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Development and *In-Vitro* simulation evaluation of a balloon-assisted gastric calibration tube for bariatric surgery

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Abstract
Some of the problems that affect the world include obesity. One form of surgery that can be performed on an individual who wants to lose weight is Laparoscopic Sleeve Gastrectomy. This is one of the surgeries that can be performed on an individual who wants to lose weight. A balloon-assisted gastric calibration tube is a medical device that is employed during the procedure of sleeve gastrectomy. The medical device is employed for the purpose of stomach sizing and stomach calibration. The medical device consists of an adjustable distal balloon that expands within the stomach for stomach stabilization and an inner lumen that allows for suction, stomach decompression, and testing of leaks. Gastric calibration is an important aspect of the procedure of sleeve gastrectomy. It is essential to obtain an optimal stomach size and minimize the risk of complications. However, it is a challenge to ensure that devices are stably placed during surgical procedures. The article presents a description of the design as well as an *in Vitro* assessment of the proposed balloon-assisted gastric calibration tube. The experiments were conducted using a gastric anatomical model to test device insertion through the orogastric path, as well as balloon expansion and stability. The results showed that it is possible to stably position the device within the stomach as well as expand the balloons while utilizing the central lumen for suction as well as leak testing. The results suggest that the proposed device has the potential to improve stability and consistency during calibration procedures in a sleeve gastrectomy.

Keywords: Gastric calibration tube with balloon, bariatric surgery, sleeve gastrectomy, obesity management, *in-Vitro* simulation

Introduction

The problem of obesity is getting worse and worse. It is one of the challenges to public health all over the world [1, 2]. Obesity is a disease that can cause a lot of health problems and even death. It can increase the risk of getting diabetes, high blood pressure, heart disease and other health issue [3]. Doctors usually tell people who're obese to change their lifestyle and take medicine. Sleeve Gastrectomy Surgery surgeon removes the portion of the stomach that makes a major appetite regulating hormone, while also making the stomach Size is too small it can cause problems [4, 11]. If it is too big the person may not lose weight. Doctors use a tool to measure the stomach. This tool is called a calibration tube. The size of the tube is to be important. It can affect how well the surgery works and whether the person has any complications [5, 6]. Some doctors have developed tools to help with this step. These tools use a balloon to help figure out the size of the stomach. The balloon gets filled with air so the stomach is the size [7, 10]. This helps the physician do the procedure right and keep the person safe. The stomach is an important part of our body and using a balloon in these tools really helps the physician work, on the stomach. This study examines a device that measures the stomach using a balloon [12, 14]. The fact that this instrument is made for surgery makes it unique. This tool is special because it is designed for surgery. It is not like tools that people use to lose weight. The tool has a balloon on the end that can be filled with air. This helps the doctor get the stomach to the size. The tool is also flexible so it can be used in types of stomach [8].The tool helps doctors do the surgery safely and accurately. It can aid in weight loss and maintain good health. The tool comes in sizes so doctors can choose the right one for each person. It can be used to help with parts of the surgery too like removing air from the stomach or checking for leaks. The goal of this study is to make surgery safer and more effective [9]. Doctors can really help people who are obese lose weight and stay healthy by using this tool. When people to lose weight they can reduce the number of health problems related to obesity. This tool is great, for people who're obese because it helps them stay healthy. The problem of obesity is very serious [15].This study Contributes to the ongoing effort. With the help of new tools and techniques doctors can do a better job of helping people who are obese.The new tool is designed to make surgery easier and safer. It can help doctors get the stomach to the size, which is very important for the surgery to be successful. The tool is also easy to use so doctors can focus on the surgery. Overall this study is, about that can help doctors do a better job of helping people who are obese. The tool is special because it is designed for surgery. It may contribute to a safer and more successful procedure [16].

Literature review

Accurate gastric calibration plays an important role in determining the success and consistency of bariatric procedures, particularly laparoscopic sleeve gastrectomy [5, 6]. Differences in final sleeve size are often linked to the type of calibration device used, the chosen diameter, and how well the device is positioned during surgery [7, 10, 12]. Traditionally, surgeons have relied on fixed-diameter bougies and calibration tubes to guide stapling, but published studies and surgeon surveys show that these fixed guides can still lead to noticeable variation in sleeve shape and size when they are not well stabilized [12,14].

Clinical and technical reports have shown that the selected calibration tube size directly influences the degree of restriction created and intragastric pressure behavior after surgery [7, 10]. Smaller sizes may increase restriction but can make staple-line alignment less consistent, while larger sizes may improve consistency but modify the restrictive effect [7, 10]. Because of this trade-off, there is growing emphasis on achieving more controlled and stable calibration rather than relying solely on fixed-diameter guides [8, 9].

To improve positioning stability, balloon-assisted calibration devices have been introduced [13]. Gastric calibration tubes with a balloon expand in a controlled manner at the distal end, helping the device sit more securely against the gastric wall and reducing the chance of movement during stapling [8]. Early experimental and clinical evaluations suggest that controlled expansion approaches may reduce user-to-user variability and produce more reproducible sleeve dimensions compared with standard bougie guidance [9].

Recent device design trends show a shift toward multifunctional gastric calibration tubes with balloon that combine sizing guidance with additional features such as suction, decompression, and leak testing through a central lumen [8, 9]. Features including clear depth markings, smooth atraumatic tips, and controlled inflation mechanisms are increasingly regarded as important for safety and ease of use [8]. The present study addresses these developments by presenting an *in-Vitro* simulation–based assessment of a gastric calibration tube with balloon design [9, 15].

Materials and Methods

'Pioneering the Development of 'Gastric calibration tube with balloon'

Device Description

The study evaluated a single-use gastric calibration tube with balloon designed for laparoscopic sleeve gastrectomy. The device features an adjustable distal balloon for intragastric stabilization and a central lumen for suction, gastric decompression, and intra operative leak testing. Tube is available in French sizes 30–45 Fr (commonly 36–38 Fr) and lengths of 850–900 mm. safe insertion via the orogastric route and positioning along the lesser curvature.

Material Selection

The gastric calibration tube with balloon is made from a kind of silicone that doctors like to use. This silicone is really flexible and strong. The gastric calibration tube with balloon can bend easily it is like it moves along the natural shape of the body without getting all kinked up. The gastric calibration tube with balloon stays firm enough to stay in the place and guide things properly when the doctors are doing a procedure. The balloon that is at the end of the calibration tube with balloon is made from a special material this material can stretch without getting too much stress on its walls so it does not get damaged easily. The gastric calibration tube, with balloon is a useful tool for doctors to use**.**

Clinical Procedure for the Use of a Gastric Calibration Tube with Balloon:

Gastric and bariatric surgeries need measurement and positioning of the stomach to get good results. To do this surgeons often use a tube with a balloon that can be inflated. This tube helps guide the stapling process keeps the stomach passage a size and helps check for leaks during surgeries like sleeve gastrectomy and gastric pouch formation. When used correctly the balloon tube helps get the size reduces differences between cases and makes the surgery safer. After the patient is given anesthesia the tube is carefully put in through the mouth. Pass Down the esophagus into the stomach. The tube is well lubricated so it doesn't hurt the lining of the stomach. The surgeon checks that it's in the place using marks on the tube and sometimes a special camera. Once the tube is in the place the balloon at the end is inflated with a certain amount of air or saline following the surgeon's instructions. Inflating the balloon gives a reference for stomach size and helps guide the stapling lines. During surgery, physicians may utilize the balloon to check for air leaks. The surgical team is currently checking the size of the balloon and the position of the tubes, then to confirm that everything is stable.They deflate the balloon once they're done. The tube is gently taken out. The device is then checked to make sure it's still good. Using a calibration tube with a balloon, in a careful and systematic way helps make procedures more consistent improves sizing accuracy and lowers the risk of complications caused by inaccurate calibration or missed leaks.

Construction and Structural Features

The device incorporates a single lumen shaft with an integrated distal balloon. This tube is connected to a channel that helps control inflation and it ends at a port near where a balloon can be attached using a standard connector. The main channel inside the tube stays open all the way through so you can use it to suck out things blow air in or add fluid without the balloon getting in the way. The end of the tube is shaped carefully so it doesn't hurt the tissue when it's inserted. The balloon inflation does not block the flow. The tube has a Luer connector for the balloon.

Working Mechanism

The doctor puts the calibration tube into the stomach through the mouth. They move the tube into the spot in the stomach and line it up along the inside curve of the stomach. When the tube is in place the doctor fills the balloon at the end of the tube, with water until it is the right size. This helps the tube push gently against the stomach wall. The tube stays in place inside the stomach because of this. It does not move around when the doctor is doing the gastric stapling on the stomach. The gastric calibration tube stays lined up right in the stomach.

Risk Analysis

The gastric calibration tube with balloon is for short-term use during surgery. Like any device that goes inside the stomach it has some risks. These risks need to be managed with good design and proper use in the clinic by inflating the balloon correctly. If the balloon has much or too little air it can affect how well the gastric calibration tube with balloon works. It can also put much pressure on the stomach wall. To deal with this risk the instructions for the device and technical papers usually say what the right amount of air is. They also have labels on the ports where you add air and special tools to measure the air so that users can add the amount of air every time. The gastric calibration tube, with balloon needs to be used right to avoid problems.

Another recognized concern is tube malposition or movement during stapling. If the calibration tube shifts, it may influence sleeve alignment and sizing consistency. To reduce this possibility, commonly described mitigation features include graduated depth markings, distal balloon stabilization, atraumatic tip geometry, and routine

intraoperative position checks. Another recognized concern is tube malposition or movement during stapling. If the calibration tube shifts, it may influence sleeve alignment and sizing consistency. To reduce this possibility, commonly described mitigation features include graduated depth markings, distal balloon stabilization, atraumatic tip geometry, and routine intraoperative position checks. Surgeons take measures to ensure everything is properly positioned during an operation. They verify the tube alignment at intervals to ensure proper positioning. The tube consists of a substance that is safe for the human body. This aids in avoiding issues such as the balloon within the tube leaking or becoming obstructed. For safety, doctors utilize plastic exclusively designed for medical purposes. They verify that the components are correctly assembled and that the tube is suitable before utilizing it. They carry out all these actions to guarantee the safety of the patient during the procedure. The doctors check the tube again to verify that it is working correctly. This is all involved in utilizing tubes similar to this one. Medical tubes must be inspected for issues such as balloon leaks or obstructions.

Single-use sterile packaging is commonly advised in published device guidelines to prevent contamination and performance decline linked to reuse. Irritation of the mucosal lining related to insertion is another possible concern mentioned in clinical usage talks. This is usually reduced by smooth surface finishing, flexible shaft design, rounded distal tips, and sufficient lubrication prior to insertion. Operator instruction and compliance with gentle insertion methods are consistently highlighted in clinical recommendations to reduce the risk of mechanical injury. Modern designs tackle functional performance risks associated with suction or leak testing channels by ensuring full-length lumen continuity, conducting bench flow tests, and performing thorough quality inspections prior to release. Numerous published procedural guidelines additionally recommend conducting device checks before and after use to ensure that the tube and balloon system stays intact and operational.

In general, literature and device recommendations suggest that when the gastric calibration tube with balloon is employed within specified inflation limits and procedural guidelines, the risk profile stays controlled and manageable during intraoperative calibration. Continued bench testing and extensive clinical assessment are typically advised to enhance safety and performance proof.

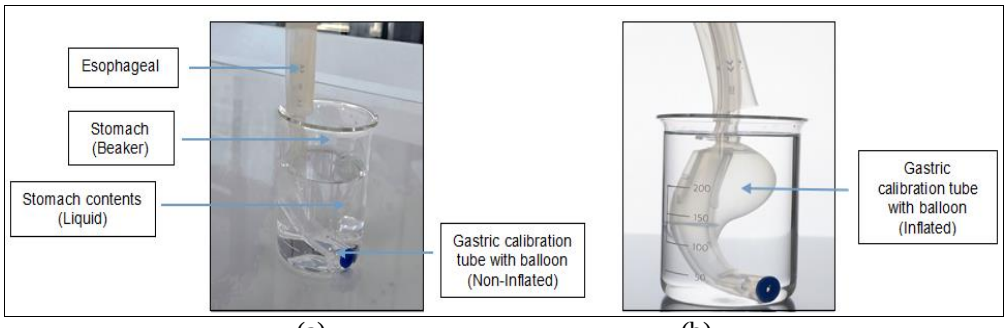
Results and Discussion

In the present research study, a gastric calibration tube with balloon was evaluated through *in-Vitro* simulation testing to assess balloon expansion behavior, positioning stability, and lumen functionality relevant to bariatric surgery. The experiments used a model of the stomach. This model was made to copy the shape and movement of a human stomach. The model helped to test things in a way that was like the body. The stomach model was designed to be, like a stomach. It was used to do experiments.

(a) (b)

Fig 1 (a, b): Simulated gastric calibration tube with balloon placement model illustratingas stomach contents and esophageal

The gastric calibration tube with balloon was easily introduced through the simulated orogastric pathway and positioned along the lesser curvature, as illustrated in Figure.01. Controlled balloon inflation resulted in secure inside the stomach stabilization, preventing longitudinal migration during simulated gastric manipulation. The balloon expanded uniformly without distortion, maintaining consistent contact with the simulated gastric wall.



(a) (b)

Fig 2 (a, b): Illustrative representation of calibration tube positioning inside stomach, balloon expansion and alignment along the simulated lesser curvature within the simulated gastric model

Following inflation, the device maintained stable positioning throughout simulated procedural steps. The balloon provided enhanced alignment during simulated stapler interaction, contributing to consistent geometric

guidance. The calibration tube retained its structural integrity and alignment, as shown in Figure.03 (a), (b) & (c).

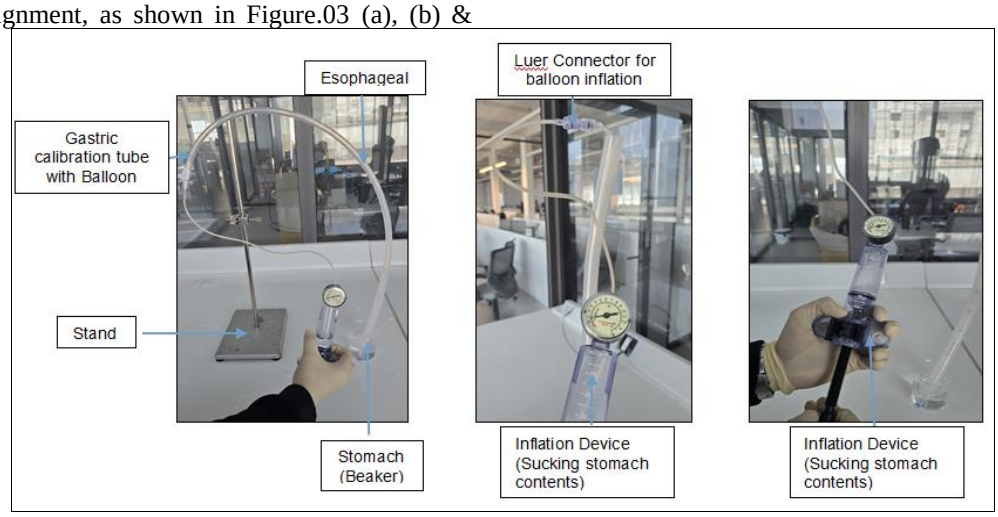


Fig 3(a, b, c): Gastric calibration tube with balloon showing stomach contents suction and maintaining dimensional integrity during simulated procedural interaction. Stable gastric calibration tube with balloon positioning during simulated procedural interaction

The surface characteristics and flexibility of the device facilitated smooth insertion and repositioning with minimal resistance. Additionally, the central lumen demonstrated effective suction and fluid instillation performance. During *in-Vitro* leak testing simulation, fluid introduced through the lumen exited uniformly from the distal tip without unintended leakage along the shaft or balloon interface. The test in a lab showed that the special tube with a balloon that goes in the stomach is really good at staying in place. The gastric calibration tube with a balloon is also easy to adjust and works well. These things help doctors do surgery the way every time and make it easier for them to use the tube during bariatric surgery on the stomach. The tests on a scale in a controlled room showed that the tube works well and is strong. We need to do more tests in a lab to see how the tube interacts with tissue and how the stomach lining reacts to it. We also need to see how well the tube works over a time. The next non-clinical studies will help us understand if the gastric calibration tube is safe to use clinically and if it really works.

Limitations

Even though a gastric calibration tube with balloon offers clear procedural benefits, a few practical limitations should be kept in mind. The people who use it know what they are doing. In surgeries things like patient body stomach wall thickness past surgeries or esophagus sensitivity can make it harder to put it in and set it up right. If the balloon is not filled up correctly the tube might not give the results. The tube works well only if the balloon is filled up properly. Most of the information we have comes from lab studies, which might not show all the problems that can happen in surgeries, with the tube and the balloon. The gastric calibration tube can be tricky to use because every bodies are different. The thickness of the stomach wall, surgeries or sensitivity in the esophagus can make it hard to put the tube in and get it calibrated. There is a chance that the tube could be put in the wrong place or the balloon could move or it could irritate the stomach lining. The gastric calibration tube is to be checked before and after they are used to reduce these risks. Larger multi center clinical studies would help confirm long term safety and consistency across bariatric procedures.

Conclusion

This research study shows that the gastric calibration tube with a balloon is very important during surgery. The main advantages of this tube are it helps keep the tube steady inside the stomach. It allows the size to be adjusted as needed. It performs reliably as shown in stomach simulation tests. The device shows potential in supporting gastric calibration tube with balloon during bariatric and sleeve gastrectomy by allowing controlled expansion to achieve the desired diameter. Providing lumen functionality for suction and leak testing. Secure positioning during procedural steps. The results of this study are important because they help us better understand how gastric calibration tubes with balloon designs affect surgery. They also highlight ways to improve sizing accuracy and give surgeons control during the procedure with gastric calibration tube with balloon. The integration of a calibration tube with balloon into routine surgical practice has the potential to improve procedural confidence, maintain calibration and support operative outcomes in the surgical management of obesity with gastric calibration tube with balloon.These findings help improve our understanding of how calibration devices like calibration tube with balloon should be designed for bariatric surgery. They highlight why stable and well-controlled positioning inside the stomach with calibration tube with balloon is important for safe and consistent procedures. While the current study represents an evaluation of gastric calibration tube with balloon, further pre-clinical and clinical investigations are ongoing to confirm safety, tissue compatibility and long-term outcomes of gastric calibration tube with balloon. Upon *in-Vitro* validation, gastric calibration tube with balloon systems may continue to play a role in improving procedural reproducibility and surgical outcomes in obesity management, with gastric calibration tube with balloon.

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