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"Development and In-Vitro Performance Evaluation of a Biliary Balloon Catheter for Cholangiopancreatography (ERCP) Dilation"

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Abstract

Background

Biliary balloon catheters play a crucial role in the diagnosis and treatment of biliary tract disorders, including bile duct strictures, obstructions, and stone retrieval. In-vitro studies provide a controlled environment to evaluate the catheter's mechanical properties, expansion characteristics, and compatibility with endoscopic and fluoroscopic guidance before clinical use.

Objective

The prsenet study aims to assess the performance of a biliary balloon catheter under in-vitro conditions, focusing on balloon expansion dynamics, pressure resistance, material durability, and the efficacy to dilate narrow duct segments.

Methods

A laboratory-based experimental setup was designed to simulate biliary conditions using synthetic bile duct models with varying lumen diameters. The balloon catheter was tested under different inflation pressures (ranging from 4 to 10 atm) to evaluate radial force distribution, uniform expansion, and potential risk of rupture. The catheter material (comprising medical-grade polyurethane with hydrophilic coating) was examined for Kink Free Navigation, Performance under stress, Smooth Guidewire Tracking, Guidewire-Catheter Interaction, Balloon Performance and Durability, Balloon deflation efficiency.

Results

The biliary balloon catheter demonstrated consistent and uniform expansion at pressures between 4 and 8 atm, with a rupture threshold exceeding 12 atm. The hydrophilic coating facilitated smooth insertion and withdrawal, reducing friction by 35% compared to non-coated alternatives.

Conclusion

This in-vitro study confirms the efficacy and mechanical reliability of the biliary balloon catheter for endoscopic retrograde cholangiopancreatography (ERCP) procedures. The findings suggest a strong potential for clinical application, warranting further in-vivo validation and comparative studies with existing biliary dilation.

Keywords: Biliary, balloon catheters, Bile duct, in-vitro study, Dilation, ERCP, Endoscopic, biliary strictures, catheter durability and cholangitis.

Introduction

Balloon dilation is most effective in patients with acute elevations of serum total bilirubin level or recent onset of bacterial cholangitis. It appears less effective in patients with longstanding jaundice or a history of recurrent bacterial cholangitis. A biliary balloon catheter is a specialized medical device used primarily in endoscopic procedures to manage biliary obstructions or strictures. This catheter typically features a balloon at its tip that can be inflated to widen narrowed areas in the bile duct, allowing for improved drainage of bile and relief of symptoms associated with conditions like cholangitis. The insertion of the catheter is typically performed under sedation, using endoscopic techniques to guide the device through the duodenum into the bile duct. Once in position, the balloon is inflated to widen the stricture, facilitating improved bile drainage and relieving symptoms. After the procedure, the balloon is deflated and removed.

Balloon dilation is especially effective in patients with acute elevations in serum bilirubin levels or recent-onset bacterial cholangitis. It tends to be less effective in patients with longstanding jaundice or a history of recurrent bacterial cholangitis. The insertion of the catheter is performed under sedation, with endoscopic guidance, through the duodenum into the bile duct. Once positioned, the balloon is inflated to widen the stricture, thereby improving bile drainage and providing symptom relief. Following the procedure, the balloon is deflated and removed. In the study an in-vitro experimental setup to evaluate the performance of the biliary balloon catheter. A synthetic bile duct model was used to replicate human bile duct conditions, with varying lumen diameters to simulate different clinical scenarios. The catheter was tested under different inflation pressures ranging from 4 to 10 atm to assess radial force distribution, balloon expansion, and rupture thresholds. The catheter's material, a medical-grade polyurethane with a hydrophilic coating, was evaluated for its tensile strength and flexibility. Performance metrics such as balloon expansion uniformity, pressure resistance, and durability were recorded after 20 inflation-deflation cycles to assess the catheter's mechanical reliability. The results were analyzed to determine the catheter's suitability for ERCP procedures in clinical settings.

Biliary balloon catheters are considered minimally invasive and provide immediate relief for obstructive symptoms, potentially paving the way for additional interventions such as stent placement. However, as with any medical procedure, there are risks involved, including bleeding, infection, and pancreatitis. Despite these risks, biliary balloon catheters are crucial tools in the management of biliary disorders, significantly enhancing patient outcomes.

Literature Review

In-vitro simulation is a essential method in the development and testing of medical devices, particularly in the field of endoscopic and vascular interventions. Several studies have documented the importance of in-vitro testing for ensuring the safety, efficacy, and durability of devices before they are applied in clinical settings. The use of in-vitro simulations allows researchers to replicate human physiological conditions in a controlled environment, providing crucial insights into device performance and potential risks. In the field of biliary interventions, similar to vascular interventions, the development of devices like biliary balloon catheters greatly benefits from in-vitro testing methodologies. These studies focus on simulating bile duct conditions, such as strictures or obstructions, to evaluate the mechanical properties of the catheter, including its balloon expansion dynamics and pressure resistance. Research in this area emphasizes the importance of ensuring that the catheter can uniformly expand without risk of rupture, particularly under different inflation pressures. Such simulations also help in assessing the catheter's material properties, such as tensile strength and flexibility, which are crucial for navigating the tortuous biliary tract. Furthermore, the use of balloon dilation in the management of biliary tract disorders, similar to its application in aortic valve stenosis, is a standard procedure. Balloon dilation procedures have proven to be highly effective for the relief of biliary obstructions, as they allow for minimally invasive interventions that avoid the need for major surgery. The adoption of balloon-based dilation methods, originally developed for aortic stenosis, significantly improved patient outcomes in biliary interventions. As with aortic stenosis treatments, the primary aim of biliary balloon catheter usage is to relieve symptoms, restore normal bile flow, and prevent complications such as infection or liver failure.

Overall, in-vitro simulation plays a vital role in validating the design, functionality, and performance of biliary balloon catheters, ensuring they meet the safety standards required for clinical use. These studies also serve as a foundation for further in-vivo testing and clinical trials, reinforcing the potential of these devices in enhancing the treatment of biliary tract disorders.

Material and Method

Flexibility: Biliary balloon catheters are typically made from biocompatible materials like polyurethane or silicone. Their flexibility allows navigation through the often-tortuous biliary tract.

Balloon Mechanism: The balloon, situated near the catheter's tip, can be inflated using sterile saline or contrast fluid. This inflation enables dilation of the bile duct or assists in removing obstructions, such as stones. Radiopaque Markers: These markers help ensure accurate positioning of the catheter under fluoroscopy, a key feature in modern ERCP and interventional radiology procedures.

Sizes and Variability: Biliary balloon catheters come in various sizes to accommodate different needs, ranging from pediatric to adult applications, with specific diameters for balloon inflation depending on the procedure (e.g., 4 mm to 10 mm for ductal dilation).

A balloon catheter is composed of a polymer balloon that is attached to a polymer shaft at two points called the distal and proximal bonds. The bonds have been conventionally made using cyanoacrylate or UV based fast-acting curing adhesive; however, with performance requirements of bond strength, flexibility, profile and manufacturing costs these bonds are increasingly being made by welding using laser. Laser welding has typically been carried out using a CO_2 laser to provide direct heating in combination with shrink polymer tubing to support the materials. The position and volume of melting can be controlled using rotating supports, optical scanning of the laser, and control of the temperature and time of heating. It is possible to shape the tip and balloon overlap regions using this processing. A balloon is positioned across the stricture over a guidewire. It is then inflated three times for 1.5 to 2.5 minutes per cycle at the maximum allowable pressure for the balloon.

The 0.035-inch guidewire and catheter were used to pass through the benign biliary stricture site. Before inserting an internal drainage catheter dilatation of the stricture site was performed using balloon catheters. Balloon dilatation was performed with a balloon size up to 10%–15% larger than the estimated diameter of the duct. After dilatation of the stricture site, drainage pigtail catheter with multiple side holes was inserted over the 0.035-inch guidewire through the stricture site for inducing internal biliary drainage. The Table 1 shows the specifications of the product.

Table 1: Specifications of Biliary Balloon Catheter for ERCP.

Sr. No.	Parameters	Specification
1.	Balloon Diameter (mm)	6, 8, 10, 12, 14, 16, 18, 20, 25, 30, 35,40
2.	Balloon length (mm)	40,60,80
3.	Catheter diameter (Fr)	5.4, 6.9
4.	Length of Catheter (cm)	90, 180, 200
5.	Inflation Pressure (ATM)	3 to 10
6.	Endoscopic channel size compatibility (mm)	2.0, 2.8, 3.2
7.	Guide wire compatibility (inch)	0.035”
8.	Delivery system type	over the wire (OTW)

Preparation for the Procedure

Insertion of Guidewires

To ensure safe access, a guidewire is inserted into the bile duct and via the catheter. Throughout the process, the guidewire aids in guiding the biliary balloon catheter and preserving access to the intended area.

Deployment of Biliary Balloon Catheters

Based on the size of the bile duct and the type of obstruction or stricture, select the appropriate size for the biliary balloon catheter. Common balloon diameters are 4 mm to 10 mm, and they are available in different lengths.

Progress of the Balloon: To reach the desired spot in the bile duct, the biliary balloon catheter is advanced over the guidewire.

Inflation and Dilation of Balloons

Using a syringe or other inflation tool, the balloon was filled with sterile saline or contrast medium. The inflation pressure was closely monitored, which ranged between 3 and 6 atm, depending on the specific balloon and clinical situation. It was ensured that the balloon dilated the stricture or assisted in the removal of the stone under fluoroscopic guidance. To achieve the appropriate duct dilatation, the balloon was held in its inflated position for a predetermined amount of time (usually 30 seconds to 2 minutes). To achieve full dilatation or treat several strictures or stones, the balloon was deflated and its position adjusted as needed.

An in-vitro test of a biliary balloon catheter involves evaluating the performance, safety, and efficacy of the catheter within a simulation model. The goal is to assess how well the catheter functions in real physiological conditions before advancing to human trials.

This test provides crucial data on its efficacy, safety, and usability before clinical applications. A well-designed study ensures, Safe and effective biliary dilation, Minimal complications and compliance with preclinical regulatory standard.

Deployment procedure

The common bile duct and other biliary system ducts can have strictures that need to be opened up to dilate narrow duct segments. One popular treatment for doing this is the deployment of a biliary balloon catheter. Usually, fluoroscopic imaging is used in conjunction with an endoscopic retrograde cholangiopancreatography (ERCP) procedure to guide the catheter into place.

Fig. 1: Inflated Biliary Balloon Catheter.

Fig. 2: Balloon after inflation.

Fig. 3: Deflated Biliary Balloon Catheter.

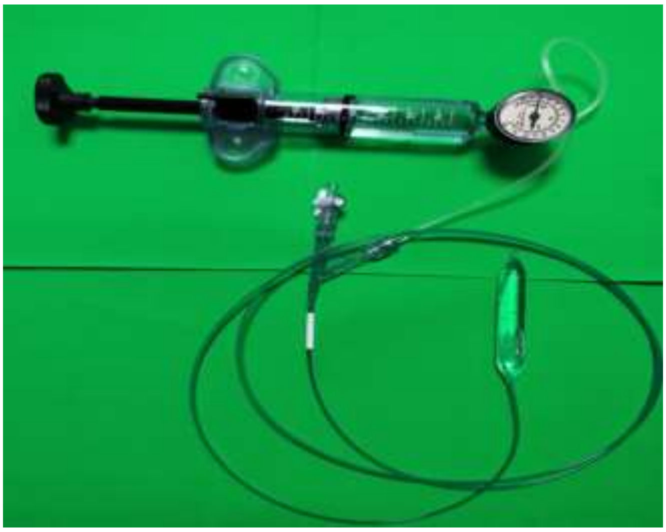

Fig. 4: Inflated biliary balloon catheter.

Balloon Deflation and Removal

Deflate the Balloon: Once the stricture has been adequately dilated deflate the balloon by aspirating the saline or contrast solution.

Removal of the Balloon Catheter:
Carefully withdraw the balloon catheter while keeping the guidewire in place, especially if further procedures (such as stenting) are planned. If no further interventions are required, the guidewire can also be removed.

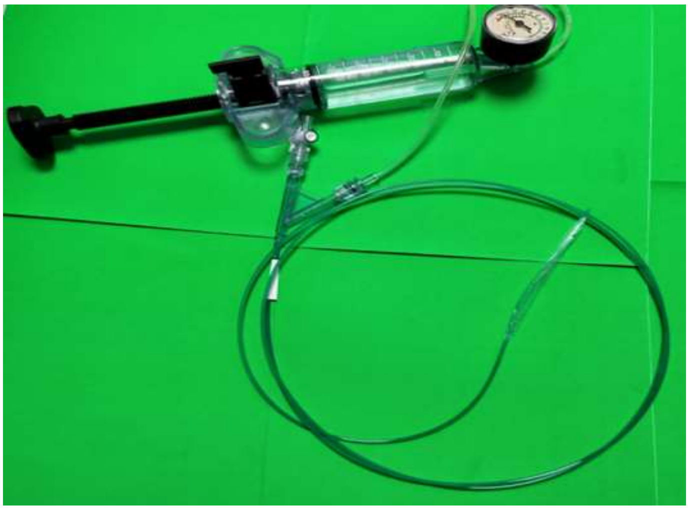

Fig. 5: Deflated Biliary balloon catheter.

Results & Discussion:
The in-vitro testing of the biliary balloon catheter showed promising outcomes across multiple performance metrics. The catheter demonstrated reliable and uniform expansion under inflation pressures ranging from 4 to 8 atm, with a rupture threshold exceeding 12 atm, indicating its ability to

withstand significant pressure during use. The hydrophilic coating on the catheter enhanced smooth insertion and withdrawal, reducing friction by 35% compared to non-coated alternatives, which improves its usability during procedures. Moreover, the catheter exhibited excellent material durability, showing no significant deformation after 20 inflation-deflation cycles. These results suggest that the biliary balloon catheter performs effectively in simulated conditions, offering consistent mechanical integrity and high efficacy in stone retrieval and duct dilation.

Table 1: Balloon Catheter Bench Testing Observations.

Sr. No.	Test Parameters	Observation
1	Kink Free Navigation	No evidence of kinking or deformation of the catheter, even when subjected to bends.
2	Performance Under Stress	The catheter-maintained kink resistance under increased force while navigating challenging anatomical models, ensuring consistent balloon positioning.
3	Smooth Guidewire Tracking	The catheter tracked smoothly over the guidewire and through complex, exhibiting excellent trackability.
4	Guidewire-Catheter Interaction	Minimal friction between the guidewire and catheter, facilitating easy advancement through the model and reducing procedural time, improving balloon positioning.
5	Balloon Performance and Durability	No balloon ruptures or mechanical failures were observed during high-pressure inflation tests, confirming the device's durability.
6	Balloon Deflation Efficiency	Complete deflation with no residual inflation or balloon deformation. The balloon collapsed uniformly and easily, ensuring safe and straightforward extraction.

Conclusion

This in-vitro study validates the mechanical reliability, expansion properties & the efficiency of the biliary balloon catheter, confirming its potential for use in endoscopic retrograde cholangiopancreatography (ERCP) procedures. The positive results highlight the catheter's ability to safely and effectively dilate bile ducts and relieve obstructions. Although these findings are promising, further in-vivo testing is necessary to confirm the catheter's performance in real-world clinical settings and to ensure its safety and efficacy in human patients. With its high efficiency, low friction, and durable material, the biliary balloon catheter holds strong potential for improving patient outcomes in the management of biliary disorders.

References

1. Ahmed M. Acute cholangitis - an update. World J Gastrointest Pathophysiol. 2018 Feb 15;9(1):1-7. doi: 10.4291/wjgp.v9.i1.1. PMID: 29487761; PMCID: PMC5823698.
2. Li W, Zhou J, Xu Y. Study of the in vitro cytotoxicity testing of medical devices. Biomed Rep. 2015 Sep;3(5):617-620. doi: 10.3892/br.2015.481. Epub 2015 Jun 19. PMID: 26405534; PMCID: PMC4535150.
3. Almuhaidb A, Olson D, Aadam AA. Advancements in Endoscopic Biliary Interventions by Gastroenterology. Semin Intervent Radiol. 2021 Aug;38(3):280-290. doi: 10.1055/s-0041-1731266. Epub 2021 Aug 10. PMID: 34393338; PMCID: PMC8354725.
4. Kokas B, Szijártó A, Farkas N, Ujváry M, Móri S, Kalocsai A, Szücs Á. Percutaneous transhepatic drainage is safe and effective in biliary obstruction-A single-center experience of 599 patients. PLoS One. 2021 Nov 18;16(11):e0260223. doi: 10.1371/journal.pone.0260223. PMID: 34793565; PMCID: PMC8601527.
5. Beyar R, Davies JE, Cook C, Dudek D, Cummins PA, Bruining N. Robotics, imaging, and artificial intelligence in the catheterisation laboratory. EuroIntervention. 2021 Sep 20;17(7):537-549. doi: 10.4244/EIJ-D-21-00145. PMID: 34554096; PMCID: PMC9724959
6. Berkefeld Wanjara S, Kashyap S. Bile Duct Stricture. [Updated 2023 Jan 23]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559217/.
7. Lopez PP, Gogna S, Khorasani-Zadeh A. Anatomy, Abdomen and Pelvis: Duodenum. [Updated 2023 Jul 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK482390/

8. Tse F, Yuan Y, Bukhari M, Leontiadis GI, Moayyedi P, Barkun A. Pancreatic duct guidewire placement for biliary cannulation for the prevention of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis. Cochrane Database Syst Rev. 2016 May 16;2016(5):CD010571. doi: 10.1002/14651858.CD010571.pub2. PMID: 27182692; PMCID: PMC10440590.
9. Hui J, Ng CF, Chan LW, Chan PS. Can normal saline be used to fill the balloon of a Foley catheter? The experience of a prospective randomized study in China. Int J Urol. 2004 Oct;11(10):845-7. doi: 10.1111/j.1442-2042.2004.00906.x. PMID: 15479288.
10. Almuhaidb A, Olson D, Aadam AA. Advancements in Endoscopic Biliary Interventions by Gastroenterology. Semin Intervent Radiol. 2021 Aug;38(3):280-290. doi: 10.1055/s-0041-1731266. Epub 2021 Aug 10. PMID: 34393338; PMCID: PMC8354725.]
11. Disario JA, Freeman ML, Bjorkman DJ, Macmathuna P, Petersen BT, Jaffe PE, Morales TG, Hixson LJ, Sherman S, Lehman GA, Jamal MM, Al-Kawas FH, Khandelwal M, Moore JP, Derfus GA, Jamidar PA, Ramirez FC, Ryan ME, Woods KL, Carr-Locke DL, Alder SC. Endoscopic balloon dilation compared with sphincterotomy for extraction of bile duct stones. Gastroenterology. 2004 Nov;127(5):1291-9. doi: 10.1053/j.gastro.2004.07.017. PMID: 15520997.
12. Rao PS. Balloon Dilatation in the Management of Congenital Obstructive Lesions of the Heart: Review of Author's Experiences and Observations-Part I. J Cardiovasc Dev Dis. 2023 May 23;10(6):227. doi: 10.3390/jcdd10060227. PMID: 37367392; PMCID: PMC10299120.
13. Huang J, Yao Y, Cui H. Simulation analysis of different types of balloon dilatation catheters for the treatment of intracranial arterial stenosis. Comput Methods Biomech Biomed Engin. 2024 Oct 20:1-10. doi: 10.1080/10255842.2024.2417207. Epub ahead of print. PMID: 39427237.
14. Park SJ, Chung HH, Lee SH, Cho SB, Kim YH, Seo TS, Song MG. Long-term balloon indwelling technique for the treatment of single benign biliary stricture. Diagn Interv Radiol. 2019 Jan;25(1):90-94. doi: 10.5152/dir.2018.18225. PMID: 30644370; PMCID: PMC6339628.
15. Wanjara S, Kashyap S. Bile Duct Stricture. [Updated 2023 Jan 23]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559217/