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FLOATING DRUG DELIVERY SYSTEM AS A NOVEL VITAL CONCEPT

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Abstract: The present study was carried out to determine the frequency and pattern of hyperlipidemia in patients with diabetes mellitus**. Objectives**: This multidisciplinary study was conducted at Government General Hospital, Department of Biochemistry, Rajiv Gandhi Institute of Medical Sciences, Kadapa. **Materials and Methods**: All known cases of diabetes mellitus (type 1 and type 2), of 1 year duration and of either gender were evaluated for their lipid profile. During six month study period, total 100 patients with diabetes mellitus were evaluated for lipid profile. Out of 100, diabetic patients 72 (72%) were males and 28 (28%) were females. 88 patients had type 2 diabetes mellitus and 12 patients had type 1 diabetes mellitus**. Results**: The mean ± SD for age of patients with type 2 and type 1 diabetes mellitus was 53. 73 ± 7.88 and 20.53 ± 1. 58. 07 (58%) patients of type 1 diabetes mellitus and 65(74%) patients of type 2 diabetes mellitus were found to be hyperlipidemic. The pattern of lipid abnormalities observed was high triglyceride in 22 (31%) patients, high LDL in 14 (19%), low HDL in 08(11%), high cholesterol in 10(14%) and combined hyperlipidemia in 18(25%) diabetic patients. **Conclusion**: The diabetic patients are more prone to develop hyperlipidemia.

Keywords: Diabetes mellitus, Hyperlipidemia, Lipid profile

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INTRODUCTION

Oral route is the most popular and convenient route for various drugs. Any route generally considered as an ideal drug delivery system that will possess two main properties:

a) It should be in a single dose for prolonging action.

b) It should deliver the active drug directly to the target site.

These considerations have led to the development of a controlled or sustained delivery system.[1]

Several difficulties are faced in designing controlled release systems for better absorption and enhanced bioavailability. One of such difficulties is the inability to confine the dosage form in the desired area of the gastrointestinal tract. Drug absorption from the gastrointestinal tract is a complex procedure and is subject to many variables. It is widely acknowledged that the extent of gastrointestinal tract drug absorption is related to contact time with the small intestinal mucosa.[2] Gastroretentive systems can remain in the gastric region for several hours and hence significantly prolong the gastric residence time of drugs.

Prolonged gastric retention improves bioavailability, reduces drug waste, and improves solubility for drugs that are less soluble in a high pH environment. To formulate a successful stomach specific or gastroretentive drug delivery system, Several approaches are currently utilized in the prolongation of the gastric residence times (GRT) such as hydrodynamically balanced systems (HBS) / floating drug delivery system[3], lowdensity system[4], raft systems incorporating alginate gels[5], bioadhesive or mucoadhesive systems[6], high density systems[7], superporous hydrogels[8] and magnetic systems[9].

Floating Drug Delivery System (FDDS): The concept of floating tablets is mainly based on the matrix type drug delivery system such that the drug remains embedded in the matrix which after coming in contact with the gastric fluid swells up and the slow erosion of the drug without disintegration of the tablet takes place. Sometimes for generating a floating system we even need to add some effervescent or gas generating agent which will also ultimately reduce the density of the system and serve the goal of achieving a floating system. These systems have a particular advantage that they can be retained in the stomach and assist in improving the oral sustained delivery of drugs that have an absorption window in a particular region of the GIT. These systems continuously release the drug before it reaches the absorption window, thus ensuring optimal bioavailability. Different approaches are currently used to prolong the gastric retention time, like hydro dynamically balanced systems, swelling and expanding systems, polymeric bio-adhesive systems, modified shape systems, high density systems and other delayed gastric emptying devices. The principle of buoyant preparation offers a simple and

practical approach to achieve increased gastric residence time for the dosage form and sustained drug release[3].

Based on the mechanism of buoyancy, two distinctly different technologies have been utilized in development of FDDS which are:

- **Effervescent System**

a) Gas generating system

b) Volatile liquid containing system

- **Non-effervescent system**

a) Colloidal gel barrier system.

b) Alginate beads.

c) Hollow microspheres / Microballons.

d) Intragastric Floating Drug Delivery Device / Microporous compartment system

Effervescent system:

These are matrix types of systems prepared with the help of swellable polymers such as methylcellulose and chitosan and various effervescent compounds, eg, sodium bicarbonate, tartaric acid, and citric acid. They are formulated in such a way that when in contact with the acidic gastric contents, CO_2 is liberate and gas entrapped in swollen hydrocolloids which provides buoyancy to the dosage forms.

a) Volatile liquid containing systems:

The GRT of a drug delivery system can be sustained by incorporating an inflatable chamber, which contains a liquid (like ether, cyclopentane), that gasifies at body temperature to cause the inflatation of the chamber in the stomach. The device may also consist of a bio-erodible plug made up of PVA, Polyethylene, etc. that gradually dissolves and causing the inflatable chamber to release gas and collapse after a predetermined time to permit the spontaneous ejection of the inflatable systems from the stomach.

b) Gas-generating Systems:

These buoyant delivery systems utilize effervescent reactions between carbonate/bicarbonate salts and citric/tartaric acid to liberate CO2, which gets entrapped in the gellified hydrocolloid layer of the systems thus decreasing its specific gravity and making it to float over chyme.

Non-effervescent systems:

This type of system, after swallowing, swells unrestrained via imbibition of gastric fluid to an extent that it prevents their exit from the stomach. One of the formulation methods of such dosage forms involves the mixing of the drug with a gel, which swells in contact with gastric fluid after oral administration and maintains a relative integrity of shape and a bulk density of less than one within the outer gelatinous barrier[10].The air trapped by the swollen polymer confers buoyancy to these dosage forms. Excipients used most commonly in these systems include hydroxypropyl methyl cellulose (HPMC), polyacrylate polymers, polyvinyl acetate, Carbopol, agar, sodium alginate, calcium chloride, polyethylene oxide and polycarbonates. This system can be further divided into four sub-types:

a) Colloidal gel barrier system / hydrodynamically balanced system

Such a system contains drug with gel-forming hydrocolloids meant to remain buoyant on the stomach content. This prolongs GRT and maximizes the amount of drug that reaches its absorption sites in the solution form for ready absorption. This system incorporates a high level of one or more gel-forming highly soluble cellulose type hydrocolloid, e.g., hydroxypropyl cellulose, hydoxyethyl cellulose, hydroxypropyl methyl cellulose (HPMC), polysacharides and matrix-forming polymer such as polycarbophil, polyacrylate and polystyrene. On coming in contact with gastric fluid, the htdrocolloid in the system hydrates and forms a colloid gel barrier around its surface[11].

b) Alginate beads:

Multi-unit floating dosage forms have been developed from freeze-dried calcium Alginate [13]. Spherical beads of approximately 2.5 mm in diameter can be prepared by dropping sodium alginate solution into aqueous solution of calcium chloride, causing the precipitation of calcium alginate. The beads are then separated, snap-frozen in liquid nitrogen, and freeze-dried at -40ºC for 24 hours, leading to the formation of a porous system, which can maintain a floating force for over 12 hours. These floating beads gave a prolonged residence time of more than 5.5 hours.

c) Hollow microspheres / Microballons:

Hollow microspheres loaded with drug in their outer polymer shelf were prepared by a novel emulsion solvent diffusion method [4]. The ethanol/dichloromethane solution of the drug and an enteric acrylic polymer was poured into an agitated solution of Poly Vinyl Alcohol (PVA) that was thermally controlled at 40ºC. The gas phase is generated in the dispersed polymer droplet by the evaporation of dichloromethane formed and internal cavity in the microsphere of the

polymer with drug. The microballoon floated continuously over the surface of an acidic dissolution media containing surfactant for more than 12 h.

d) Microporous compartment system:

This technology is based on the encapsulation of a drug reservoir inside a microporous compartment with pores along its top and bottom walls [12]. The peripheral walls of the drug reservoir compartment are completely sealed to prevent any direct contact of gastric surface with the undissolved drug. In the stomach, the floatation chamber containing entrapped air causes the delivery system to float over the gastric content. Gastric fluid enters through the aperture, dissolves the drug and carries the dissolved drug for continuous transport across the intestine for absorption.

Advantages of FDDS:

1. Floating dosage forms such as tablets or capsules will remains in the solution for prolonged time even at the alkaline pH of the intestine.

2. FDDS are advantageous for drugs meant for local action in the stomach eg: Antacids

3. FDDS dosage forms are advantageous in case of vigorous intestinal movement and in diarrhea to keep the drug in floating condition in stomach to get a relatively better response.

4. Acidic substance like aspirin causes irritation on the stomach wall when come in contact with it hence; HBS/FDDS formulations may be useful for the administration of aspirin and other similar drugs.

5. The FDDS are advantageous for drugs absorbed through the stomach eg: Ferrous salts, Antacids [14, 15].

Limitations of FDDS:

1. Floating systems are not feasible for those drugs that have solubility or stability problems in gastric fluids.

2. Drugs such as Nifedipine, which is well absorbed along the entire GI tract and which undergo significant first-pass metabolism, may not be suitable candidates for FDDS since the slow gastric emptying may lead to reduced systemic bioavailability. Also there are limitations to the applicability of FDDS for drugs that are irritant to gastric mucosa.

3. One of the disadvantages of floating systems is that they require a sufficiently high level of fluids in the stomach, so that the drug dosages form float therein and work efficiently.

4. These systems also require the presence of food to delay their gastric emptying. [16,17].

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