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Novel Therapeutic Strategies for Gastric Ulcer Healing and Antibiotic Resistance Management

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Abstract

The disease of gastric ulcers remains a significant source of health and socioeconomic burden in the globe despite modern techniques emerging in diagnosis, elimination of Helicobacter pylori, as well as acid-lowering medications. Mainstream therapy regimens such as proton pump inhibitors (PPIs), H2 receptor antagonists, antacids and antibiotic regimens are proving effective but are progressively limited due to increasing resistance in antibiotics, incomplete mucosal healing, elevated rates of recurrence and safety issues with long term acid suppression. Such restriction has prompted the innovative therapeutic mode of action of both the pathogenic and the shortcomings of conventional care. New nanomedicine systems like liposomal systems, polymeric nanoparticles, nano emulsions, and green-synthesized metallic nanoparticles are providing superior drug stability, targeted delivery, bio adhesion, and drug release; preclinical studies show these nanoparticles are having superior anti-inflammatory and antioxidant as well as anti-H. pylori effects, but still in early translational development. GRDSS Complementary gastro retentive drug delivery systems (GRDSS) which are: floating, swelling, mucoadhesive, super-porous hydrogel and high-density systems, all exhibit long gastric retention, high local

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drug concentration, and better eradication results than traditional preparations. New technologies in gene therapy, stem-cell delivery, growth-factor-based treatments, stimuli-responsive smart materials and precision-medicine devices, such as 3D-printed dosage forms and computerized health, are evidence of a paradigm shift with regards to customized and regenerative management of ulcers.

Keywords: -

Helicobacter pylori, Nanomedicine, Polymeric nanoparticles, Gastro retentive drug delivery systems, Mucoadhesive systems, Microbiome-targeted therapy.

1. INTRODUCTION

Gastric ulcers, which are a field of peptic ulcer disease (PUD), are serious health issues in the world, and frequently bring about a lot of clinical and socioeconomic costs. Recent epidemiological investigations suggest that, though the general incidence of peptic ulcer disease has passed a downward trend in the world courtesy of improved sanitation and extensive eradication programs against Helicobacter pylori, gastric ulcers continue to contribute a significant percentage of PUD diseases particularly in older individuals and the risk population who include prolonged use of NSAIDs as well as infection with Helicobacter pylori [1].

The estimated lifetime incidence of PUD worldwide is between 5-10% with gastric ulcers contributing significant percentage to the reported incidence. Epidemiological also indicates that gastric ulcers are more common in men and have a sharp rise in infection rates with age. As a case in point, endoscopy examinations have revealed that gastric ulcers are among the causes of about 45-60% of the total PUD cases and the rates of gastric ulcers become higher among individuals aged above 40 years [2].

Gastric ulcers may clinically manifest themselves in terms of persistent abdominal pains in the epigastrium, nausea, loss of appetite, and in some cases, upper stomach bleeding. The main issue in complications is that it leads to potentially life-threatening gastrointestinal bleeding, the development of holes in adjacent organs, the obstruction of gastric outlets and less frequent, but with the highest seriousness, the emergence of the risk of gastrointestinal cancer development especially when the H. pylori infection is left unresolved. Such complications may lead to more hospitalizations, significant spending of health resources, and low standards of living of those involved [3].

1.1 Limitations of current therapies and the need for innovative approaches

The pillars of gastric ulcer include today the use of proton pump inhibitors PPIs, H 2 antagonists, eradication of H.

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pylori and, in some cases, the prevention of ulcerogenic factors, like NSAIDs. Despite these advances. There is the increasing prevalence of H. pylori cases that are resistant to the action of an empirical eradication regimen. Narrow-spectrum antibiotics (polypharmacy- taking more than one antibiotic or anti-ulcer regimen) are associated with patient non-adherence, development of adverse drug reactions, and likelihood of relapse. In the case of NSAID induced ulcers, it is not always possible to continue or reduce the doses because of underlying medical requirements [4].

Moreover, modern treatments mainly facilitate the recovery of ulcers without necessarily preventing the appearance of new ones in the regularly exposed high-risk groups, which indicates the necessity of a comprehensive treatment strategy that provides the strengthening of mucosal functions and includes the destructive factors of the pathogen like microbial resistance. With these great constraints, new interventions are highly demanded [5]. New studies are looking to cover extended-release preparations, gastroretentive preparations, shorter nano-use preparations to achieve improved bioavailability such, other antimicrobial substances or combinations of antimicrobial preparations plus probiotics or phage therapy can be where we go in the future. Such novel approaches are not only intended to break the existing objects of therapy but also to decrease the risk of repeated presence, ensure the reduction of the sitting drug resistance, and help patients to increase the quality of life [6].

The current review aims to give an overview of the gastric ulcer disease focused on such issues as modern epidemiological situation, clinical consequences, and intricate treatment environment. Particular emphasis is also placed on the summation of the recent evidence regarding the limitations of traditional treatment methods and features of the most promising strategies of experimental treatment that are still being explored and developed [7].

1.2 Review of conventional treatments: PPIs, antibiotics for H. pylori, lifestyle Modifications

Proton Pump Inhibitors (PPIs)

Those in the frontline are PPIs (omeprazole, pantoprazole, rabeprazole, lansoprazole) that lead to the irreversible inhibition of gastric proton pumps on parietal cells, which reduces the output of acid significantly. The PPIs also improve healing and symptomatic relief by increasing attribution of intragastric pH, and the vast majority of ulcers are healed in a 4-week period. Overall PPIs (rabeprazole, esomeprazole) are also effective, with higher levels of acid repression than conventional agents in a shorter time span [8].

Antibiotics for H. pylori

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In the case of H. pylori-associated ulcers, such treatment leads to the elimination: a combination of PPI and two antibiotics (clarithromycin, amoxicillin or metronidazole). Most cases can be cured by means of successful eradication and prevent relapses. Quadruple coverage with the use of bismuth is given in cases considered resistant, and regular cases are more often classified with sequential/customized treatment when triple culture treatment is no longer effective [9].

Lifestyle Modification

NSAIDs off and reduce stress. Restrict alcohol and tobacco which inhibit the healing of the mucosa. Normalize eating habits, eliminate irritants to the gastrointestinal system, and enlarge the dietary diversity of the fiber [10].

1.3 Challenges like recurrence, resistance, and healing complications

Recurrence

Although recurrence is high, the risk classifications that exhibit a high occurrence even after initial ulcer healing include high risk groups (long-term NSAID users, partial elimination of H. pylori) [11].

Antibiotic Resistance

The resistance of H. pylori to clarithromycin, levofloxacin and metronidazole is rapidly on the increase across the world with the over 30-50 percent prevalence level recorded in a few places. Utilities Failure to respond and sequential or customized therapies. Raised level of multi-drug resistant strains, notably in the recurrent or atrophic cases of gastritis [12].

Healing Complications

Some ulcers get sluggish or refractory- due to chronic infection, continued taking NSAID or alcohol or underlying neoplasia. Though both tend to be effective, enormous ulcers, those that are found in the body of the stomach, and complications by underlying illness, may respond poorly to acid suppressive therapy [13].

The **Table 1** compares the traditional methods of treating gastric ulcers according to their mechanisms of action, advantages, and disadvantages. Although the use of PPIs and H2 blockers as primary agents is reasonable because they are effective in the treatment of acid, the prolonged use of these agents is linked to safety issues and decreased effectiveness with time progression. Cytoprotective therapy and prostaglandin analogs offer protection to the mucosal defense, but they have the disadvantage of inconvenience during dosing and adverse effects. Even though the treatment of H. pylori eradication has dramatically reduced the recurrence of ulcers, the rise in

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antibiotic resistance and non-adherence to treatment has reduced its success in the long run, hence the necessity of sophisticated treatment plans.

Table 1: Comparison of Conventional Gastric Ulcer Treatments and Limitations

S.No.	Treatment Type	Mechanism	Advantages	Limitations	Reference
1.	Proton Pump Inhibitors (PPIs)	Strong inhibition of gastric acid secretion; promotes ulcer healing	Highly effective; rapid healing of ulcers; first-line therapy	Nutrient malabsorption, fracture risk, kidney complications, rebound acid hypersecretion with chronic use	[14]
2.	H2 Receptor Blockers	Reduce acid secretion by blocking H2 receptors on parietal cells	Provide short-term symptomatic relief	Less effective than PPIs; development of tolerance with prolonged use	[15]
3.	Antacids	Neutralize existing gastric acid	Immediate symptomatic relief	Very short duration; no significant ulcer healing effects	[16]
4.	Cytoprotective Agents (sucralfate, bismuth salts)	Form protective barrier over ulcer and improve mucosal stability	Useful in mucosal protection; beneficial in NSAID-related ulcers	Require multiple doses; may interfere with absorption of other drugs	[17]
5.	Prostaglandin Analogues (misoprostol)	Increase mucus and bicarbonate secretion; protect gastric mucosa	Effective for NSAID-induced ulcers	GI side effects (cramping, diarrhea); contraindicated in pregnancy	[18]
6.	H. pylori	Eliminates H.	Improves	Rising antibiotic	[19]

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	Eradication Therapy (antibiotics)	pylori, a major etiologic agent	healing rates; reduces recurrence	resistance; complex multi-drug regimen reduces compliance	
7.	Lifestyle & Dietary Measures	Avoid irritants (alcohol, tobacco, spicy foods) to reduce mucosal stress	Supportive role; helps prevent recurrence	Cannot function as standalone treatment; adherence varies	[20]

2. Nanomedicine Approaches for Gastric Ulcer Therapy

Several solution methods are provided by nanomedicine to treat gastrointestinal ulcers, and these include the use of such nanocarriers like liposomes, nanoparticles, and nano emulsions to enhance drug stability, targeted delivery, and increase the healing rates of ulcers. These systems evolve distinctive mechanisms and benefits, signs of good preclinical and emerging clinical data, with safety and regulatory issues of great concern [21].

2.1 Types of nanocarriers (liposomes, nanoparticles, nano emulsions)

Liposomes are vesicles composed of lipids which carry both the lipophilic and hydrophilic drugs. They can be used in protection of gastro intestinal sensitive drugs and slow site release because of their bilayer structure. Liposomes may be modified to be resistant to gastric destruction and extend their residence duration at the ulcer module and enhance the uptake of the mucosa by drugs [22].

Polymeric Nanoparticles worked out of biodegradable and biocompatible polymers such as chitosan, PLGA or starch are characterized by the management of release and increased penetration into the tissues. Individually, chitosan nanoparticles, e.g., possess mucoadhesive capacity, which means that the nanoparticles closely approach the gastric mucosa, thereby enhancing the healing of ulcers the nanoparticles will maintain the levels of drugs at the lesion site. The synthesis of metallic and metal oxide nanoparticles through the green (plant-based) approaches also indicates high level of antioxidant, anti-inflammatory, and even anti-H. pylori activity [23].

Nano emulsions involve managers on oil-in-water emulsions with a submicron-size to transport poorly soluble drugs. Self-nano emulsifiable drug delivery systems (SNEDDS) are becoming increasingly popular due to the characteristics of drug solubility in lipophilic drugs under

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investigation, the enhancement of oral bioavailability, and the ability to prevent chemical degradation of effector molecules in the stomach cavity [24].

Table 2 brings into focus some of the recent nanomedicine preparations that have been designed to treat gastric ulcers, their composition, mechanism, and effects. These nanoparticle systems increase the antioxidant, anti-inflammatory, mucoadhesive and antimicrobial effects resulting in better mucosal protection and healing. All in all, nanocarrier-based delivery has better ulcer preventive and therapeutic potential than conventional therapy.

Table 2: - Recent Nanomedicine Formulations Tested for Gastric Ulcer Treatment

S.No.	Nanomedicine Formulation	Composition / Design	Mechanism of Action	Key Therapeutic Outcomes	Reference
1.	Selenium Nanoparticles (SeNPs)	Yeast-mediated synthesized selenium nanoparticles	Reduce oxidative stress (↓MDA); increase antioxidants (↑GSH, catalase); restore epithelial integrity; modulate gut microbiota	Accelerated healing of ethanol-induced gastric ulcers in animal models	[25]
2.	Glycyrrhizic Acid Nanoparticles (GLY-NPs)	Nanoparticle formulation of natural anti-inflammatory compound glycyrrhizic acid	Targets oxidative stress and inflammatory pathways more effectively than standard drugs	~87% ulcer inhibition; ulcer index reduced to ~1%; superior to omeprazole	[26]
3.	RESV-MNP System (Nano-in-Microparticles)	Trans-resveratrol-loaded chitosan nanoparticles embedded in hyaluronic acid–alginate microparticles	Sustained drug release; strong mucoadhesion; H. pylori eradication; protection against NSAID-induced lesions	Significant reduction of indomethacin-induced gastric damage; improved mucosal healing	[27]
4.	Chitosan-Coated Boswellic Acid	Boswellic acid nanoparticles	Mucosal adhesion; modulation of	Enhanced gastroprotection;	[28]

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	Nanoparticles (CT/BA-NPs)	coated with mucoadhesive chitosan	RAS/ERK signaling pathways	improved tissue regeneration; reduced inflammation	
5.	Green-Synthesized Metallic Nanoparticles (AgNPs, ZnO-NPs)	Silver or zinc oxide nanoparticles synthesized using plant extracts	Antioxidant and antimicrobial actions; neutralize pathogens and oxidative injury	Promote mucosal healing; inhibit gastric pathogens; support tissue repair	[29]

2.2 Mechanism of action and advantages for drug delivery and ulcer healing

First, Improved Mucoadhesion Polymeric nanoparticles and liposomes may be surface-modified in order to high affinity adsorption to the gastric mucosa, resulting in higher drug intensity in the vicinity and faster recovery frequencies [30].

Degradation Defense against acidic and enzymatic inactivation Nano systems deliver a defense against acid and enzymatic inactivation of drugs in the stomach improving bioavailability of acid-labile agents and therapeutic peptides [31].

Specific and Controllable Release: Nanocarriers designed to release drugs stimulates experiments deliver drugs to ulcer levels more slowly, raising the frequency of medication intake causing fewer side effects [32].

Antioxidant/ Anti-Inflammatory Effects: There are nanocarriers (e.g., hesperidin-loaded chitosan nanoparticles) that provide synergistic anti-ulcer activity and reduces oxidative and inflammatory pathways and resuming the activity of antioxidant enzymes [33].

Overcoming Resistance: Nanoparticles are capable of overcoming efflux pumps and offer, at great local antimicrobial concentrations, treatment of resistant strains of H. pylori [34].

The **Figure 1** is an illustration of drug delivery using nanoparticles to the gastric mucosa whereby the drug saturated nanoparticles are put into the stomach lumen. These nanoparticles are structured to pass or stick on the mucus coating so that they can avoid quick gastric elimination and stay in close contact to the mucosal lining. The nanoparticles are targeted to the gastric mucosa, which achieves targeted and sustained delivery of drugs, avoids the degradation of the

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drug in the acidic environment of the stomach, and increases the therapeutic efficacy and reduces any systemic side effects.

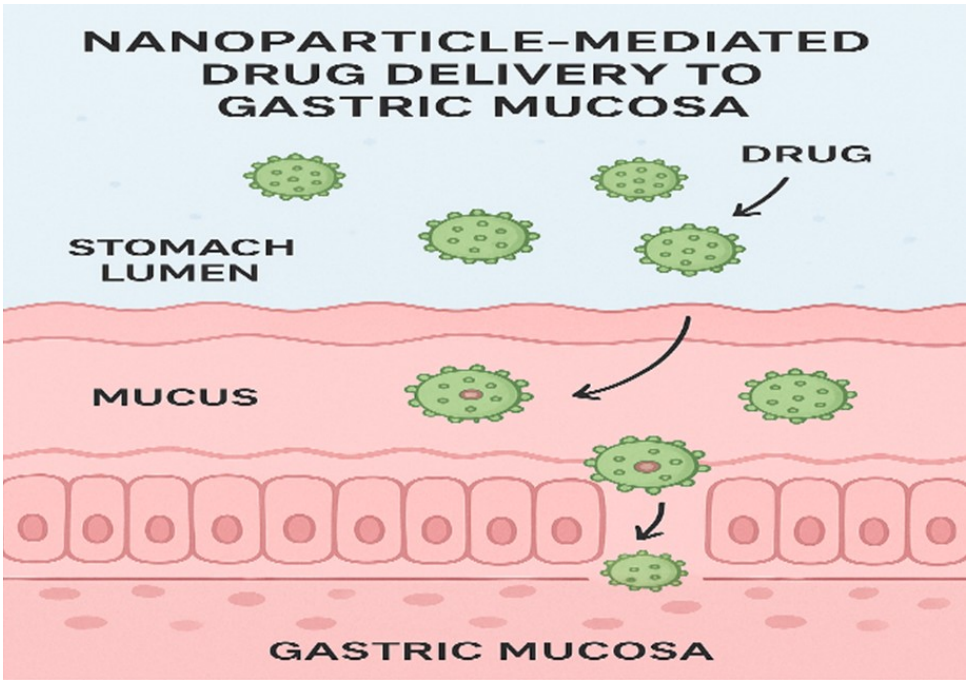

Figure 1: - Illustrating Nanoparticle-Mediated Drug Delivery to Gastric Mucosa

The picture demonstrates the mechanism of drug-loaded nanoparticles moving through the lumen of the stomach and penetrating the mucus layer to reach gastric mucosa.These nanoparticles are associated with mucoadhesion that ensures its prolonged retention and closer contact with ulcerated tissue, which increases the efficacy of local drug delivery over the conventional formulations.

2.3 Preclinical and clinical study summaries

Preclinical Studies: Drugs dox grouping chitosan/hydroxypropyl methylcellulose nanoparticles with hesperidin have demonstrated to have better gastroprotective effects against ethanol-induced ulcerative models in rat, significantly reducing inflammation, oxidative stress and gastric acidity, over free drugs as well as the esomeprazole [31].

Plant-based metal or metal oxide nanoparticles (e.g., green synthesis) and showed high antiulcer, anti-inflammatory, and antibacterial in different models of ulcers, particularly in ulcers provoked by NSAIDs, ethanol, or H. pylori. Starch nanoparticles and resveratrol-loaded nano-in-

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microparticles possessed a lesser level of hemorrhagic harm, enhanced the curing of the mucosal lesion, and enhanced the histological safeguard [35].

Clinical Studies:

Clinical translation is at a young phase and most information is obtained serving as animal tests and ex vivo models. Oral nano formulations and nano emulsions developed to delivery antiulcer agents have been first tested in a few pilot and translational studies suggesting there is enhanced remediation and drug targeting at minimal toxicity. Nevertheless, currently, large-scale clinical trials need to be conducted to establish effectiveness, safety, and long-term human outcomes [36].

2.4 Safety and regulatory considerations

Safety: although most nanocarriers incorporate biocompatible and bio-degradable materials (e.g., chitosan, PLGA, natural oils) the long-term security platform, especially in terms of particle aggregation, nanotoxicity and immunogenicity is an issue. Without any special attention to variations in metallic nanoparticles or inappropriate choice of the surfactant, oxidative stress or cytotoxicity may occur [37].

Biodistribution and Clearance: In order to prevent the unexpected negative outcomes, the behavior of nanoparticles within the gastrointestinal system of the organism, the processes of interacting with the microbiome, and the systemic absorption of the nanoparticles should be studied in detail. Scalability and Manufacturing: Technologically, it is both cost-intensive and difficult to meet the requirements of pharmaceutical production through nanocarriers at consistency, stability, and scalability, which requires validated protocols and approval by regulation authorities [38].

Regulation: There is emerging regulation of nanomedicines. The complexity of nanoscale materials requires customized preclinical and clinical approach based on pharmacokinetics, tissue distribution, toxicity and efficacy endpoints. Other bodies such as the FDA and EMA are revising their frameworks even though the assessments are case-by-case as a result of the variations of nanomedicine [39].

3. Gastroretentive Drug Delivery Systems

GRDDS Gastroretentive drug delivery systems (GRDSS) are sophisticated oral preparations that are meant to remain in the stomach so as to achieve direct, regulated drug delivery and enhanced therapeutic response, particularly that achieved by orally absorbed drugs, local gastric action drugs etc.

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3.1 Principles of gastroretentive delivery (floating, mucoadhesive, swelling systems)

GRDDS work by some of the following retention mechanisms:

Floating (Low-Density/ Buoyant) Systems: These are the formulations whose density is lesser than that of the gastric fluid, which can be floated on the top of stomach food and enhances gastric retention. These can be in the form of effervescent pills and inflatable pills used to release carbon dioxide when they come into contact with gastric acid that makes them light in weight and thus are able to travel in the air over a few hours [40].

Mucoadhesive Systems: These employ polymers with potential to bind to the mucosa of the stomach using hydrogen bonds as well as other bio adhesive relationships. This increases the residence time as it does not allow dislodgement during peristalsis and gastric emptying. Mucoadhesive dosages forms are gels, patches and polysaccharide-coated (chitosan, Carbopol and polyacrylates) tablet [41].

Swelling/Expandable Systems: These systems are made with hydrophilic polymers so that they grow in size in the stomach as the gastric fluid gets into them and they are unable to exit back through the pylorus. The swelling enhances the gastrointestinal holding ability and provides prolonged drug delivery. Depending on the choice of polymer, the swelling could be reversible or irreversible [42].

The **figure 2** shows different gastroretentive drug delivery mechanisms that are aimed at extending the stay of dosage forms in the stomach. It demonstrates floating/swelling/expandable, mucoadhesive, super-porous hydrogel and high-density systems, which inhibit rapid gastric emptying. These systems can also allow prolonged drug delivery, enhanced bioavailability and therapeutic efficacy by staying in the stomach.

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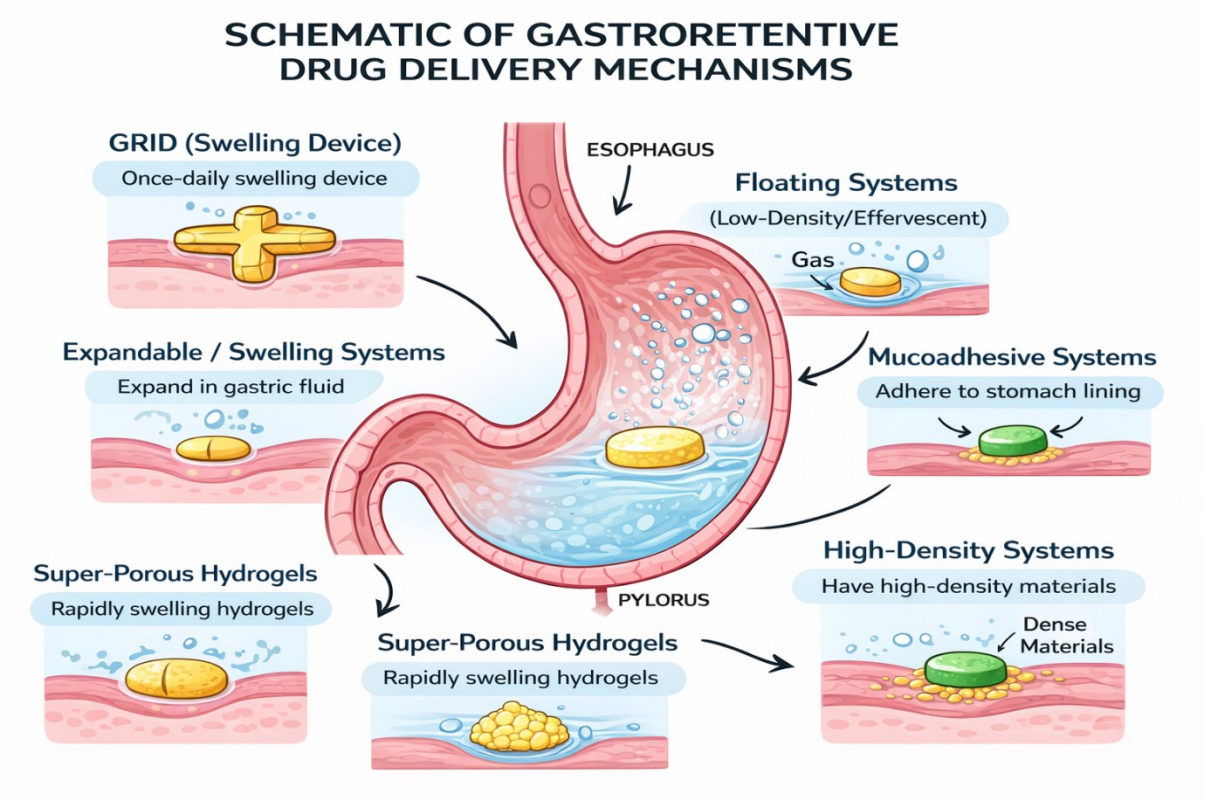

Figure 2: Schematic of gastroretentive drug delivery mechanisms

Schematic depiction of various gastroretentive drug delivery systems such as floating, mucoadhesive, expandable, high-density and super-porus systems based on hydrogel. Such systems help in increasing the gastric residence time and controlled drug release by avoiding premature gastric emptying.

3.2 Benefits for prolonged drug release and improved eradication rates

Sustained/Controlled Release: GRDS remain to be in the stomach, maintaining stable concentrations of drug, improving the efficacy of drugs with limited absorption with narrow half-lives [43].

Increased Bioavailability: Unstable or poorly absorbed drugs in the intestine (such as metformin, furosemide, riboflavin, etc.) have an advantage as they are exposed to increased time in the stomach. Lower Dose Nobody needs a lot of drug administration: GRDDS provides sustained delivery allowing an increased interracial time, thereby increasing patient convenience and compliance [41].

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Enforced Local Therapeutic Efficiency: In medications having an effect on the stomach, (films antibiotics to kill H. pylori) GRDDS allow an augmentation in gastric levels and eradication results. Pain reliever strain that is localized eliminates systemic exposure and side effects [44].

3.3 Latest advances and product developments

GRDDS is currently being enhanced tremendously by the new inventions:

Floating tablets/ beads: This involves using gas generating agents or inflatable chambers to make floating possible. Examples are floating beads whereby carbon dioxide is formed by coating of hydrophobic polymers onto the bicarbonate ions [45].

Smart/Responsible Polymers: Polymers that can react to changes in pH or temperature are in the process of change in shape or binding strength with respect to the conditions in the gut that are in relation to gastric and maximize retention and release [46]. Nanostructured/Microparticulate Formulations: Mucoadhesion + Controlled Release Enhanced local drug delivery together with greater local therapy. Commercial Products: A number of commercial formulations involving the use of GRDDS have been developed, including Madopar HBS (levodopa/benserazide floating capsule to treat Parkinson's), Cifran OD (ciprofloxacin floating tablets) and Gaviscon (raft-forming alginate treatment of reflux) [47].

3.4 Clinical evidence of efficacy and patient compliance

A variety of clinical trials and product releases to the market, confirm the positive results and usability of GRDDS:

Efficacy: The GRDDS have demonstrated vast empowerment on drug bioavailability, reduction in ulcer healing, as well as, eradication of H. pylori in comparison to traditional oral formulations. Mucoadhesive and floating systems result in higher drug concentrations at the site, which provide more therapeutic benefits and fewer failures [48].

Dose frequency: Lower dosing schedule and fewer side effects have increased the rate of compliance among chronic diseases such as diabetes, hypertension, Parkinson and local stomach infections. Specifically, once-daily floating preparations are better preferred by patients to various-daily standard-dose preparations [49].

Commercial Success: Sold GRDDS have proven to be generally acceptable as the patients have fewer gastric irritations and have improved symptom management. They are delayed-release capsules, raft-forming antacids, and floating pills, which have become part of the regimen of management of ulcers and reflux [50].

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The **Table 3** provides an overview of different gastroretentive drug delivery system that was designed to increase the gastric residence time with mechanisms of floating, swelling, adhesion, expansion, or increased density. These systems inhibit quick emptying of the stomach which enables slow and controlled emptying of drugs to the stomach. In general, gastroretentive methods enhance bioavailability, administration comfort, and patient compliance particularly in the case of drugs with requirements of a lengthy duration of gastric retention.

Table 3: - Examples of Gastroretentive Systems in Development or Market

S.No.	Gastroretentive System	Description	Key Mechanism for Gastric Retention	Therapeutic Advantages	Reference
1.	Gastro-Retentive Innovative Device (GRID)	Once-daily swelling device that expands after ingestion	Swells to a size that prevents gastric emptying; remains in stomach for >8 hours	Enables controlled drug release; improves dosing convenience and adherence	[51]
2.	Floating Systems (Low-density/Effervescent)	Formulations containing polymers (e.g., HPMC) and gas-generating agents (sodium bicarbonate, citric acid)	Reduced density allows tablet to float on gastric fluids	Prolonged gastric retention; slow and sustained drug release	[52]
3.	Mucoadhesive Systems	Use mucoadhesive polymers (chitosan, carbomer) that adhere to gastric mucosa	Adhesion to stomach lining prevents rapid emptying	Enhanced drug absorption; extended contact with gastric tissues	[53]

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4.	Expandable / Swelling Systems	Polymers swell in gastric fluid to enlarge significantly	Becomes too large to pass through pylorus	Long residence time; sustained drug delivery	[54]
5.	Super-Porous Hydrogels	Rapidly swelling hydrogels with interconnected pores	Quick expansion upon water absorption holds system in stomach	Immediate swelling and prolonged retention; supports continuous drug release	[55]
6.	High-Density Systems	Formulations incorporate heavy materials (zinc oxide, barium sulfate)	High density keeps dosage form settled in gastric antrum	Maintains position despite peristalsis; suitable for local delivery	[56]

4. Microbiome-Targeted Strategies and Antibiotic Resistance Management

The gut microbiome has well-rounded and essential roles in the development of gastric ulcers, healing, and treatment of ulcers. Innovative approaches to ulcer care are changing the paradigm of management probiotics, prebiotics, microbiome moderation supplementation, and rational antibiotic stewardship Microbial balance, mucosal regeneration, and antibiotic resistance containment are advancing the microbiome-targeted approaches to ulcer management. The combination of these modalities with the traditional ulcer therapies will give the gastric ulcer disease holistic and long-term management [57].

4.1 Role of gut microbiota in ulcer pathogenesis and healing

The the genesis of peptic and gastric ulcers is not limited by the effects of the Helicobacter pylori and mucosal damage caused by NSAIDs. Dysbiosis, the effects of change in the makeup or the functioning of the intestinal microbiota, influence the gastrointestinal barrier functions and regulatory immune activities that implicate in the development of ulcers in predisposed individuals [58]. Key mechanisms include:

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Dysbiosis and Inflammation: The beneficial flora is lost and an overgrowth of the harmful microbes triggering the release of pro-inflammatory cytokines (tumor necrosis factor-a, IL-1b, IL-6), impair the mucosal integrity, cause the oxidative stress, and disrupt the gastric defense barrier [59].

Metabolite Effects: Microbiota shifts influence the synthesis of short-chain fatty acids (SCFAs) by butyrate and propionate, which mediate global epithelial stability, anti-inflammatory system, and mucosal repaired injury [60].

Microbial Mediators: Some of them, like Lachnospiraceae and Butyriciccus Lachnospiraceae UCG004 pulls inflammatory levels down, a process that assists mucosa in recovering and decreases ulcer rates [61].

Acid-protective Bacteria: There are intestinal pathogenic microorganisms (e.g. Enterobacteriaceae) that elevate the local pH by metabolic activity, alleviating the stress on the mucosal acid, and have a protective effect [62].

Gut microbiome promotes angiogenesis, epithelial regeneration and anti-inflammatory activities in healing, which are paramount to the noxious recovery of gastric trauma. Probiotics can enhance these mechanisms, increasing the growth factor production and the recruitment of bone marrow stem cells in the ulcer site [63].

4.2 Probiotics, Prebiotics and Modulating Approaches.

Probiotics (live beneficial microorganisms) and prebiotics (non-digestable substrates which allow the growth of beneficial bacteria) have increased rapidly in ulcer management:

Probiotics: ulcer healing increases in response to administration of probiotic strains such as Lactobacillus rhamnosus GG, L. acidophilus, L. gasseri, Bifidobacteria and Clostridium butyricum. Resistance to ulcers through upregulation of more mucus, bicarbonate release and repair of epithelial cells.Anti-inflammatory cytokines and heat sho ck proteins, inhibition of gastric acidity, or prevention of ulcers caused by NSAID or stress. Angiogenesis (via escalated endothelial growth factor) and re-epithelialization of the ulcer margins. The various prebiotics such as fibers and oligosaccharides (e.g., inulin, fructooligosaccharides) are selective and promote the growth of bacteria that produce SCFA, which binds Drummond diaphragms together and reduces the healing of ulcers [64].

Symbiotics: The synergistic activity of probiotics with prebiotics (synergies) is strongly observed which brings colonization, enhanced disease protection by antiulcer action and barricades.

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An encapsulated Delivery: Techniques like encapsulation of the probiotics in alginate or chitosan based bead material have enhanced probiotic survival in the severe gastric environment as well as ensure viable delivery of the probiotics to the gut and prolonged mucosal restorative impacts [65].

4.3 Novel antibiotics and resistance management tactics

The healthcare administration of antibiotics appears to face increasing resistance, especially to clarithromycin, metronidazole, and levofloxacin, associated with overuse and disturbance of the microbiome:

Rational Therapy Options: The current suggestions sense ability to think into regionally customized schedules, rotation of first line antibiotics with expected changes in resistance and use of bismuth-based quadruple regimens where triple options are ineffective. No attention is given to new types of molecules based on novel mechanisms, including potassium-competitive acid blockers (vonoprazan-based combinations), novel macrolides, and non-traditional antimicrobials (phage therapy, antimicrobial peptides), which theoretically are the making of resistance and minimize microbiome disruption [66].

Probiotic-Assisted Therapy Probiotic co-administration with antibiotics does have two things going in its favor: the ability to enhance the success of H. pylori eradication, via competitive exclusion and diminished length of exposure to antibiotic development as well as enhanced rates of H. pylori eradication via suppressive action over pathogenic bacteria and restoration of Homeostasis in vivo. Nevertheless, in many instances, probiotics may not aid the cause of the primary infections, and therefore, dwelling on self-administered microbial research ought to be avoided merely because prior stratification has been done. The probiotics in most cases may not be beneficial to the aetiology of the underlying infections, and thus, simplistic self-measured microbiome surveillance should be consequentially disregarded simply because secondary prevention has been previously stratified [67].

4.4 Integration of microbiome therapy with conventional treatments

Combined regimens involving the use of classic regimens (PPIs, antibiotics, NSAID modulation) combined with the use of microbiome-targeted colonies provide better results:

Trauma Therapy-Induced Dysbiosis: - Proton pump inhibitors and antibiotics induce a shift in the microbiota in the gut that exposes the patient to dysbiosis, infection, and susceptibility to recurrence. Intensive care following conventional therapy and enhancement of mucosal integrity through microbiome restoration (through probiotics/prebiotics) helps in prevention of complications. Probiotic or symbiotic supplementation helps to boost mainstream healing as it

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increases the production of prostaglandin, growth factor, production of anti-inflammatory cytokines, and hastens healing in the mucosa. Gut-Immune Synergy Intruder Normal microbiome also leads to improvements in the immune response to anti-H. pylori infection, the maintenance of the epithelial barrier, and the prevention of excessive inflammation to accompany standard treatments of ulcers [68].

Personalization: The combination of the most beneficial and the least harmful effects of pharmacologic and microbiome treatment is possible using individualized regimens, i.e. based on microbial profile, resistance patterns, and ulcer etiology. The prospective directions and emerging technologies in the treatment of gastric ulcers revolve around innovative therapeutic indices, smart systems and delivery of drugs, and the combination of precision medicine, which are bound to culminate in shifts in the treatment regulations and enhancement of patient outcomes [69].

The approaches to microbiome-targeted therapies to restore gut microbial homeostasis and gastrointestinal health are summed in **Table 4.** The probiotics, prebiotics, synbiotics, postbiotics, FMT, and microbiome-directed drugs represent the categories of strategies, all of which affect microbial composition, metabolites, and immune reactions. When put together, these interventions demonstrate superior mucosal protection, less inflammation and desirable clinical outcomes, especially in microbiome-related gastrointestinal diseases.

Table 4:- Microbiome-Targeted Therapeutic Agents and Clinical Outcomes

S.No.	Therapeutic Category	Description / Components	Mechanism of Action	Clinical Outcomes	Reference
1.	Probiotics	Lactobacillus, Bifidobacterium species	Restore microbial homeostasis; enhance mucosal integrity; suppress pathogens; regulate immune responses	Reduced antibiotic-associated diarrhea; improvement in IBS symptoms; decreased recurrence of C. difficile infection	[70]
2.	Prebiotics	Non-digestible fibers (inulin, fructooligosaccharides)	Selectively stimulate beneficial gut bacteria; strengthen intestinal barrier; reduce	Enhanced gut barrier function; improved metabolic and immune responses	[71]

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			inflammation		
3.	Synbiotics	Combination of probiotics + prebiotics	Provide synergistic microbial stimulation and colonization	Greater clinical improvement than probiotics or prebiotics alone; improved gastrointestinal health	[72]
4.	Postbiotics	Bioactive microbial metabolites with anti-inflammatory and antioxidant properties	Modulate immune responses; provide antimicrobial and metabolic benefits without live organisms	Reduced gut inflammation; enhanced mucosal protection	[73]
5.	Fecal Microbiota Transplantation (FMT)	Transfer of healthy donor microbiota to a diseased recipient	Restores balanced microbial ecosystem rapidly and effectively	Highly effective in recurrent C. difficile infection; improved microbial diversity	[74]
6.	Microbiome-Directed Pharmaceuticals	Agents targeting microbial metabolites (SCFAs, bile acids, indoles)	Regulate immune pathways and metabolic functions by modulating microbial signaling molecules	Improved metabolic regulation; enhanced immune tolerance; targeted treatment of microbiome-linked diseases	[75]

5. Challenges, Safety, and Regulatory Considerations

The drawbacks of innovations that are aimed at treating gastric ulcers such as nanomedicine, gastroprotective systems, and microbiome-targeted therapies have several challenges in relation to technical, safety, and regulatory aspects. To achieve success in clinical translation and patient outcomes, it is important to approach such factors comprehensively [76].

5.1 Technical and manufacturing challenges

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Complicated Formulation and Stability: More complex delivery platforms like nanocarriers, floating devices and pH sensitive hydrogels cannot be formulated in a uniform manner to achieve relative side distributions of buoyancy, muco adhesion, controlled release, and drug stability within the hostile gastric milieu. Some of the manufacturing problems also involve the consistency of drug loading, repeatability of particle size and density, and ability to withstand degradation during storage and usages. The use of several drugs in several compartments or polymer layers makes production and quality control difficult [77].

Nano-scale to Mass Production: Going beyond small-scale synthesis of a specific substance to mass will require increased expenses because of specialized materials and complex technologies such as 3D printers and intensive quality control measures. Other methods like fused deposition modeling (FDM) adopted in 3D-printed gastroprotective devices involve the use of drugs grade polymers that are not readily available and this limits the scaling [78].

Physiological Variability: Physiological variability among the patients, in gastric emptying, motility, pH, and volume makes it difficult to optimize the retention and release characteristics of gastroretentive and nanomedicine system. The performance may vary unexpectedly due to disease states, food intake, and position [79].

Microbiome and Drug Interactions: Due to the role of the microbiome in drug metabolism and mucosal health, unexpected impact on microbial composition/function whenever embracing new systems requires careful in vitro and in vivo testing [80].

5.2 Potential safety issues and toxicity concerns

Nanotoxicity: depending on their composition, size, and the chemical of surface, nanoparticles and advanced materials can cause cytotoxicity, oxidative stress, inflammation, or immunogenicity. The biocompatibility determination should be cautiously performed, especially regarding either metallic nanoparticles or synthetic polymers [81].

Long-Term Effects: There is a dearth of understanding of how the gastrointestinal tract might remain persisted with some of the delivery systems or the elements of the delivery system. The risks in chronic exposure comprise of mucosal irritation, unintentional absorption in the system and Finland up to toxicity. Introductions of Novel Materials and Microbial Products: immunological reaction and allergy in sensitive persons: Insensitive persons may develop an immune reaction or allergy to novel materials or products (e.g., advancing the example further, probiotics) [82].

Dose Flexibility and Reversible Dosing: The gastroretentive and sustained-release systems can reduce drug exposure discontinuation caused by either side effects or technological reasons. It is

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a safety issue that requires reversible formulations or disintegrates fast and active post-market surveillance [83].

Interaction with Concomitant Medications: The effect of emergent delivery systems on noncontaminated drug absorption and metabolic processes needs cautious pharmacokinetics and pharmacodynamic research to circumvent the pernicious action [84]

Strict Preclinical: Regulatory agencies require much toxicological, pharmacological, and biocompatibility information in terms of new materials and formulations. This will involve the characterization of nanoparticle behavior, toxicity during long-term, biodistribution and interaction with host microbiota [85].

Clinical Trials and Demonstrated Benefit: Clinical development: This should have well-designed Clinical studies that show superiority over non-inferiority to standard therapies in terms of efficacy, safety, and quality of life to the patient. Considering complexity, adaptive design, inclusion of biomarkers and real-world evidence are typically needed in multi-phase trials [86].

Quality and Compliance of Manufacturing: The practice of good manufacturing (GMP) is extremely important. Consistency between batches of particles, drug loading, drug release and device functionality should be shown and this place difficult analytical and process control demands. Decision Making between Nanomedicines and the case devices has been in the shape of regulatory guidance that is undergoing the evolution of the regulations of the nanomedicines and various highly complex drug devices depicted by agencies like the FDA and EMA that aims at case-by-case evaluation. Preliminary regulatory involvement and the understanding of classification (drug, device, combination) facilitation make approval avenues easier [87].

Post-Marketing Surveillance: The continuous investigation of the preventable adverse events, their effectiveness, and the development of microbial resistance is required. Early recognition of safety and patient registries and pharmacovigilance programs enhance the early detection of safety indicators [88].

Patient-Certifications: Regulatory frameworks are increasingly making ease of use, enhancement of adherence, and low invasiveness standards of an innovative therapy in the quest to enhance patient outcomes and practical results [89].

Although emerging methods of managing gastrointestinal ulcers such as nanocarriers, gastroretentive system, and microbiome interventions have the potential to transform the therapy, technical manufacturing challenges, possible toxicity, and increasing regulatory requirements pose daunting challenges. Sustained interdisciplinary collaborations, developed preclinical and

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clinical testing, efficient manufacturing tasks, and aggressive regulatory activities are central to convert appealing research into attainable, dependable, and secure medications to patients [90].

5.3 Regulatory environment and pathway for novel therapies

Regulatory layers will demand long preclinical information regarding the toxicity of chemicals, pharmacology, biodistribution, and microbiome interference, on a case-by-case basis upon fresh material groups and delivery routes. Images Clinical trials should depict safe use, efficacy and benefit with respect to existing therapies which may involve adaptive procedures as well as actual world experience [91]. GMP-compliant pharmaceutical production where batch consistency is strictly required i.e. particle size, drug loading, drug release profile, and device integrity are all difficult in formulations with complexity. Nanomedicine and combination drug-device product regulatory guidance is dynamic and requires establishing arrangements with the regulators should one want to pursue a smooth regulatory approval pathway [92]. Post-marketing surveillance, such as pharmacovigilance and patient registries are also important to ensure the long-term safety, the effectiveness of treatment, and resistance occurrence. Easy to use and adherence potential is patient-focused issues that are referred to as regulatory issues Horizon by regulatory bodies to these advanced therapies [93].

6. Future Perspectives and Emerging Technologies

New therapeutic interventions to address gastric ulcer involve growth factors, gene therapy as well as stem cell therapy to promote mucosal healing, angiogenesis and epithelial healing. Growth factors, including EGF, promote healing, whereas gene editing and targeted gene delivery can control the production of prostaglandins, inflammatory cytokines, and the mucosal defenses systems to be beneficial in the long run. Mesenchymal stem cells also promote tissue healing by differentiating and immunology. Sustained, targeted, environment-sensitive drug release with enhanced bioavailability and decreased side effects are possible through development of smart drug delivery systems, such as pH-responsive systems, nanotechnology, multilayered devices 3D-printed and stimuli-responsive hydrogel-based hydrogels. The methods of precision medicine based on microbiome profiling, genomic and proteomic biomarkers, and digital health integration enable individual therapy, selection of antibiotics and real-time monitoring. All these innovations could change the guidelines of treatment, be focused on tissue healing, increase safety and effectiveness, patient compliance, healthcare expenses, patient-centered care.

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7. Conclusion

Gastric ulcers are changing their management because the traditional treatment approaches are constrained by such factors as resistance to Helicobacter pylori, recurrence, and incomplete healing of the mucosa. The conventional pharmacologic interventions primarily target the symptoms and acute recovery but do not fix dysbiosis, chronic inflammation, and dysfunctional mucosal immunity. This has fuelled the curiosity in nanomedicine, gastroretentivity drug delivery, microbiome modulation, and regenerative therapies. Liposomes, nanoemulsions, and chitosan-based systems represent nanoparticles that enhance targeted delivery, stability of drugs and release control, but the scalability and safety in the long term is a challenge. Gastroretentive formulations, which are floating, swelling, mucoadhesive and high-density formulations increase gastric retention, local effects, and compliance in the patients. The drug therapies involving microbiomes such as probiotics, prebiotics, synbiotics, and fecal microbiota transplantation are intended to restore the microbial balance, decrease inflammation, and enhance the mucosal barriers. Immune and metabolic control is also further selective to microbiome-directed pharmaceuticals. These methods combined with conventional regimens can help to decrease treatment failure and dysbiosis. To be successfully adopted to the clinic, it must be safe, affordable, scalable, and effective in the long-term. Altogether, nanotechnology, microbiome science, bioengineering and precision medicine could all combine to provide a more successful, patient-centered future of gastric ulcer therapy.

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