10]
- **Fasting vs fed state:** In the fed state, the pylorus is relatively closed and the dosage form may be retained longer, whereas in the fasted state, clearance via the MMC phase III may occur.[8]
- **Size and density of dosage form:** Larger dosage forms (>7.5 mm) and those with densities significantly higher or lower than gastric fluid can impact retention.[10]
- **Gastric pH and fluid volume:** In the fed state, pH rises and fluid volume increases; the dissolution, buoyancy, and swelling of the dosage form are affected accordingly.[9]
- **Formulation geometry and location:** Multiple unit systems vs single unit, and whether the system adheres to the gastric wall or floats on fluid.[11]

Understanding these factors helps in the rational design of GRDDS: for example, one may take advantage of the fed state to prolong GRT, or design a system with buoyancy independent of feeding conditions.[7]

METHODS FOR GASTRIC RETENTION

A variety of formulation strategies have been examined to extend gastric residence time by counteracting physiological forces that favor gastric emptying.[12] Each method has been

designed based on one or more mechanisms such as adhesion, expansion, density alteration, or magnetic force. These methods can be classified into five major types.[13]

A. Floating Drug Delivery Systems (FDDS)

Floating or low-density systems remain suspended in gastric fluid without affecting the gastric emptying rate.[6] As their density is below 1.0 g/cm³, these systems can float on top of gastric contents, and the slow release of the drug is possible.[14]

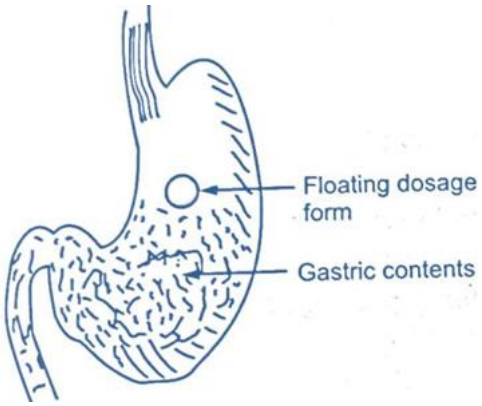

Fig. 2: Floating System.

There are two basic types of FDDS

1) Effervescent Systems

These systems contain gas-generating agents (sodium bicarbonate and citric acid) that react in the stomach and generate CO_2 within the polymer matrix, lowering density and providing buoyancy.[15]

a) Volatile Liquid/Vacuum Type

- **Inflatable System:** This system comprises a pullout mechanism containing a chamber of volatile liquids that evaporate at body temperature.[16] The inflatable chamber is comprised of a blend of bioerodible polymer filaments such as polyvinyl alcohol and polyethylene throughout its pore structure.[14] Once the polymer starts to dissolve, the drug will be released, and the inflatable chamber continues to float in the GI fluids. After the polymer is completely dissolved, the inflatable portion collapses.[16]
- **Intragastric Floating System:** It includes a vacuum chamber and has a microporous section that acts as a drug reservoir.[17] Hydroxypropyl methylcellulose (HPMC), carbopol, and xanthan gum as gel-forming agents with sodium bicarbonate and anhydrous citric acid as the effervescent mixture have shown promising results.[18]

- **Intragastric-Osmotically Controlled System:** A biodegradable capsule consisting of an inflatable floating support with an osmotic pressure-controlled drug delivery device can provide osmotic control.[19] Mesoporous silica nanoparticles preloaded with fenofibrate in push-pull osmotic pump formulations can remain in the stomach for up to 21.72 hours.[19]

b) Matrix Tablets

They are classified into two types: single-layer and bilayer matrix tablets.[20] The single-layer matrix tablets are made with a drug and a hydrocolloid forming gel, while the bilayer matrix tablet consists of a layer for immediate release and a layer for sustained release.[20] Floating matrix tablets of losartan potassium using HPMC-K4M and karaya gum as the retarding polymer, with sodium bicarbonate as the effervescent agent, have shown extended GRT to around 12 hours.[21]

c) Gas-Generating Systems

Gas-generating systems are prepared using effervescent compounds along with hydrophilic polymers.[15]

- **Floating Capsules:** These dosage forms contain drugs embedded in hydrophilic polymers (ethyl cellulose, Eudragit RS-100) and effervescent agents such as sodium bicarbonate or calcium carbonate.[22] Hydrodynamically balanced capsules of nicardipine hydrochloride have demonstrated sustained gastric retention.[22]
- **Floating Pills:** Multiple-unit floating dosage forms utilize a hydrophilic polymer outer layer and an effervescent inner layer.[23] Captopril minitabs developed utilizing gas formation with cores coated with different levels of seal coats, the effervescent layer, and the outer polymeric membrane have shown improved gastric retention.[23]
- **Floating Systems with Ion Exchange Resins:** These floating systems consist of drug-resin complex beads containing bicarbonate and water-soluble polymer coatings.[24] Systems employing Amberlite IRA-400 and Dowex resins have produced more than 24 hours of in-vitro floatation and greater than 3 hours of gastric retention.[24]

2) Non-Effervescent Systems

These systems are based on swellable polymers such as hydroxypropyl methylcellulose (HPMC), ethylcellulose, or chitosan, forming a gel barrier, allowing for lower density and prolonged floating capacity.[14]

FDDS is simple and effective; however, it can fail for the conditions of low gastric fluid volume and high motility, and is not suitable for all drugs, such as those that irritate the gastric mucosa.[6]

B. High-Density (Sinking) Systems

In this system, the dosage form is prepared with materials that have a density greater than 2.5 g/cm³ (e.g., barium sulfate, zinc oxide, iron powder).[25] The small particle density assures that it sinks to the bottom of the stomach, and because it is dense, it is likely not emptied through the pylorus.[25]

These systems would be most appropriate for non-effervescent drugs and are also independent of gastric fluid volume, but it may be difficult to formulate a dense system that does not negatively impact drug release.

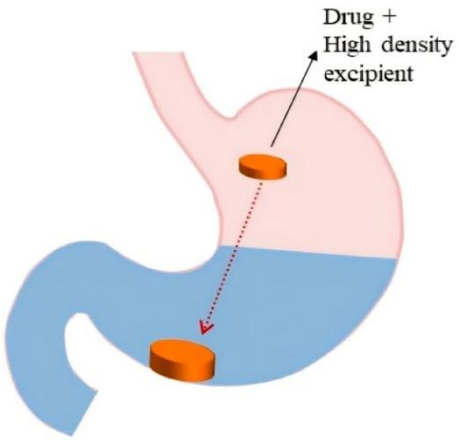

Fig. 3: High density GRDDS.

C. Mucoadhesive or Bioadhesive Systems

These systems were formulated to stick to the gastric mucin layer through both physical and chemical interactions, like electrostatic attraction, hydrogen bonding, and van der Waals interactions.[5] The polymer materials most commonly used are Carbopol, chitosan, sodium alginate, polycarbophil, and HPMC due to their hydrophilic nature and adhesive characteristics.[13]

The efficacy of the bioadhesive or mucoadhesive system is attributed to the localized drug delivery, delay in gastric emptying, and narrowing of the absorption window; however, there are hurdles associated with mucus turnover, limited area of adherence, and differences in mucosal pH.[12]

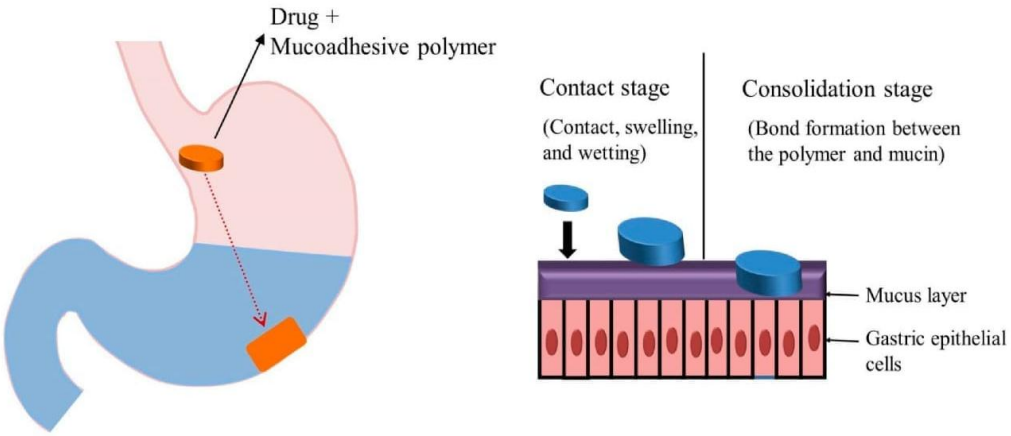

Fig. 4: Bioadhesive Systeam.

D. Raft-Forming System

Raft systems are typically liquid formulations that, upon contact with gastric acid, form a viscous, cohesive gel "raft" that floats on gastric contents.[12] The mechanism involves sodium alginate reacting with calcium ions and CO_2 generation, forming a cross-linked matrix.[26] Originally used for gastroesophageal reflux disease (e.g., alginate-based antacids), raft systems can be adapted for sustained local delivery of drugs such as antacids, antibiotics, and anti-ulcer agents.[12]

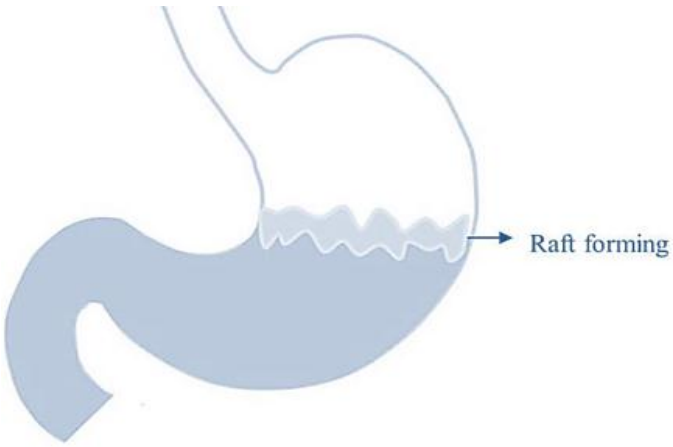

Fig 4. Raft forming system.

E. Ion-Exchange Resin Systems

These systems consist of the drug complexed to a cationic or anionic resin, which swells in the gastric fluid and exchanges ions, gradually releasing the drug.[24] By changing the crosslinking of the resin and modifying the swelling characteristics of the resin, the gastric retention and sustained release of hydrophilic drugs can be achieved.[24]

FORMULATION ASPECTS: POLYMERS, EXCIPIENTS, AND DESIGN ASPECTS OF GASTRORETENTIVE DRUG DELIVERY SYSTEM

Developing a GRDDS that produces the desired therapeutic effect requires full consideration of excipients, polymer systems, gas-generators/swelling agents, density modifiers, and their impact on release kinetics.[11]

a. Polymer Selection

Polymers utilized in GRDDS can be both natural and synthetic, and hydrophilic and hydrophobic.[11] Some examples include HPMC, Carbopol®, chitosan, sodium alginate, ethylcellulose, Eudragit®, polyvinyl alcohol (PVA), and cross-linked hydrogels.[13] The selected polymer system is preferred to be compatible with the desired mechanisms (floating, mucoadhesion, or swelling), should be biocompatible, and should support the desired release profile.[12] In the case of mucoadhesives, polymers that are hydrophilic swelling polymers or positively charged (e.g., chitosan) can be utilized.[5] In a floating GRDDS, a low-density polymer or hollow microspheres can be incorporated to create a floating system.[14]

b. Gas-Generating/Swelling Agents

In floating systems, CO_2-generating agents (sodium bicarbonate combined with citric acid) can be used to provide bubbles that reduce density and maintain stability while floating.[15] In terms of swelling/expandable systems, superporous hydrogels, cross-linked networks, or foaming agents can provide the system with rapid swelling when exposed to gastric fluids.[11]

c. Density Modifiers

To change a GRDDS to either float or sink, a formulation may contain microspheres, air-filled cavities, or hollow beads to reduce density.[14] The formulation could also incorporate high-density fillers (e.g., barium sulphate, iron oxide) in a heavy GRDDS.[25]

d. Development of Drug Release Profile

Sustained or controlled drug release is the foremost goal of several GRDDS and is dependent on the formulation providing a predictable drug release throughout gastric residence time.[12] This may be accomplished using a matrix, a reservoir, a layered tablet approach, or a multiple-unit/multiparticulate system.[13] In vitro release kinetics should be evaluated in relation to in vivo behaviour (zero order, first order, Higuchi model, Korsmeyer-Peppas indexes).[11]

e. Single Unit Versus Multiple Units

Single-unit dosage forms (tablet or capsule) provide simple systems, although they have the risk of dose dumping and variability in gastric residence time.[20] Multiple units (microspheres, pellets, or beads) provide more uniform distribution and less risk of catastrophic failure.[13]

f. Consideration of Food Effect and Patient Variable

The gastric residence time of dosage forms may be affected by various factors, including food intake, posture, the age of the patient, and the patient's disease state.[8] Hence, the formulation has to be robust enough to perform under fasted and fed conditions.[9]

EVALUATION APPROACHES

To ascertain that a GRDDS operates as anticipated, a suite of in vitro, ex vivo, and in vivo evaluation techniques is available.[12]

a. In Vitro Testing

Buoyancy/floating lag time and total floating time: Time to float in simulated gastric fluid and the time until the system maintained buoyancy.[17]

Swelling/expansion studies: Dimensional change in simulated gastric fluid for swellable/expandable systems.[11]

Adhesion strength (for mucoadhesive systems): Includes detachment force or residence time on mucosal tissue.[13]

Dissolution/release studies: Agglomeration, use of USP apparatus with simulated gastric fluid (pH 1.2) or biorelevant media, drug release kinetics, and modeling (Higuchi or Korsmeyer-Peppas models).[11]

Density/porosity measurements, micromeritic properties, and mechanical strength: For robustness assessment.[14]

Table 1: Evaluation Parameters and Their Purpose for Gastroretentive Floating Drug Delivery Systems.

Parameter	Purpose
Tablet hardness	Ensures mechanical strength of dosage form
Friability	Checks resistance to breakage during handling
Weight variation	Confirms uniformity of dosage units
Thickness	Ensures dimensional consistency
Floating lag time (FLT)	Time taken for dosage form to float
Total floating time (TFT)	Duration it remains floating
Buoyancy stability	Ensures long-term floatation
Swelling index	Measures swelling ability for retention
Water uptake study	Determines hydration behavior
Dissolution profile	Measures drug release over time
Release kinetics	Determines release mechanism
Apparent density	Ensures density < gastric fluid for floating
Matrix integrity	Checks polymer stability
Mucoadhesive strength	Measures adhesion to gastric mucosa
Ex-vivo residence time	Time dosage stays attached
X-ray / Radiographic imaging	Checks gastric retention
Scintigraphy	Tracks dosage transit
Pharmacokinetics	Measures Cmax, Tmax, AUC
Accelerated stability study	Evaluates stability under stress
Shelf-life estimation	Predicts long-term stability

b. In Vivo and Imaging Studies

In vivo studies often utilize gamma scintigraphy, X-ray imaging, or the tracking of magnetic markers to characterize gastric residence times in human volunteers or animal studies.[12] Defining the in vitro release-to-in vivo absorption relationship (IVIVC) remains a considerable challenge.[26] Some clinical studies of GRDDS have reported improved bioavailability and in vivo residence times; however, these findings remain confined to specific regions.[16]

GRDDS APPLICATIONS

There are multiple application niches for GRDDS.[3]

a. Narrow Absorption Window Drugs

Drugs that are only absorbed in the stomach or upper small intestine (e.g., riboflavin, levodopa) will benefit from increased gastrointestinal residence time and thus improved absorption.[5]

b. Unstable Drugs at Alkaline pH

Drugs that are not stable in an alkaline small intestine environment (e.g., ranitidine, metformin) will benefit from drug release in the acidic gastric environment.[5]

c. Local Drug Delivery to the Stomach

For diseases that benefit from high local gastric drug delivery (e.g., Helicobacter pylori infection, peptic ulcer), outcomes may be improved as GRDDS can maintain a high concentration of the drug within the target site for a longer time.[12]

d. Increased Bioavailability & Reduced Dosing Frequency

By prolonging the drug residence time and drug release period, an anticipated outcome of GRDDS is improved bioavailability and potentially decreased dosing frequency, leading to improved patient compliance.[6]

e. Applications in Special Populations

GRDDS was developed, particularly considering that altered gastric residence time may be applicable for the elderly population, postoperative patients, and patients with altered gastric motility.[8]

CHALLENGES AND LIMITATIONS

Although GRDDS shows potential, it faces numerous practical and regulatory obstacles[2]:

1. Substantial inter- and intra-subject variability in gastric residence time (resulting from intake of food, body position, disease, and age) leads to unpredictable pharmacokinetics.[9]
2. Many of the newer designs are still in preclinical development, with only a handful of products available on the market.[2]
3. Designing a system to retain under both fasted and fed state conditions can be challenging.[8]
4. The degree of complexity of manufacture, reproducibility, mechanical robustness, and cost can hinder commercial viability.[13]
5. The potential for dose dumping or formulation failure (as in the case of single-unit dosage forms).[20]
6. Safety issues in the event that large swellable systems do not pass through the pylorus and, also, in the event of obstruction; these types of systems may require creative thinking and regulatory considerations.[11]

7. The lack of a strong in vitro-in vivo correlation (IVIVC) for many GRDDS types.[26]
8. Limited application of the technology to drugs that provide a true benefit from gastric retention, as it is not intended to be universally applied across all drugs.[3]

FUTURE PERSPECTIVES

The future of GRDDS is promising, and several emerging trends deserve attention[1]:

a. Stimuli-Responsive and Smart Polymers

Polymers that respond to pH, temperature, magnetic field, or other stimuli allow on-demand retention or release.[1] Recent reviews highlight novel polymer systems for GRDDS.[1]

b. 3D-Printing and Additive Manufacturing

Additive manufacturing enables personalised geometry, multi-layered systems, and complex architectures (e.g., "accordion" shapes) to fine-tune retention and release characteristics.[1]

c. Combined Mechanisms and Multipronged Designs

Hybrid systems combining floating + mucoadhesive + swellable mechanisms may provide robustness across variable gastric conditions.[12]

d. Improved In Vitro-In Vivo Modelling

Better biorelevant testing models, imaging techniques, and dissolution/absorption correlation will facilitate the translation of GRDDS.[26]

e. Market Translation and Regulatory Pathways

Greater emphasis is needed on demonstration of safety, reproducibility, scalability, and cost-effectiveness to drive GRDDS into marketed products.[2]

f. Personalised Gastro-Retentive Systems

In the future, systems designed for individual patient physiology (age, gastric motility, feeding pattern) may optimise therapeutic outcomes.[1]

CONCLUSION

Gastroretentive drug delivery systems represent a flexible and exciting approach for enhancing the oral delivery of drugs that are limited by a narrow absorption window, are unstable at alkaline pH, or are meant to act locally in the stomach.[5] Numerous technological approaches - floating, mucoadhesive, high-density, expandable, raft, and magnetic systems - have been developed, each with their own benefits and limitations.[13] Formulation factors

(polymer type, density modifiers, swelling agents), assessment strategies (in vitro and in vivo), as well as a solid understanding of gastric physiology, are all critical to success.[12] Although variability in gastric retention, complicated manufacturing, and translating technologies into marketed products remain challenges, developments in smart polymers, 3D printing, and hybrid systems present very promising applications.[1] Further research and development into GRDDS may enable its use as a conventional oral drug delivery option, creating and supporting more efficacious, patient-centric therapies.[2]

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