

Intra Gastric Balloon for Weigh Reduction

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Abstract

Elips balloon is new generation of intragastric balloon similar to action of other type of intragastric balloon the only difference in method of implantation and extraction which is very important to patient and phycision .

The function of balloon to tack space in stomach more the 2/3 of stomach and felling of fullness after that .

The elips balloon its very simple to insertion or implant to stomach by swallowing with cup of water within 2-4 minuts only by patient its self similar to swallowing big tablet or big bite of food some time need to help by use guide wire inside the balloon tube .

The balloon remain inside the stomach for about 4 months rang from 3 to 5 months and the average of weight loss its about 10-38 kg its depend on the patient how much he or she is sticky to instruction about type and amount of food during the balloon implant .

The balloon rupture spontaneously after end of its age and it will pass smoothly through GIT and leave the body with stool some time associated with abdominal cramp during passing .

In this paper I will tock about my experience only in Iraq with elips balloon for about 185 balloon about side effect and complication and result in weight loss , induration from January 2018 to October 2021

All of its implant in my clinic under close fellow up to the patients for 6 months duration.

Keywords- Gastricballoon , allurion .Intragastricballoon .Weight loss .Overweight .Obesity.Elips Balloon .Haider ALRamahi

Introduction

Many peoples in the world suffering from obesity or over weight ,the surgery is solution for this problem in about 4-5% many parients not prefer the surgery at least at the beginning [1].the reason for that is duo to complication of bariatric surgery which associated of high morbidity and mortility in comparism with other method of weight loss.

Many options available to the patient like intragastric balloon or diet program or physical activity as change of life style [2]

Intra gastric balloon by endoscope or without endoscope have good result and accept to the patient and doctors as safe and short duration of placement

,the balloon in stomach have different size and shape and if its full with fluid or gas or both also difference in remain duration in stomach [3-6]. However the intra gastric balloon the require endoscope is not free from complication as its invasive procedure and require endoscope available and cost of its and also require training for the doctore about the endoscope and also the time (gastroscope) added to that all its require some type of anesthesia or some sedation [7] and some patient a fried from spontaneous deflation of balloon and migration to small bowel and lead to small bowel obstruction [8-10]

Elipse™ (Allurion balloon Technologies, Wellesley, USA) is a swallowed in the clinic under guide of u/s or X –ray , self-emptying, and excreted deflated and

pass spontaneously gastric balloon for weight loss (Fig. 1 and 2).

(1) The balloon



(2) The kit of the balloon



The balloon is folded for small size about olive size inside the capsule that attach to small caliber tube catheter its self sealing valve .once the capsule swallowed and confirm position of its inside the stomach by X-ray as the tube is radiopaque then inflate the balloon with fluid from about 400 to 550 ml then the tube is pulling back slowly to be release from the balloon that keep in stomach with fluid

.after finish the duration the balloon start to decrease in size gradually as deflated spontaneously from site of the valve then pass from gastrointestinal tract with stool no need for any sedation or endoscope as this is the advantage of allurion or elips balloon

The capacity of allurion ballon about 550ml about half KG in the stomach .the objective of this study to focusing about safety and duration and result of allurion balloon as its easy inflate and spontaneous deflate and pass through gastrointrstinal tract without any problem

Methods

This study had a prospective , and non-randomized design . the subject or sample of the patients have BMI 27% to 35% without any sign and symptom of gastrointestinal disease like gastric erosion or reflux or GIRD or epigastric pain or inflammatory disease in small bowel or cancer . the subject also include stope Asperin and NSAID 14 Days before balloon implant and also stope any medication for weight loss as to decrease appetite or for malabsorbation and depend on effect of balloon only during this study .the patient will keep on antiemetic like ondandrone and PPI for first 5 days after balloon placement and then on PPI only for 4 months as protective measure for stomach from any erosion duo to direct contact of balloon with stomach and to prevent gastric upset . also the patient fellow up every 3 -4 weeks to check the size of balloon by U/S and to asses the nutritional state of the patient if need for any supplement ,no endoscopy was perform before balloon implant some time H- pylore eradication need in symptomatic patients .the diet program and exercise or physical activity as change in life style of the patient as prescribed are important part of treatment for the patient

Safety Measures

The safety measures include easy to ability swallow of the smaal size of allurion balloon in the clinic or in the hospital and then fellow the capsule and catheter or guid wire by X ray or other type of image to be sure about position of the capsule as its radio opaque and the inflate the balloon slowly with felling any resistant during pushing the fluid through the

catheter ,then follow up the patient every 3 -4 weeks .our study include 185 case (109 femals and 76 males)

Safety measures included also include present of legale distributor of company in our country Iraq (allurion or elips office).

Results

185 case of balloon, The mean age group was 40 years (range 24–60), mean BMI was 31.0% kg/m² (range 27.6–35.0 %kg/m²), and mean weight was 88.0 kg (range 74.8–112.8 kg) and mean weight loss about 10.5 – 33.4 kg

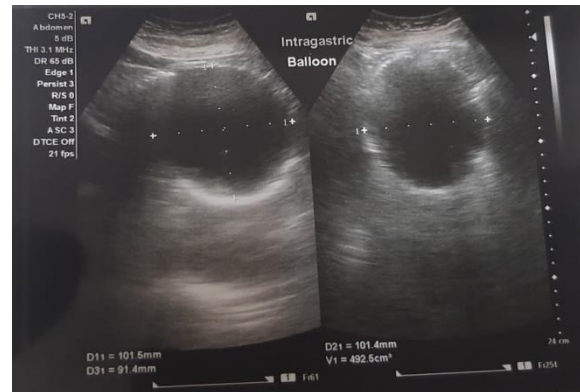
The capsule elips was swallowed by the patient without any help with cup of water or we can help the patient by push the capsule with guild wire inside the catheter with swallowed of the patents and no need for endoscopy or sedation .. All balloons were filled successfully (mean fill time=15 min) with 400 mL to 550 ml filling fluid and visualized successfully on x-ray and U/S (Fig. 3 and 4).

Figure 3

X –ray show catheter and capsule inside the stomach



Figure 4



U/S show inflated balloon inside the stomach

The mean visit time was 3 weeks. were visualized the balloon on U/S as part of follow-up during visits to clinic or center to confirmed the balloon to be full. They then self-emptied and were excreted. An abdominal U/S was taken at trial exit to confirm that the balloon had passed. Two balloon had problem in the catheter tube as leak of fluid during inflation of the fluid due to a manufacturing defect or may be duo to damage by tooth of the patient .

The collapsed balloons was found in the stomach after 2 months for 5 balloon on ultrasound. 2 patient intolerance and removed after 2 days as endoscopy was performed, and the esophagus and stomach were normal. The balloon film was punctured with a needle, torn with forceps, and extract from the stomach as in traditional procedure .

133 patient get weight loss in range from(22 kg - 28 kg)

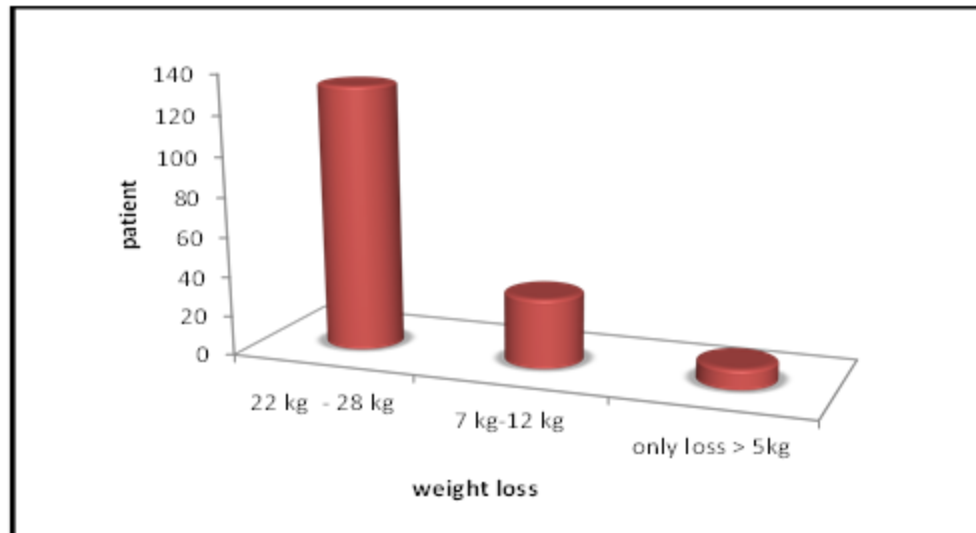
and 35 patient weight loss about (7 kg-12 kg)

and only 10 patients only loss > 5kg

the mean weight loss(12.3% – 33.4%) of %EWL

after spontanuose deflation of balloon It passed in the stool 4 days later some time asymptomatic .

patient	weight loss
133	22 kg - 28 kg
35	7 kg-12 kg
10	only loss < 5kg



Above Diagram for our conclusion

Safety

As no anastethia or sedation and no endoscope so the allurion balloon is very safe and accepted from the patients.

About 75% of my patient suffering from nausea and vomiting in first 3 -5 days .and about. They was treated by antiemetic with regulate amount ant time of oral fluid intake.

37.5% of the patient report abdominal cramping attack on and off also treated by medication as antispasmine injection or paracetamol ampule for first 3 days. As conclusion the nausea and abdominal pain some time self- limiting or can tolerance by the patients without any medications

All the above symptom can be classify as mild in 92.4% and moderate in 5.5% .

Discussion

There are many method of weight loss either surgical or non surgical (like balloon). Till now any surgical intervention not free from complications even the gastroscope .

There are many modules of balloons actually I was used most of its either made in USA or in rusia or others FDA approved either contain gas or fluid or half (fluid and gas) the result finally depend on the patient who is change the life style not only the food eating I means physical activity and sleep time .so duo to those reason we are looking now for safety and early reacavery as well as all the procedure depend on the patients response to change his life style.

This pilot study about the safety and efficacy result of weight loss by allurion (elips) balloon and this version of balloon easy swallow by the patient and not need for endoscope or sedation and no any report about gastric perforation or bleeding duo to allurion

balloon as in comparison with other type of balloon orbera or spatze or medside balloon which was report some cases of gastric perforation . the allurion balloon visualize by U/S and by X –ray and no any report study of aspiration during balloon swallowing or intestinal obstruction during balloon passage after deflated and because the allurion ballon not made from silcon so its friend to gastric mucosa and no any report study of haematemasis or melena duo to balloon effect (this complications was reported in others type of balloon .

[3, 11]. Unlike to endoscopic gastric balloons (orbera ,BIB, spatze), the allurion balloon is entirely designed from a thin film without any rigid parts with the sole purpose like olive shape for allowing safe passage through the gastrointestinal tract. Allurion balloon is designed to be implant in the clinic or hospital out patient clinic without need for any sedation and pass spontaneously without need for endoscopy which is not free from complication and added more cost on the patient and need sedation or anastethia while the other type of gastric balloon like orbera or spatze or BIB or others type need gastroscope (endoscope) for placement and extraction of the [12]. The use of sedation or anastethia and endoscope is very important point to try to avoid as much as possible in obese patients because this type of patient associated with risk of all type of [7]. In addition, to that many patient try to repeat the procedure of allurion balloon swallow for contanouse weight loss or to maintain the body weight with continouse fellow up or visit to clinic every 3 -4 weeks .

The complication that occur with other type of balloon as intestinal obstruction when balloon deflate and not able to pass spontaneously throught gastrointestinal tract ,this complication occur where the patient not have good fellow up and the time of balloon finished then the balloon deflate and migrate to small bowel and cause obstruction, occasionally the balloon can pass spontaneously

[8–10]. Even the filling of traditional balloon with methylene blue stain as the first sign for alarm for rupture of the balloon its not safe because the stain with the time it will be not dark and the patient some time not awake about the collour duo to mixed with

food particles and some time the balloon rupture and migrate to small bowel immediately [13]. However, since the allurion or elips balloon is specifically designed to self-empty and pass through the stool , so not need to methylene blue stain even this stain not good for the kidney so no need to exposure the body for risk of methylene blue dye only fellow up patient with allourin balloon by.. However, when the patient not suffering from gastric upset or any others sign or symptom of upper gastric tract disease so not need foe endoscope which its not free from complication .

As comparism with free patient from sign of gastric upset who underwant balloon implant with endoscope we didn't find any new pathology in stomach or duodenum by use endoscope so the use of allurion balloon without endoscope in asyptomatic patient its totally safe . [12].. The allourion balloon used in this study was filled with fluid from 450 mL or 550 ml and remain in stomach for about 4 to 5 months . [13].however , previous studies was demonstrated that the allurion balloons can be repeated in patients for 2 to 3 time who require additional weight loss or to maintain his body weight [14–16].

Conclusion

our pilot study demonstrated the safety and feasibility of the allurion gastric balloon and rang of weight loss . In particular, allourion was successfully swallowed by the patient with or without guid wire then , filled with fluid , imaged was taking , and passed in all patients without the use of endoscopy or sedation. In addition, all patients lost weight depend on patient himself .Future studies will do comparism in weight loss and safty between Elips balloon and endoscopic balloon like endolis or orbera or spatize adjustable balloon . Since it does not require endoscopy(gastrosocopy) or sedation or anesthesiatha ,the allurion balloon can place or implant in the doctore office (clinic) no more investigations and no admission to hospital and no endoscope for implant and for extract, even the cost for the patient is very important.

Ethical Standards All this study and procedures performed in studies involving human participants for treatment of overweight or obesity were in

accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments and recommendation or comparable ethical standards.

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