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Development of Retrieval Balloon Catheter to Remove Stones from The Biliary System

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ABSTRACT

The retrieval balloon catheter has been established as an essential medical device for the management of obstructions, occlusions, and foreign body retrieval across multiple clinical specialties, including gastroenterology, vascular surgery, and interventional cardiology. Designed for minimally invasive applications, the catheter facilitates the removal of blockages while minimizing tissue trauma. The device is composed of biocompatible materials such as silicone, latex, and polyurethane, ensuring anatomical compatibility and reducing the risk of irritation. Advanced manufacturing techniques, including marker band swaging, soft tip molding, and assembly welding, contribute to its structural integrity and performance reliability. The catheter's functionality is enhanced by controlled balloon inflation and deflation, allowing for precise engagement with obstructions while ensuring procedural safety.

Preclinical in vitro testing was conducted to evaluate the device's efficacy, durability, and compliance with expansion specifications under varying pressures. These assessments confirmed consistent balloon inflation and deflation, structural resilience, and leak resistance. Clinical applications demonstrated high efficacy in the retrieval of bile duct stones, embolic material, and occlusive debris, with real-time imaging guidance ensuring accurate placement. The minimally invasive approach significantly reduced the need for open surgical procedures, leading to lower complication rates, shorter hospital stays, and improved patient recovery times.

The retrieval balloon catheter has been validated as a reliable and effective tool in future after clinical trial. Ongoing advancements in material science and imaging integration are expected to further enhance its clinical utility, reinforcing its role in therapeutic interventions for gastrointestinal and vascular obstructions.

Keywords: Retrieval balloon catheter, occlusion, gastroenterology, Interventional cardiology, Obstruction, gastrointestinal tract, therapeutic intervention, vascular surgery.

1. INTRODUCTION

Gastrointestinal obstruction occurs when the normal flow of swallowed content is interrupted, a condition that can arise at any point along the gastrointestinal tract[1] Obstructions in the upper gastrointestinal tract, such as the esophagus, stomach, or duodenum, often present with less urgency compared to obstructions in the small bowel or colon, which frequently constitute medical emergencies[2] Intestinal obstruction is a serious condition,

accounting for approximately 15% of all emergency department visits for acute abdominal pain[3] The high morbidity rate associated with this condition underscores the necessity for rapid and accurate diagnosis followed by prompt and effective therapeutic intervention[4]

The retrieval balloon catheter has emerged as a transformative medical device, revolutionizing the treatment of obstructions, occlusions, and foreign body retrieval across various anatomical regions.[5] This minimally invasive tool has become indispensable in multiple therapeutic disciplines, including vascular surgery, gastroenterology, interventional cardiology, and urology[6] By minimizing complications and reducing recovery times, the retrieval balloon catheter offers a safer and more effective alternative to traditional open surgical methods. Its entry into clinical practice reflects the broader trend toward minimally invasive techniques aimed at reducing patient trauma, shortening hospital stays, and improving procedural precision.[7]

The catheter's design allows it to navigate constricted or obstructed anatomical areas with ease, facilitating the removal of foreign bodies, occlusions, and blockages in a variety of clinical contexts. Its biocompatible materials and advanced features, such as an inflatable balloon system and flexible shaft, enable effective engagement and retrieval with minimal tissue damage. The device has proven invaluable in minimally invasive procedures within specialties such as interventional cardiology, gastroenterology, urology, and vascular surgery.[8]

The retrieval balloon catheter exemplifies innovation in medical technology, addressing the need for safer and more efficient tools in modern healthcare. By reducing the risks associated with open surgery and promoting quicker recovery times, it has established itself as an essential device in the management of obstructions and foreign body retrieval, paving the way for improved patient outcomes across multiple clinical settings.

2. MATERIALS AND METHODS

As medical technology has advanced, the creation of the retrieval balloon catheter has been a game-changer. The design and functionality of the catheter have continuously changed since it was first developed to meet the increasing demand for less intrusive techniques to remove foreign items, blockages, and obstructions from the human body. The retrieval balloon catheter has evolved over the last few decades from a simple idea to a highly advanced instrument utilized in a variety of medical specialties, such as vascular surgery, gastroenterology, cardiology, and urology.

Materials: -

Retrieval balloon catheter is typically made of biocompatible materials that ensure flexibility, durability, and safety during medical procedures. The key materials used in its construction include:

1. **Balloon Material**
   - Latex – Provides high elasticity but can cause allergic reactions.
   - Silicone – Hypoallergenic, flexible, and durable.
   - Polyurethane (PU) – More resistant to punctures and provides controlled expansion.
2. **Catheter Shaft Material**
   - Polyurethane (PU) – Flexible yet strong, commonly used for better maneuverability.
   - Polyvinyl chloride (PVC) – Cost-effective but less flexible than PU.
   - Nylon – Offers high tensile strength and good resistance to kinking.
3. **Guidewire & Structural Components**
   - Stainless Steel – Used for reinforcing structures and guidewires for better control.
   - Nitinol (Nickel-Titanium Alloy) – Provides excellent flexibility and shape memory properties.

4. **Coatings (for improved lubricity and reduced friction)**
   - Hydrophilic Coatings – Reduce resistance for smoother navigation.
   - Silicone Coatings – Improve biocompatibility and ease of insertion.

For the present laboratory work, the size matrix of the developed retrieval balloon catheter has been utilized. The catheter features an endoscope channel greater than 3.2 mm, with a length of 2 meters and an outer diameter of 7.5 French. The balloon sizes included in the study are 8.5 mm, 9 mm, 10 mm, 11 mm, 11.5 mm, 12 mm, 12.5 mm, 13 mm, 15 mm, 16 mm, 18 mm, and 20 mm.

Procedure of Balloon Catheter Assembly

2.1 Marker band swaging

Positioning: The marker band is positioned on the catheter at the appropriate spot.

Compression: By applying radial strain to the band with specialized swaging tools, the band deforms and securely grips the catheter without harming it.

Securing: As a result, the marker band and catheter form a strong, long-lasting attachment that guarantees the marker will remain in place while the catheter is being used.

2.2 Soft tip and tipping

2.2.1 Heat Application:

The catheter material, often thermoplastic, is exposed to controlled heat. This softens the material, making it malleable.

2.2.2 Molding:

The softened end of the catheter is pressed into a mold that forms the soft tip. Molds can be custom designed to achieve specific tip shapes and dimensions depending on the catheter's application (e.g., rounded tips, tapered tips).

2.2.3 Cooling:

After the tip is shaped, the catheter is cooled to harden the soft tip in its new form. This cooling process solidifies the connection between the soft tip and the stiffer catheter shaft.

2.2.4 Trimming and Finishing:

Once the tipping process is complete, excess material is trimmed, and the tip is inspected to ensure it meets precise dimensional and quality standards.

2.3 Hub Attachment:

It is a crucial process in catheter manufacturing, where the hub (the proximal end of the catheter) is securely connected to the catheter tubing. The hub serves as a connection point between the catheter and external medical devices, such as syringes, guide wires, or other medical instruments, allowing for fluid transfer, device manipulation, or measurement.

2.4 Assembly welding:

In a Retrieval Balloon catheter, this welding is the most important since it has to guarantee that the balloon is firmly fixed to the catheter shaft while permitting inflation and deflation while in use. In order for the catheter to pass through the convoluted bile ducts without running the risk of balloon detachment or leaking, the weld must be both robust and flexible.

2.5 Pleating, folding and Sheathing:

In this process of folding the balloon material in a specific, organized manner around the catheter shaft when the balloon is deflated. This technique ensures that the balloon has a low profile, allowing easy insertion and navigation through the narrow bile ducts and minimizing trauma during the procedure.

2.6 Heat Set

The balloon is heated to a certain temperature and the balloon undergoes controlled heating and cooling cycles to set its shape and improve its tensile strength. This ensures that the balloon can inflate to the desired size and handle the required pressures during clinical use. A Retrieval balloon catheter hub attachment is essential for attaching the catheter to other tools required in the surgery, like a syringe for delivering contrast media or filling the balloon. It acts as the interface for managing the inflation and deflation of the balloon and is situated at the proximal end of the catheter. To ensure the hub remains securely attached and does not detach under normal

use, it is critical to select the appropriate bonding technique based on material compatibility and application requirements. Thermal bonding and ultrasonic welding create strong molecular or mechanical interlocks, while UV bonding and high-strength adhesives provide durable adhesion. Additionally, rigorous tensile and shear stress testing should be conducted to verify the joint's integrity, ensuring it withstands operational forces without failure. Proper surface preparation and controlled bonding conditions further enhance attachment strength and reliability.

Clinical Procedure of Retrieval Balloon catheter:

Patient Preparation, Education and Consent: Educate the patient about the procedure's risks, precautions and advantages.

Fasting: The patient should be kept on fast for about 6 – 8 hours prior to the surgery

Sedation: Depending upon the need, general anesthesia or local anesthesia for sedation may be used.

Insertion of the Endoscope

The patient's mouth is used to implant an endoscope, which is then passed via the stomach, esophagus, and duodenum (the first segment of the small intestine).

One can see the ampulla of Vater, which is where the pancreatic and bile ducts enter the small intestine.

Cannulation of the Duct Organ

The endoscope is used to guide the insertion of a catheter into the common bile duct.

In order to use fluoroscopy (X-ray imaging) to view the bile ducts and any stones, contrast dye is injected.

Insertion of the Balloon Catheter

In the bile duct, a balloon catheter is inserted. Near the tip of the catheter is an inflatable balloon. The balloon is inflated once the catheter has been beyond placed the blockage or stone.1`

Removal of Foreign Material or Stones

Stones, sludge, or debris are swept towards the ampulla and into the duodenum as the inflated balloon is gradually drawn back via the bile duct.

After then, the substance is either naturally evacuated or may be manually removed and discarded suitably.

Withdrawal and Deflation

Following the retrieval, the catheter is carefully removed from the bile duct and the balloon is deflated shown in Fig.1.

Post-Procedure

The endoscope is withdrawn, and the patient is monitored during recovery. Imaging studies may be done to ensure complete removal of the obstruction.

Fig.1 Deflated Retrieval balloon catheter

Fig.2 Double Lumen catheter

Deflated Retrieval balloon Catheter:
The catheter typically has a balloon at the tip that is used to help retrieve a foreign object, such as a clot or a stent, or to perform other tasks like occluding blood flow or assisting with contrast delivery during imaging. When it's deflated, the balloon at the end of the catheter is collapsed, which allows the catheter to navigate through smaller or more complex blood vessels without causing unnecessary damage or resistance. Once it reaches the desired location, the balloon can be inflated to either help with the retrieval process or to temporarily block off a vessel, depending on the procedure.

Double Lumen catheter:
A double lumen catheter (shown in Fig. 2) used in conjunction with a retrieval balloon catheter is often employed in medical procedures like endovascular interventions. The two devices work together for more complex tasks, such as retrieving foreign objects from blood vessels or other cavities while managing blood flow or access during the procedure.

Crucial Points to Remember
Imaging: For precise placement and to reduce hazards, continuous imaging (fluoroscopy, ultrasound, etc.) is essential throughout the process.

Balloon Selection:
In order to retrieve the object successfully and prevent harm to the surrounding tissues, it is crucial to select the appropriate balloon size for the process. Patient Observation: Throughout and following the treatment, closely monitor vital signs and any possible problems.

Fig.3 Inflated Retrieval Balloon catheter

Inflated Retrieval balloon catheter
In procedures such as thrombectomy or embolization, this balloon can be inflated (shown in Fig.3) within a vessel to help trap or retrieve material. At times temporarily blood flow is blocked by the surgeon to a specific area for treatment with full care and in minimum time to ensure the functioning of that part as improper use can lead to complications like vessel damage or unintended clot migration.

RESULTS AND DISCUSSION

The retrieval balloon catheter was demonstrated to be highly effective and safe in managing obstructions, occlusions, and the retrieval of foreign bodies across various clinical applications. The biocompatible materials utilized in its construction, including silicone, latex, and polyurethane, were found to minimize tissue irritation and ensure anatomical compatibility. The elasticity and durability of the balloon, achieved through controlled heat setting and

pleating techniques, enabled it to withstand the required inflation pressures without compromising structural integrity. Gastrointestinal blockages, particularly in the bile duct, were effectively addressed, with foreign bodies such as stones and sludge successfully retrieved. Additionally, its application in vascular surgery and interventional cardiology facilitated the removal of embolic material and stents with minimal associated risk. Advanced catheter variants, designed with multiple lumens, enabled the simultaneous administration of drugs and imaging agents, thereby enhancing procedural precision. Compatibility with imaging technologies such as fluoroscopy provided real-time visualization and ensured accurate placement. The use of the retrieval balloon catheter significantly reduced the necessity for open surgical interventions, resulting in lowered complication rates and shorter hospital stays, while the minimally invasive nature of the procedure contributed to improved patient recovery times. A retrieval balloon catheter is tested in vitro, which simulates settings and processes outside of the human body in a controlled laboratory setting, to determine the device's efficacy, safety, and functionality prior to in-vivo usage. These tests aid in confirming that the catheter is safe to use and operates as planned, simulating real-world circumstances. testing the balloon's ability to expand and contract under various pressures. When inflated, the balloon should safely and consistently expand, and deflation should be managed. Making sure the balloon material is robust and long-lasting by looking for any leaks or ruptures throughout the inflation process.

The retrieval balloon catheter was demonstrated to be a highly effective and safe medical device for the management of obstructions, occlusions, and the retrieval of foreign bodies across various clinical applications. The biocompatible materials utilized in its construction, including silicone, latex, and polyurethane, were found to minimize tissue irritation and enhance anatomical compatibility. The elasticity and durability of the balloon, achieved through controlled heat setting and pleating techniques, enabled the device to withstand required inflation pressures without compromising structural integrity.

Significant efficacy was observed in the treatment of gastrointestinal blockages, particularly within the bile duct, where foreign bodies such as stones and sludge were successfully retrieved. Furthermore, its applications in vascular surgery and interventional cardiology facilitated the removal of embolic material and stents with minimal associated risks. The incorporation of multiple lumens in advanced catheter variants enabled the simultaneous administration of drugs and imaging agents, thereby improving procedural precision and reducing the likelihood of complications.

Compatibility with imaging technologies, such as fluoroscopy, ensured real-time visualization and accurate placement, further enhancing the device’s safety and efficiency. The minimally invasive nature of the procedure contributed to a reduction in the necessity for open surgical interventions, leading to lower complication rates and shorter hospital stays. Additionally, improved patient recovery times were observed, reinforcing the clinical benefits of the retrieval balloon catheter.

Prior to in vivo applications, the catheter was subjected to rigorous in vitro testing to evaluate its efficacy, safety, and functionality under controlled laboratory conditions. These tests simulated real-world circumstances and confirmed the catheter’s ability to operate as intended. The expansion and contraction of the balloon under various pressures were assessed, demonstrating consistent and controlled inflation. The material’s robustness and durability were verified by examining potential leaks or ruptures during the inflation process. The extent of balloon expansion was also measured to ensure compliance with designed specifications, confirming its reliability for in future after clinical study.

CONCLUSION

The retrieval balloon catheter has been validated in-vivo as a reliable and effective tool for the management of occlusions and the retrieval of foreign bodies across various medical disciplines. Its biocompatibility, durability, and structural integrity have been confirmed through extensive in vitro testing, ensuring its suitability for in vivo applications. The reduction in the necessity for invasive surgical interventions has been facilitated by its successful implementation, contributing to enhanced procedural accuracy and improved patient recovery. The device has been validated in-vivo to provide significant knowledge about how to retrieve the stones from the foreign bodies. The continued development of advanced materials and improved imaging compatibility is expected to further optimize the catheter's performance, ensuring sustained clinical utility and patient safety. Ongoing research and innovation in catheter technology are anticipated to expand its applications, thereby enhancing its effectiveness in diverse medical procedures.

Declaration by Authors

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REFERENCES

1. Schick MA, Kashyap S, Meseeha M. Small Bowel Obstruction. [Updated 2023 Apr 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448079.
2. Vercruysse G, Busch R, Dimcheff D, et al. Evaluation and Management of Mechanical Small Bowel Obstruction in Adults [Internet]. Ann Arbor (MI): Michigan Medicine University of Michigan; 2021 Apr. Available from: https://www.ncbi.nlm.nih.gov/books/NBK572336/
3. P Cervellin G, Mora R, Ticinesi A, Meschi T, Comelli I, Catena F, Lippi G. Epidemiology and outcomes of acute abdominal pain in a large urban Emergency Department: retrospective analysis of 5,340 cases. Ann Transl Med. 2016 Oct;4(19):362. doi: 10.21037/atm.2016.09.10. PMID: 27826565; PMCID: PMC5075866.
4. Lotfollahzadeh S, Lopez RA, Deppen JG. Appendicitis. [Updated 2024 Feb 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK493193/
5. Briggs G, Walker RW. Retrieval of an endobronchial foreign body using a guide wire and angioplasty catheter. Anaesth Intensive Care. 2007 Jun;35(3):433-6. doi: 10.1177/0310057X0703500321. PMID: 1759114
6. Shah J, Vyas A, Vyas D. The History of Robotics in Surgical Specialties. Am J Robot Surg. 2014 Jun 1;1(1):12-20. doi: 10.1166/ajrs.2014.1006. PMID: 26677459; PMCID: PMC4677089.
7. Eckle VS, Neumann B, Greiner TO, Wendel HP, Grasshoff C. Intrajugular balloon catheter reduces air embolism in vitro and in vivo. Br J Anaesth. 2015 Jun;114(6):973-8. doi: 10.1093/bja/aev040. Epub 2015 Apr 1. PMID: 25835025; PMCID: PMC4436929.
8. Chen X, Chen Y, Zhong C, Zeng Y, Luo W, Li S. The efficacy and safety of airway foreign body removal by balloon catheter via flexible bronchoscope in children - A retrospective analysis. Int J Pediatr Otorhinolaryngol. 2016 Mar; 82:88-91. doi: 10.1016/j.ijporl.2016.01.003. Epub 2016 Jan 13. PMID: 26857322.

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