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Gastro Retentive Drug Delivery System For Cancer Chemotherapy

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ABSTRACT: Gastric cancer remains a major cause of cancer-related mortality worldwide, largely due to late diagnosis and the systemic toxicity of conventional chemotherapy. Oral anticancer therapy is often limited by poor bioavailability, short gastric residence time, narrow absorption windows, and drug instability in the intestinal environment. Gastroretentive drug delivery systems (GRDDS) offer an effective approach to overcome these limitations by prolonging gastric retention and enabling controlled, site-specific drug release.

This review summarizes recent advances in gastroretentive drug delivery systems for cancer chemotherapy, with emphasis on gastric cancer treatment. Various GRDDS strategies, including floating, mucoadhesive, swelling, magnetic, and expandable systems, are discussed along with the role of polymers and nanocarrier-based formulations. Recent studies involving anticancer agents such as 5-fluorouracil, capecitabine, curcumin, and doxorubicin are highlighted. Overall, GRDDS show strong potential for improving the safety and efficacy of oral cancer chemotherapy.

KEYWORDS:- Gastro retentive drug delivery system; Gastric cancer; Chemotherapy; Floating drug delivery system; Mucoadhesive system; Controlled drug release; Site-specific drug delivery; 5-Fluorouracil; Capecitabine; Polymer-based drug delivery.

INTRODUCTION:-Cancer ratio increased to 19.7 million new around 9.7 million deaths in cases 2022 Cancer is Ore of cancer cause of related death worldwide → Gastric the leading Cancer Over time, lifestyle-related factors such as diet, tobacco use, alcohol consumption, and others have been linked to a rise in stomach cancer cases and poorer treatment outcomes[1]. Compared to many other types of cancer, stomach cancer has a relatively low survival rate. Treatment options for stomach cancer may include surgery,[2] chemotherapy, radiation therapy, immunotherapy, or a combination of these methods, depending on individual circumstances[3].

Chemotherapy is often paired with other treatment strategies—such as surgical procedures, hormonal treatments, or radiation—to improve effectiveness. Despite the use of standard treatments...While chemotherapy has shown some effectiveness, its clinical application is still challenged by significant side effects and a high risk of developing resistance to multiple drugs. Bernards et al. reported that conventional chemotherapy is effective in only a subset of patients, with many experiencing tumor recurrence that no longer responds to initial treatments[4]. Recent progress in controlled and site-specific drug delivery technologies has allowed pharmaceutical scientists to maintain drug concentration at the intended site for extended durations.

This approach helps reduce side effects, lowers the frequency of doses, and enhances overall patient satisfaction.[5]

Among the available methods, oral drug delivery is often favored for treating gastric diseases, as it facilitates better drug concentration at the affected stomach tissues[6]. In recent years, gastro retentive drug delivery systems (GRDDS) have been widely explored as a way to treat various stomach-related conditions.[7] The advantages of GRDDS include targeting the drug directly to the stomach, minimizing sudden drug release, overcoming delivery challenges associated with different drug types, extending the drug's residence time at the target site, lowering dosing frequency, and improving patient compliance[8]. Nevertheless, selecting the right drug compounds and polymers is essential for designing an efficient GRDDS. These systems are most suitable for powerful medications that have a narrow therapeutic range. A narrow therapeutic window, a brief half-life, activity localized within the stomach, and a tendency to degrade or become unstable in alkaline conditions[9].

According to recent research findings, gabapentin has shown effectiveness in alleviating pain among patients suffering from neuropathic cancer. However, gabapentin possesses a narrow absorption window, and its absorption depends on L-amino acid transporters. Studies indicate that extending the drug's residence time in the stomach,[10] combined with a controlled-release mechanism, enhances its bioavailability by maintaining adequate concentrations to fully saturate the transporter. Consequently, a recent clinical trial reported that a once-daily gastro retentive formulation of gabapentin was both effective and well-tolerated in the management of diabetic neuropathic pain[11].

Various drugs from different therapeutic categories and disease conditions have been explored for gastro retentive delivery systems, highlighting their wide applicability and potential benefits. Commonly studied drugs for such systems include amoxicillin, used in treating H. pylori infections; 5-fluorouracil (5-FU), employed in gastric cancer therapy; and levodopa, used for Parkinson's disease management. A number of newly developed gastro retentive formulations designed for anticancer drug delivery are summarized in Table 1.

Table 1: Composition and types of gastro retentive formulation used for anticancer drug delivery

Gastro retentive Systems	Polymer	Drug	Outcomes	Refs.
Floating mucoadhesive system (Nano micelle based floating mucoadhesive beads)	Chitosan and Sodium carboxy methyl cellulose (CMC-Na)	Emodin	* About 80% of the beads floated within 5 minutes. * 60% still floated after 8 hours. * Stuck better to the stomach lining when more CMC was added. * Released the drug in two phases (fast then slow).	1
Floating mucoadhesive sys- tem (Nano fibers)	Eudragit S-100	5-FU	* Drug-loaded fibers attached well to the stomach lining. * Very light fibers that float for more than 48 hours. * About 90% of the drug was released in 12 hours. * Stayed in the stomach for up to 12 hours.	3
Floating System (Effervescent floating matrix tablets)	Microcrystalline cellulose	Neratinib	* Floated for more than 24 hours. * Started floating within 2 minutes. * Slow and steady drug release for up to 12 hours. * Showed strong cancer-killing effects on breast cancer cells (MCF-7).	4
Swell able System (In-situ polyhydrogel)	Gellan gum	Curcumin	* Started floating in about 1–2 minutes. * Floated for over 48 hours. * Released 0.5% of the drug after 1 hour and 11% after 24 hours.	612
Floating, swelling and muco-adhesion based preparation (Microparticles)	Xanthan gum	Capecitab ine	* Showed good swelling and sticking ability. * Increased drug absorption 1.44 times compared to normal drug solution.	8
Floating system (Polymeric aggregates)	Molecular imprinted poly-mer consists of 4-methyl phenyl di cyclon hexyl	Capecitab ine	* Stayed floating for at least 24 hours. * Released about 48% of the drug in 2 hours. * Stayed in the stomach longer (over 2.5 hours).	9

	ethylene and polyhedral oligomer silsesquioxanes		* Gave more than 1.6 times better absorption than plain drug.	
Floating system (Micro-sponge)	Ethyl cellulose and polyvinyl-alcohol	Curcumin	* Good floating ability. * Released 88% of the drug by 8 hours. * 25 times better absorption than normal curcumin.	11
Floating system (Beads)	Alginate with N, N- dimethyl amino ethyl meth- acrylate	Amoxicillin trihydrate	* Density allowed long stomach retention. * Stayed in the stomach for up to 24 hours. * Killed H. pylori bacteria more effectively after 10 hours.	13
Swelling system (Hydrogel)	Locust bean gum and sodium alginate	Capecitabine	* Floated longer than 10 hours. * Swelled strongly. * Showed much better absorption than plain drug.	142
Floating system (Floating capsule)	Alginate and chitosan	Procyanidins	* Floated completely in lab tests. * Floated for 5 hours in the stomach-like conditions.	15

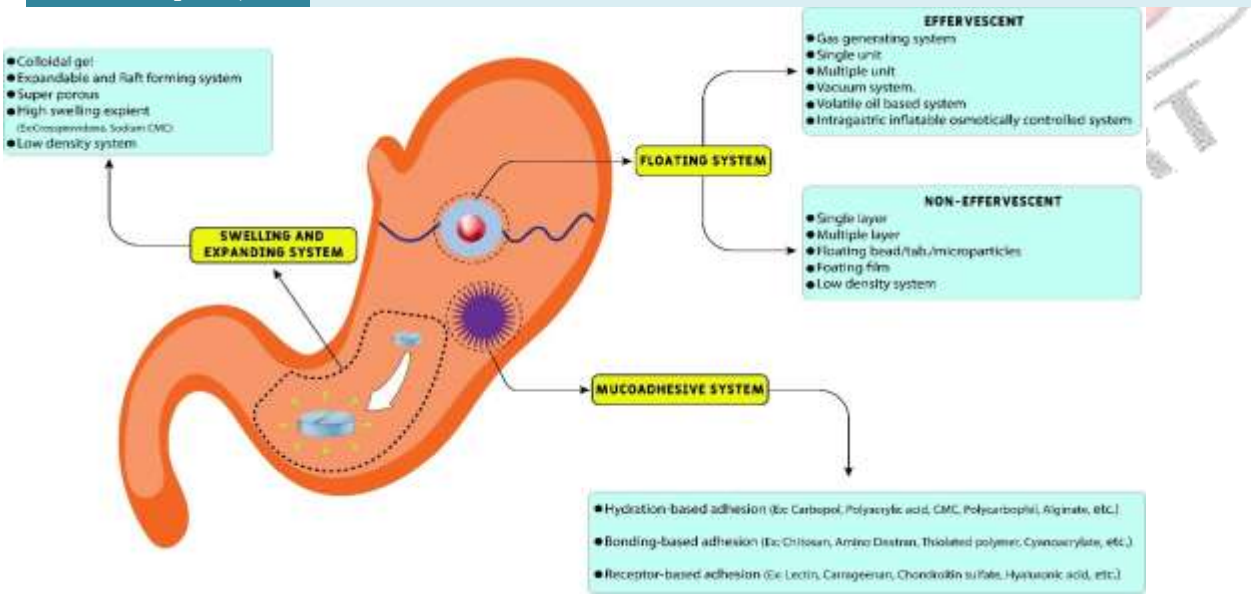

Fig 1: Major gastro-retentive drug delivery approaches used for the treatment of stomach cancer

5-Fluorouracil (5-FU) is considered the primary therapeutic option for treating gastric cancer. Nevertheless, its clinical performance is limited by its poor solubility in water and instability under alkaline conditions[1]. Compared to the pure form of the drug, Huang et al. demonstrated that 5-FU exhibited approximately 1.6 times greater bioavailability when incorporated into floating gastro retentive hollow microspheres [6]. In a similar manner, the choice of polymer significantly influences the success of gastro retentive drug delivery systems (GRDDS). An ideal GRDDS polymer should be biocompatible,[16] possess excellent mucoadhesive properties, exhibit low density, and have strong hydration and swelling capacity in simulated gastric fluid. These features promote controlled drug release and prolonged retention in the stomach.

Devoid and coworkers examined how various formulation parameters affect the buoyancy and drug release profile of Capecitabine tablets prepared using hydroxypropyl methylcellulose (HPMC), carbomer 934P, sodium alginate, and sodium bicarbonate. Their findings indicated that the optimized gastro retentive capecitabine formulation displayed a floating lag time between 30 and 200 seconds, along with sustained drug release for up to 24 hours in simulated gastric conditions[1].

Gastric cancer can originate in different regions of the stomach, including the gastroesophageal junction, fundus, cardia, pylorus, and antrum. The body of the stomach represents the most frequent site, accounting for around 40.7% of cases, followed by the pylorus, which contributes approximately 35.5%[17]. Developing site-specific delivery systems based on these anatomical regions provides significant flexibility for GRDDS design[3]. Various approaches, such as floating systems, high-density system mucoadhesive formulations, hydrodynamically controlled systems, and super porous hydrogels, have been employed to develop GRDDS (Fig. 1). Carbon nanotubes (CNTs) have recently gained attention as an effective platform for anticancer drug delivery. Due to their intrinsic biocompatibility, CNTs serve as efficient carriers capable of transporting therapeutic agents to targeted sites in a controlled manner, thereby enhancing stomach cancer treatment outcomes[4].

Doxorubicin, a chemotherapeutic agent used against gastric cancer, acts primarily by inhibiting DNA replication necessary for protein synthesis and by deactivating the topoisomerase II enzyme[3]. Despite its effectiveness, Doxorubicin also damages healthy cells. The drug's performance has been investigated using a simulated model of single-walled carbon nanotubes (SWCNTs). Results indicated that ethanol presence reduced the degree of Doxorubicin encapsulation within SWCNT cavities, thereby weakening drug–nanotube interactions. However, molecular dynamics simulations revealed that extracellular ethanol increased the pulling force on the drug molecule, promoting its release through the cell membrane. These findings suggest that alcohol plays a crucial role in modulating anticancer drug delivery in Nano carrier systems[18]. In recent years, significant progress has been achieved in the development of gastro retentive drug delivery systems (GRDDS) for the treatment of gastric cancer. Since gastric cancer initially develops within the mucosal lining of the stomach, localized drug delivery through GRDDS can potentially enhance the therapeutic effectiveness of anticancer agents. The performance and therapeutic efficiency of GRDDS largely depend on the physicochemical characteristics and structural composition of the polymers used[4].

Over the past few decades, formulation scientists have designed a variety of gastro retentive systems aimed at prolonging the residence time of drugs in the stomach and improving the efficacy of chemotherapeutic treatments. Several strategies have been adopted in the design of GRDDS—such as floating systems, magnetic field-assisted retention, mucoadhesive systems, and expandable or swellable systems—each selected based on the specific drug attributes, polymer properties, and physiological condition.[7]

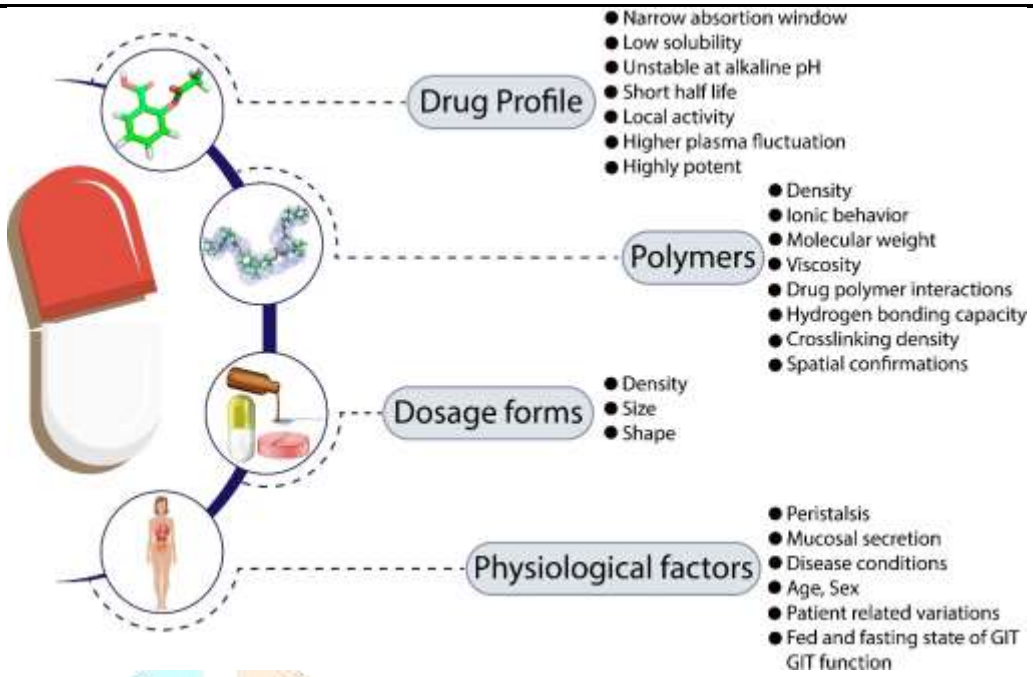

Fig. 2: Illustrating key factors influencing the therapeutic efficacy of gastro-retentive dosage forms

- **Classification of Gastro retentive Drug Delivery System[19]:-**

1) **Floating System**
2) **Mucoadhesive System**
3) **Swelling System**
4) **Magnetic System**
5) **Expandable System**

Table 2: The advantages and limitations of these different gastro retentive dosage forms are summarized in below table

Types	Introduction	Advantages	Disadvantage	Ref
Floating systems	These systems are lighter than stomach fluid, so they float. Because they float, they stay in the stomach for a long time.	Help the body absorb drugs that depend on pH. Reduce side effects that happen in the lower part of the intestine. Useful for diseases in the upper part of the digestive tract. Give slow and controlled release of medicine, so dosing frequency reduces. Improve patient comfort and convenience. Can be made using many types of polymers and designs.	May cause blockage in the digestive tract. Food in the stomach can reduce their effect. May irritate the stomach lining. May disturb digestion and nutrient absorption. Need enough stomach fluid to work. If stomach fluid is less, release rate becomes unpredictable.	4
Mucoadhesive sys- tems	These systems stick to the stomach wall (mucus membrane). They use different mechanisms to stay attached and increase time in stomach.	Large surface area helps them stick better. Help reduce problems caused by fast stomach emptying. Increase time the medicine stays at the absorption site. Can sense changes in stomach condition and adjust. Reduce dosing frequency and improve patient comfort.	Difficult to keep stuck because stomach mucus is replaced quickly. Food or diseases in stomach can reduce sticking power. No reliable testing model available. Difficult to maintain proper drug release. Polymer type and stomach pH affect sticking ability.	6
Swelling systems	These systems swell (become bigger) in stomach fluid. When swollen, their size becomes larger than pylorus (opening), so they stay longer in stomach.	Useful for preventing fast stomach emptying. Can be designed for different types of controlled-release medicines. Less chances of dose dumping. Improve patient comfort. Reduce frequency of taking medicine.	Need enough stomach fluid to swell properly. If they swell too fast, they may leave stomach early. Long time in stomach can affect nutrient absorption. Food may change their swelling behavior. Long retention may cause nausea or delayed stomach emptying.	820

Magnetic systems	These systems have a magnet inside the dosage form. Another magnet is placed outside the body (on the stomach area). The external magnet helps keep the dosage form in a specific part of the stomach for a longer time.	These systems help keep the medicine at a fixed location in the stomach for a longer period. Useful to handle problems like differences between patients and changes in stomach movement.	Hard to move or control inside the body. Difficult to get exact control of the magnetic field. These systems are costly and need trained professionals to manage and use them. Treating more than one disease area requires separate targeting each time. Magnetic particles may build up in blood vessels, increasing the risk of blockage.	9
Expandable systems	These dosage forms are folded before swallowing. In the stomach, they unfold and expand when they touch gastric fluid. After expanding, their size becomes larger than the pyloric opening, so they stay longer in the stomach	Small and flexible when swallowed, so they do not block the passage while going down. Expand later in the stomach, so they avoid gastric obstruction. Reduce how often the medicine has to be taken.\ Improve patient comfort and compliance.	Making these systems takes more time and money. They must unfold quickly; otherwise, they may leave the stomach too early. Food and stomach conditions can affect how they unfold. There is a lot of difference between lab results (in vitro) and real body results (in vivo).	112

2.1. Floating Drug Delivery system:-

Floating drug delivery systems are designed as low-density dosage forms that possess a density lower than that of gastric fluid (≥1.004), allowing them to remain buoyant in the stomach for an extended period[6]. Therefore, selecting suitable formulation components is essential to achieve the desired floating ability. During oral chemotherapy, common gastrointestinal side effects such as gastric reflux,[21] heartburn, abdominal pain, and cramps are frequently reported. H2-receptor antagonists, including famotidine and ranitidine, are often employed as the initial therapy for chemotherapy-induced gastric discomfort.[22]

However, their limited bioavailability and short plasma half-life lead to suboptimal therapeutic outcomes. To address these drawbacks, Kumar et al. developed a floating famotidine tablet using an optimized ratio of a gel-forming polymer (HPMC K4M) and a release retardant (Na-CMC), achieving a gastric retention time of 12 hours. This resulted in improved drug safety and efficacy compared to the marketed formulation[8]. Floating tablets not only sustain an optimal therapeutic concentration at the target site but also reduce systemic side effects. [23]

Capecitabine, a prodrug of fluorouracil commonly used in gastric cancer therapy, exhibits rapid intestinal absorption due to its weakly acidic nature (pka 8.8), which may cause cardiotoxic effects. A suitable gastro retentive drug delivery system (GRDDS) that prolongs gastric emptying could potentially reduce systemic toxicity by controlling intestinal drug absorption.[24] The physicochemical characteristics and concentration of the polymers play a crucial role in determining gastric retention. Davoudi et al. (2011) formulated floating capecitabine tablets using a polymer blend of HPMC K4M, sodium alginate,[8] and sodium

bicarbonate. The optimized combination demonstrated effective buoyancy for over 12 hours without causing systemic toxicity, as confirmed by in vivo data[25].

Tadrosetal. (2010) reported that incorporating retarding polymers (HPMC K15M or sodium alginate) into ciprofloxacin floating tablets provided controlled drug release. They also studied the effect of gas-forming agents (sodium bicarbonate or calcium carbonate) on the buoyancy of the formulation. A composition containing HPMC K15M (21.42% w/w), sodium alginate (7.142% w/w),[26] and sodium carbonate or calcium carbonate (20% w/w) maintained buoyancy for over 12 hours[27]. Similarly, ciprofloxacin combined with a swellable polymer exhibited enhanced floating ability[8].[3] In another investigation,[28] a pharmacokinetic comparison was made between a conventional immediate-release tablet[14] (administered twice daily) and a gastro retentive once-daily formulation with delayed release. Results indicated that the gastro retentive form provided superior gastric retention, sustained drug release,[29] improved pharmacokinetic performance, and reduced systemic toxicity compared to the standard tablet[9].

Like floating tablets, floating capsules also have a density lower than that of gastric fluids, allowing them to remain afloat in the stomach for a prolonged period regardless of gastric motility.[7] Mouzam et al. (2011) designed an innovative floating "ring-cap" system utilizing a cross-linked hard gelatin capsule shell for site-specific gastric delivery. The capsule consisted of two parts—a hydrocolloid cap and an enteric-coated body—separated by a ring band containing the drug. Upon ingestion, the hydrocolloid cap rapidly dissolved in gastric media for immediate action, while the enteric body stayed intact to maintain prolonged therapeutic effect.[30] Among the polymers studied, an optimal ratio of HPMC and CMC exhibited superior floating performance, consistent quality, and satisfactory in vivo outcomes[11].

Mechanism of Action of Floating Drug Delivery Systems (FDDS):- [8]

There are different researchers have developed gastro-retentive floating tablet formulations for anticancer drugs to improve treatment effectiveness. There are some researches based on formulation that have been made available in the market as follows:

Salma Shaik et al. prepared floating tablets of Capecitabine using HPMC polymers and gas-generating agents to achieve sustained drug release in the stomach. Ling-Chun Chen et al. developed a swellable and floating system for Nilotinib,[31] which showed better gastric retention and improved oral bioavailability compared to conventional tablets. Bharat W. Tekade et al. formulated an alternative floating tablet of Capecitabine using HPMC, carbomer, and sodium alginate, and confirmed good buoyancy and controlled drug release in in-vitro studies. Detail information is given in Table 3.[32]

Table 3: Published Floating gastro retentive Drug Delivery System Formulation for Cancer Chemotherapy

Drug	Key Formulation Features	Authors	Ref
Capecitabine (stomach cancer)	Floating tablets using HPMC K4M & K15M as release retardants, gas-generating agents ($NaHCO_3$, $CaCO_3$), fillers like MCC, DCP; direct compression with sustained release	SalmaShaik, Sudhir Mandela, Buchi N. Nalluri	633
Nilotinib (anticancer tyrosine kinase inhibitor)	Swellable & floating GRDDS with HPMC, HEC, PEO & Kollidon® SR; enhanced gastric retention & improved oral bioavailability compared with conventional formulation	Ling-Chun Chen, Wen-Ting Cheng, Wei-Jie Cheng, Hsiu-O Ho, Ming-Thau Sheu	8
Capecitabine (alternative formulation)	Floating tablet formulation of anticancer agent Capecitabine using HPMC K15M, carbomer, sodium alginate, gas-forming agents; in vitro evaluation of buoyancy and release	Bharat W Tekade, Umesh T Jadhao, Pooja Patil, Sagar Mahajan, Vijay R Patil	9

CONCLUSION AND FUTURE PROSPECTIVE:-

Gastro retentive drug delivery systems (GRDDS) improve the effectiveness of oral cancer chemotherapy by keeping the drug in the stomach for a longer time and releasing it in a controlled manner. These systems enhance drug absorption, reduce dosing frequency, lower side effects, and improve patient compliance, especially in gastric cancer treatment.

Future research will focus on developing smarter and Nano-based gastro retentive systems with better stomach retention, targeted drug delivery, and improved safety. With more clinical studies, GRDDS may become a reliable and patient-friendly option for oral cancer therapy.

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