

Pharmacy Practice Communicator



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OBALON BALLOON SYSTEM- A NEW APPROACH FOR WEIGHT LOSS

Nandakumar U.P.*

Obesity has become a major risk factor for most of the diseases and is likely to develop risk for many serious health issues.¹ According to public health experts; more than 640 million people globally have obesity. Although patients are advised to adopt weight loss exercises, they often find it difficult in following them or controlling their weight.²

The researchers have brought about an innovative, non-invasive treatment strategy for people dealing with their weight gain troubles. This weight loss regimen called as “Obalon Balloon System”. Obalon Balloon System is a novel, non-surgical fully reversible device; developed by Obalon Therapeutics Inc. It has recently received approval from the US Food and Drug Administration (FDA). This swallowable intragastric balloon system is indicated for temporary use to facilitate weight loss in adults with Body Mass Index (BMI) of 30-40 kg/m², who have failed to lose weight through diet and exercise. It is intended to be used along with a moderate intensity diet and behavioural modification program.³

How it Works:

The system consists of a balloon folded inside a capsule that is swallowed by the patient. This procedure does not require any sedation or anaesthesia. Once the balloon reaches the stomach it is inflated with gas using a micro catheter, which is then removed, leaving a lightweight buoyant balloon in the stomach. During the next three months of treatment, two additional balloons are swallowed and inflated. At the end of 6-months treatment period, all three balloons are removed via outpatient endoscopy under conscious sedation.⁴ The study outcomes are summarized in the table given below.⁴

Study design	Sample size	Study site	Procedure
Double-blind sham- controlled study	387	Fifteen study sites in United States (US)	Patients received either 3 Obalon balloons or 3 sham-placebo devices filled with sugar. All patients were given minimal diet counselling of 25 minutes every 3 weeks. The co-primary weight loss endpoints of both studies were met.

The research team found that within Obalon balloon treatment group, the average loss of total body weight was 6.81%, while the control group only displayed an average of 3.59%. These individuals also significantly improved in other health indicators such as systolic blood pressure, fasting glucose, Low-density lipoprotein (LDL) cholesterol levels and triglycerides. It was also found that 64.3% of individuals who received the Obalon balloon achieved at least a 5% total body weight loss compared to only 3.2% in the control group.⁵

Adverse events:

Nine of 10 patients experienced mild to moderate rated discomforts such as abdominal cramping and nausea. It was managed with over the counter medications.

Conclusion

This system is expected to be available in early 2017 to physicians who have completed a training program. The research team believes that the Obalon balloon system could be the solution to the dilemma faced by patients for whom all other remedies for weight loss have been rendered incompetent.

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RECENT TRENDS IN INSULIN DRUG DELIVERY SYSTEM

Gayathri Baburaj*

Introduction

Diabetes mellitus represents a group of disease of heterogeneous aetiology, characterized by chronic hyperglycaemia and metabolic abnormalities. The etiological classification of diabetes includes type I, type II, those due to specific mechanisms or diseases and gestational diabetes. To attain strict glucose control, daily subcutaneous injections of human insulin is utilized. The development of novel non-invasive routes of insulin administration promises to further improvement in diabetes management.¹

Novel Non-Invasive Devices of Insulin Drug Delivery System:

The novel non-invasive devices of insulin drug delivery system are depicted in the Figure 1.¹

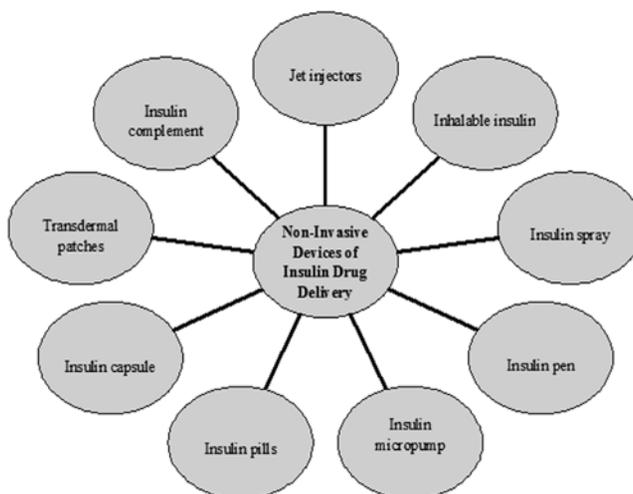


Figure 1: Novel Non-Invasive Devices of Insulin Drug Delivery System

1. Jet injectors

It is a type of medical injecting syringe that uses a high-pressure narrow jet of the injection liquid instead of a hypodermic needle to penetrate the epidermis.

2. Inhalable insulin

First product to be marketed as an Insulin inhalation, a powdered form of recombinant human insulin. It is delivered through an inhaler into the lungs where it is absorbed.

3. Insulin spray

The leading product of buccal spray formulation sprayed onto the buccal mucosa and allows drug to be absorbed into the bloodstream.

4. Insulin pen

Insulin pen is comprised of disposable pens-needles and a vial of insulin pen.^{1,3}

There are two types of pen systems:

Replaceable cartridge pen: It reuses the pen portion, when the insulin is empty; the vial is replaced by inserting a new one.

Prefilled pen: It is a disposable pen, when the insulin is used. The entire unit can be discarded.

The number of companies makes insulin pens including Novo Nordisk, Aventis and Eli Lilly. These companies produce pens for most of their insulin's.

Advantages:

- More convenient and easy to transport than traditional vial and syringe
- Repeatedly more accurate dosages
- Easier to use for those with visual or fine motor skill impairments
- Less injection pain

Disadvantages:

- Unlike traditional syringe, pens are usually restricted to full or half unit dosing

5. Insulin micropump :

The Flamel micropump technology is a controlled release system, which permits delayed and extended delivery of small molecule drugs.

6. Insulin pills

To control postprandial glycaemia several daily injections of insulin are necessary. However, subcutaneous or parenteral use of insulin is known to cause peripheral hyperinsulinemia. Presently, the human digestive system poses the biggest challenge with insulin pills.

Azopolymer coated pellets to deliver insulin to the colon region were studied earlier. The azopolymer protects the entrapped therapeutic agent until the pellets reach the colon. As only the bacteria inhabiting the colon secrete enzymes that can breakdown the azopolymer, insulin release will be initiated once the pellets reach the large intestine.²

Microencapsulation of insulin in polymeric microspheres coated with pH responsive polymers such as alginate. Alginate coating protects the spheres in the acidic pH of the stomach but dissolves in the intestine where the pH increases to above 7 and liberates the entrapped insulin.²

Insulin capsule

Researchers have developed polymeric capsules to protect insulin from destructive effect of digestive juices. These polymeric capsules are stable and remain intact in acid medium and they gradually excrete the insulin in a neutral medium. The positive protamine and negative dextran sulphate are the two polymers used in polymeric capsules. They form layers in series one upon the other according to the plus towards minus principle and make a multi-layer covering around the insulin filling, which makes upto 85% of the entire microparticle. Insulin is covered by protective capsule which is stable in acidic medium of pH ranged from 1.7 to 5 units. When pH increases to a level above 5 units, the insulin gets released.

7. Transdermal patches

Transdermal patch was the first product in development shown in US FDA clinical trials to provide a non-invasive, controllable and efficient way to deliver insulin via patch on the skin. It enables fast, controlled drug delivery without the pain of an injection or the possible complications associated with inhaled medications.³

8. Insulin complement

One new drug Symylin is ready to be launched by Amylin Pharma, San Diego. Symylin is a synthetic version of human hormone amylin, which moderates the glucose lowering effect of insulin. It is designed to complement insulin action and has been shown to reduce blood glucose without causing an increase in hypoglycaemic episodes.¹

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SNAIL VENOM TO UNLOCK NEW 'ULTRA FAST ACTING' INSULIN FOR DIABETICS

Sandra Sunny*

Insulin is a hormone that is important for metabolism and utilization of energy from the ingested nutrients - especially glucose. If the body does not produce sufficient insulin or the body becomes insulin resistant, the sugar level increases in the body.¹

According to the World Health Organization (WHO) figures, the number of people with diabetes has alarmingly risen from 108 million in 1980 to 422 million in 2014. WHO estimate that by 2030, diabetes will be the seventh leading cause of death in the world. Since then, there have been several attempts to improve the treatment options for its cure.¹

Major Breakthrough in the Research

A recent Australian study revealed that the venom of *Conus geographus*, a species of carnivorous marine cone sea snail could be a major key in developing artificial, fast-acting insulin that could be a more effective insulin therapy for the treatment of type-1, type-2 and gestational diabetes. The venom was found to contain a highly efficient natural protein called Cons-Ins G1 that is believed to operate faster than human insulin. They also found that the protein was able to bind to human insulin receptors, suggesting it could work as a treatment for diabetes.²

Researchers from Melbourne's Walter and Eliza Hall Institute (WEHI) discovered an unusual three-dimensional structure of insulin in the cone snail's venom, which showed that natural proteins Con-Ins G1 can function faster than human insulin.²

Snails Use Insulin in Chemical Warfare against Fish

The researchers discovered that the marine snail used insulin to capture the fish by releasing a mixture of toxins to target the nervous system. Further investigations revealed that the presence of a unique form of insulin, which drowns the fish into coma, allowing the snail to capture its prey.³

The scientists searched the gene sequences coding for all of the proteins expressed in the venom gland of the snail and found two sequences similar to insulin. They believed that adding insulin to the mix of venom has allowed the snail to disable the prey.³

To test the above-proposed theories, a synthetic form of cone snail insulin was created. They analysed by an assay with the prey fish, which confirmed that the insulin of cone snail drastically dropped down the blood glucose.⁴

Further Investigations

The researchers expressed their hope that further research would enable scientists to engineer an artificial version of fast acting insulin that could work instantaneously compared to the insulin currently used which requires fifteen minutes to take effect. The research findings also suggest that the future studies will be designed for the new and better treatment for diabetes.

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4. Cone Snail venom insulin – A key to better treatment for diabetes. Available from: www.sciencereport.com/articles/475U/20160914/diabetes-news-and-latest-update-cone-snail-venom-insulin-a-key-to-better-treatment-for-diabetes [last accessed on 26 Sept 2016]

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LIXISENATIDE FOR TYPE 2 DIABETES MELLITUS

Rajesh K.S.*

Background

In the United States (US) alone, type 2 diabetes mellitus affects nearly 30 million people. High blood sugar levels intensify the risk of severe problems like heart disease, kidney disease, nerve and eye damage. The U.S. Food and Drug Administration in July 2016, approved Lixisenatide for once-daily injection to improve blood sugar levels in adults suffering from type 2 diabetes mellitus, along with diet and exercise, adding to the available treatment options.¹ It was developed by Sanofi-Aventis, is a hormone that helps normalize blood sugar levels.

Mechanism of action

Lixisenatide is a glucagon-like peptide-1 (GLP-1) receptor agonist, which stimulates the GLP-1 receptor. GLP-1 is a hormone that aids pancreatic beta cells to secrete insulin in response to higher blood sugar. Like GLP-1, Lixisenatide also reduces gastric emptying.¹

Prescribing information²

Lixisenatide is indicated to improve blood sugar levels as an adjunct to diet and exercise in type 2 diabetes mellitus patients. The safety data is insufficient in patients with history of pancreatitis. It is not indicated for the patients with diabetic ketoacidosis or type 1 diabetes mellitus.

Dosing information:

Lixisenatide should be started with 10 mcg once daily subcutaneously for 14 days, thereafter 20 mcg once daily as maintenance dose. It should administer one hour before first meal of the day.

Injection sites:

The injection must be administered subcutaneously at abdomen, thigh or upper arm

Safety and Efficacy aspects:

Five thousand four hundred patients were participated in a multicentric clinical trial in which the drug was evaluated alone and in combination with other Food and Drug Administration (FDA) approved antidiabetic agents like metformin, sulfonylurea, pioglitazone and insulin, which confirmed the safety and efficacy of the molecule. Lixisenatide did not increase the risk of cardiovascular adverse effects in patients with cardiovascular disease alongside type 2 diabetes mellitus when compared with placebo.¹

Adverse effects:

Common side effects that are reported during clinical trials include nausea, vomiting, headache, diarrhoea and dizziness. Lixisenatide rarely causes hypoglycaemia in combination with other antidiabetic agents. Severe hypersensitivity reactions were also reported.

Contraindications

Hypersensitivity to Lixisenatide or any other ingredient of the injection. Lixisenatide is not indicated for patients with diabetic ketoacidosis or type 1 diabetes mellitus.

Further studies are under consideration for evaluating dose, efficacy and safety in children and to evaluate the immunogenicity of Lixisenatide.¹

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[Last assess on 30 September 2016]

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NEW DRUGS APPROVED BY U.S. FOOD AND DRUG ADMINISTRATION (FDA) (JULY – SEPTEMBER 2016)

Dr. Uday Venkat Mateti*

Specialty	Drug Name	Brand Name	Company Name	Uses	Approved (Month, Year)
Cardiology/ Vascular Diseases	Aspirin and Omeprazole	Yosprala	Aralez Pharmaceuticals	Prevention of cardiovascular and cerebrovascular events	September 2016
Musculoskeletal	Eteplirsen	Exondys 51	Sarepta Therapeutics	Treatment of Duchenne muscular dystrophy with mutated DMD gene amenable to exon 51 skipping	September 2016
Neurology	Oxycodone + Naltrexone	Troxyc ER	Pfizer	Management of severe pain	August 2016
Oncology	Pembrolizumab	Keytruda	Merck	Treatment of head and neck squamous cell cancer	August 2016
	Granisetron	Sustol	Heron Therapeutics	Prevention of chemotherapy- induced nausea and vomiting	August 2016
	Dronabinol oral solution	Syndros	Insys Therapeutics	Treatment of anorexia associated with AIDS and nausea and vomiting associated with cancer chemotherapy	July 2016
Endocrinology	Lixisenatide	Adlyxin	Sanofi Aventis	Treatment of type II diabetes	July 2016
Ophthalmology	Adalimumab	Humira	Abbvie	Treatment of uveitis	July 2016
	Lifitegrast	Xiidra	Shire	Treatment of dry eye disease	July 2016

Reference: <http://www.centerwatch.com/drug-information/fda-approved-drugs/>. (Last accessed on Sept 30, 2016)

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NEW DRUGS APPROVED BY CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO), INDIA (JULY – SEPTEMBER 2016)

Dr. Uday Venkat Mateti*

Drug Name	Strength	Indication	Date of issue
Phospholipids Fraction from Bovine Lung (surfactant)	50 mg/vial	Preventive use in premature neonates with a high risk of respiratory distress syndrome	12th September 2016
Midodrine Hydrochloride Tablet	2.5 mg	Treatment of symptomatic orthostatic hypotension	2nd September 2016
Palbociclib Capsule	75mg/100mg/125 mg	Indicated in combination with Letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease	11th August 2016
Fenticonazole Nitrate Vaginal Capsule	600 mg	Treatment of vulvovaginal candidiasis	10th August 2016
Lurasidone Hydrochloride Tablet	40mg/80mg	Treatment of Patients with schizophrenia	18th July 2016
Sacubutril+ Valsartan Film coated tablet	50mg/100 mg/200mg	To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction	14th July 2016
Acotiamide Hydrochloride Tablet	100mg	Treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia	6th July 2016

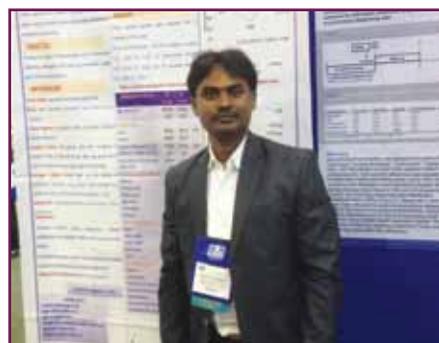
Reference: <http://www.cdsc0.nic.in/forms/list.aspx?lid=2034&ld=11>. (Last accessed on June 30, 2016)

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DEPARTMENT OF PHARMACY PRACTICE NEWS

International Travel Scholarship Award to Dr. Uday Venkat Mateti

Dr. Uday Venkat Mateti, Asst. Professor, Dept. of Pharmacy Practice, Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences has been awarded International Society for Pharmacoepidemiology (ISPE) International Travel Scholarship 2016 to participate and present the paper entitled “Impact of Pharmaceutical Care on Medication Adherence, Hemoglobin Levels and Interdialytic Weight Gain Among Hemodialysis Patients - A Multicentric Trial” at 32nd International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) in Dublin, Ireland from August 25-28, 2016



As a recipient of a Travel Scholarship, he has been awarded free pre-conference courses on “Introduction to the Evaluation of Therapeutic Risk Management Programs”, “ISPE Newcomers/Early Stage Investigators Workshop”, “Pharmacovigilance & Signal Detection”, and “Advanced Topics in Pharmacoepidemiology” and conference registration completed by ISPE prior to the conference and inclusive of coach airfare and hotel up to a total of \$425 USD. In addition to that, 50% of the expenditures incurred towards attending the conference such as travelling are borne by Nitte University, Mangalore as a privilege.

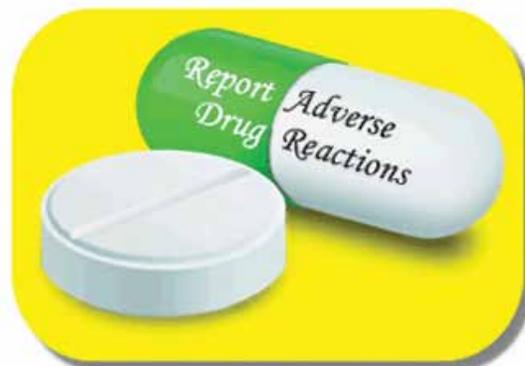
Dept. of Pharmacy Practice Faculty attended the CME on Pulmonary Medicine Meet 2016

The Department of Pharmacy Practice faculty members Dr. Juno J Joel, Mr. Javedh Shareef, Dr. Uday Venkat Mateti and Dr. Rovin M Theempalangad have been participated in the CME on “KMC Mangalore Pulmonary Medicine Meet-2016” conducted by Dept. of Pulmonary Medicine, Kasturba Medical College, Manipal University, Mangalore on 18th September 2016.

Pharmacovigilance Activities

Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects or any other drug related problem”. (WHO)

The Department of Pharmacy Practice has actively involved in reporting Adverse Drug Reactions (ADRs) in the Justice K.S. Hegde Charitable Hospital. The Department is also actively involved in reporting ADRs to the Pharmacovigilance Program of India (PvPI), New Delhi.



Please report any type of ADRs to the Department of Pharmacy Practice, **Tel. 0824-2202739**

NGSM Institute of Pharmaceutical Sciences



Nitte Institutions

Health Science Institutions, Hospitals and Research Centres

1. K.S. Hegde Medical Academy, Mangaluru
2. A.B. Shetty Memorial Institute of Dental Sciences, Mangaluru
3. Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Mangaluru
4. Nitte Usha Institute of Nursing Sciences, Mangaluru
5. Nitte Institute of Physiotherapy, Mangaluru
6. Nitte Institute of Medical Laboratory Sciences, Mangaluru
7. Nitte Institute of Speech and Hearing, Mangaluru
8. Justice K. S. Hegde Charitable Hospital, Mangaluru
9. Nitte Meenakshi Institute of Craniofacial Surgery, Mangaluru
10. Leela Narayana Shetty Memorial Cancer Institute, Mangaluru
11. Nitte-Gajria Hospital, Karkala
12. Kshema-IVF: Fertility & Reproductive Medicine Centre, Mangaluru
13. Nitte Rural Psychiatry Centre, Nitte.
14. Kowdoor Gopal Hegde & Smt. Manorama Hegde Hospital, Bailur.
15. Nitte University Centre for Science Education & Research (NUCSER), Mangaluru
16. Nitte University Centre for Animal Research & Experimentation (NUCARE), Mangaluru
17. Nitte University Centre for Stemcell Research & Regenerative Medicine (NUCSReM), Mangaluru

Engineering Institutions

18. Nitte Mahalinga Adyanthaya Memorial Institute of Technology, Nitte
19. Nitte Meenakshi Institute of Technology, Bengaluru
20. Nitte Institute of Architecture, Mangaluru

Management Institutions

21. Justice K. S. Hegde Institute of Management (Dept. of Management Studies, NMAMIT, Nitte), Nitte
22. Nitte School of Management, Bengaluru
23. Sarosh Institute of Hotel Administration, Mangaluru
24. Nitte Institute of Banking & Finance, Mangaluru
25. Nitte Institute Communication, Mangaluru

Technical Institutions

26. Nitte Rukmini Adyanthaya Memorial Polytechnic, Nitte
27. Mulki Ramakrishna Punja Industrial Training Institute, Thokur

Science and Commerce Institutions

28. Dr. Nitte Shankara Adyanthaya Memorial First Grade College, Nitte
29. Dr. Nitte Shankara Adyanthaya Memorial First Grade College, Bengaluru
30. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Nitte
31. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Mangaluru
32. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Bengaluru

Schools

33. Dr. Nitte Shankara Adyanthaya Memorial Senior Secondary School, Nitte
34. Dr. Mundkur Ramanna Shetty Memorial English Medium High School, Thokur
35. Nitte International School, Bengaluru
36. Dr. Nitte Shankara Adyanthaya Memorial Higher Primary School, Bolakodi

Satellite Health Centres:

Bailur | Bellikoth | Bengre | Dabbekatte | Farangipet | Hejamadikodi | Kadri
| Karkala | Mangalagangothri | Madikeri | Mukka | Mulki | Mundkur | Nada
| Nitte | Sasihithlu | Sringeri | Subrahmanya | Thalipadi