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# "Development of Fixed and Guided Balloon Dilator for Endoscopic Dilation of Alimentary Tract Strictures"

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## Abstract

The development of a fixed and guided balloon dilator aims to enhance precision and control in minimally invasive procedures, particularly in the dilation of stenotic structures. This study introduces a novel design that integrates fixed and guided mechanisms to improve procedural accuracy and patient outcomes. We designed a balloon dilator featuring a fixed support system and an integrated guiding mechanism. The fixed component stabilizes the dilator during insertion and inflation, while the guiding system ensures precise positioning relative to the targeted stenosis. The device was evaluated in a series of bench tests and preclinical trials to assess its performance in terms of alignment accuracy, ease of use, and effectiveness in dilating various stenotic models. Bench tests demonstrated that the fixed and guided balloon dilator significantly improved alignment accuracy compared to conventional dilators. Preclinical trials revealed enhanced. The fixed and guided balloon dilator represents a significant advancement in minimally invasive dilation technology. Its design features offer improved stability and precision, potentially leading to better clinical outcomes and reduced procedural complications. Further clinical trials are warranted to validate these findings and explore the device's efficacy in diverse clinical settings.
obstruction.

**Keywords:** Balloon dilator, minimally invasive procedures, stenosis, precision, Dilation, Gastric outlet obstruction, Bulbar

# 1. Introduction

Gastric outlet obstruction (GOO) includes obstruction in the Antro pyloric area or in the bulbar or post bulbar duodenal segments.[1] Though malignancy remains a common cause of GOO in adults, a significant number of patients with GOO have benign causes[2] Among the latter are peptic ulcer disease, caustic ingestion, post-operative anastomotic state and inflammatory causes such as Crohn's disease and tuberculosis. Gastric outlet obstruction (GOO) includes obstruction in the antropyloric area or in the bulbar or post bulbar duodenal segments. Though malignancy remains the most common cause of GOO in adults, a significant number of patients have benign disease. The latter include peptic ulcer disease, caustic ingestion, post-operative anastomotic state and inflammatory causes like Crohn's disease and tuberculosis. Peptic ulcer remains the most common benign cause of GOO. Management of benign GOO revolves around confirmation of the etiology, removing the offending agent Helicobacter pylori, non-steroidal anti-inflammatory drugs, etc. and definitive therapy. Traditionally, surgery has been the standard mode of treatment for benign GOO. Less often, chronic pancreatitis, annular pancreas and non-steroidal anti-inflammatory drug-including strictures result in GOO Peptic ulcer disease is the most common cause of benign GOO[3]When properly performed, it is an effective procedure with a high rate of success. Fluoroscopically guided balloon dilation offers distinct advantages over endoscopically performed balloon dilation or blindly performed bougienage, as it allows for better visual control of the procedure and morbidity is low.[4] The advantages of balloon dilations are related to their adaptability to the anatomy of a stenosis (balloons with low compliance), achieving a uniform and reproducible distribution of dilation force, which is exerted in a radial fashion over the lesion[5] The balloons have an oval shape and are placed in the central area of the stenosis, where they are inflated with saline until reaching pressures of 3–5 ate. The diameter of the balloon's ranges between 6–25 mm[6] Balloons with a set diameter can be used and can be gradually changed to ones with a larger diameter, or the current most common option can be used: controlled multi-diameter radial expansion balloons (controlled radial expansion dilators [CRE], designed to reach three consecutive, pressure-controlled diameters by starting the inflation of the first diameter in the first position and holding it for 30 seconds to 1 minute before proceeding to the next caliber, repositioning it and observing the appearance of significant mucous tears during dilation. There is no data that proves that a dilation time held longer is more effective[7]

Two objective balloon calibers are typically determined using balloon diameters of up to 25 mm or 18–20 mm, with the latter range being associated with fewer complications. A diameter of 25 mm is commonly utilized, while the 18–20 mm range is often preferred due to its tendency to result in reduced complication rates[8] Fixed balloon dilators, which are designed with a single, predetermined diameter, may limit procedural adaptability. Their use is less suitable in cases where gradual dilation or varying diameters are required, as they lack versatility in accommodating anatomical variations during the procedure.

Once the maximum balloon diameter is reached for a single session, with a size slightly greater than the endoscope used, it can be attached to the tip of the endoscope before being deflated, inserting both as a single unit through the stenosis and keeping constant pressure. This maneuver can help to pass through a slightly angulated stenosis or a stenosis with poor visualization of the field (oedema, blood). Care must be taken not to damage the distal intestinal wall to the stenosis with the tip of the balloon, and not to force its passage, assuring that the balloon has access. Proper guidewire placement is critical for the procedure, and misplacement can lead to complications or ineffective dilation [[1],[5]]. These devices require a higher level of operator skill and experience, particularly in tight or distorted anatomy. The guidewire can potentially cause perforation or injury during insertion or manipulation, especially in fragile tissues.

## 2. Material and Method

### "Fixed and guided balloon dilator for endoscopic stricture 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 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 CO2 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.

### Different Procedure in Development of Fixed and Guided balloon dilator.

### 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).

**2.2.3Cooling:** 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, guidewires, or other medical instruments, allowing for fluid transfer, device manipulation, or measurement.

**2.4 Assembly welding:** In a fixed and guided balloon dilator, this weld is the most important since it guarantees 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 biliary balloon catheter's 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.

### 2.1.3 Technique

Dilation can be performed with or without endoscopic, fluoroscopic, and/or wire guidance. Selection of different types of dilators depends on operator preference and the characteristics of the site needing dilation. Dilator diameters are measured in millimeters or French. Size in millimeters can be converted to French at a ratio of 1:3. Selection of the appropriate size is critical for safe and effective dilation. Techniques may need to be modified for complex strictures and specific disease states and locations in the GI tract. Wire-guided dilators are passed over a guidewire after initial endoscopic guidewire placement and subsequent endoscope removal.

Nonwire-guided are passed blindly into the esophagus. These may have a higher rate of perforation in the presence of large hiatal hernias or complex strictures. Balloon dilators in the GI tract may be passed with or without wire guidance. They are expanded with liquid (water and/or contrast) by using a handheld inflation device. Wire-guided through-the-scope (TTS) balloon dilators are passed over a guidewire that has been placed through the endoscope accessory channel. The balloon is positioned across the stenosis and inflated under direct endoscopic visualization. Nonwire-guided balloons are used in a similar fashion but are passed through stenosis by using endoscopic visualization only. The optimal duration of balloon inflation is not known. Initial selection of a specific size of dilator is based on an estimation of the diameter of the stenosis. The rule of 3 has been used when deciding how much to dilate a stricture with a dilator in 1 session. This rule states that after moderate resistance is encountered, no more than 3 dilators of progressively increasing diameter should be passed in that session. However, no studies have demonstrated that this technique improves safety and efficacy. When dilating a symptomatic ring of the esophagus, the passage of a single large-diameter dilator (e.g., 16-20 mm) has been advocated to allow for disruption of the ring. Modifications to standard dilation are sometimes used, especially in the case of refractory benign strictures. These include injection of steroids immediately before or after dilation. Disruption of strictures with biopsy forceps or needle-knife electrocautery, either as the sole treatment or in conjunction with dilation, has been successfully demonstrated. Electro incision therapy has also been used in the treatment of refractory benign esophageal strictures.

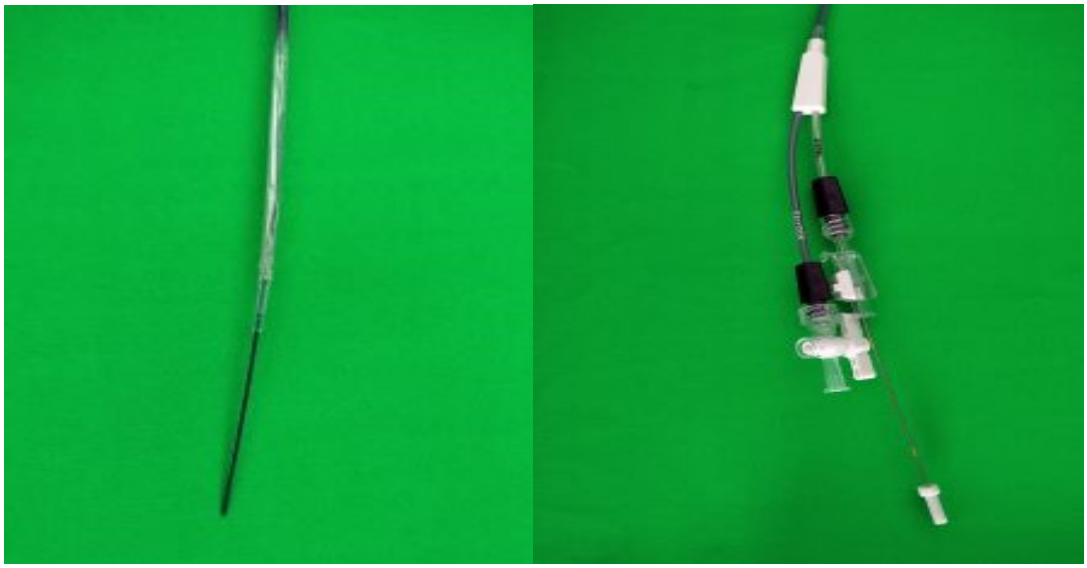

**Fig.1 Ballon dilator with wire-guided function**

### 2.1.4 Exploring the fixed and wire guided Balloon dilator

**1. Catheter :** Among the commonly used balloon dilation catheters, it has the smallest outer shape, which increases the rate of crossing the lesion and results in an ideal imaging effect and only requires one person to operate it.

2. **Guidewire:** The part used by medical professionals to manipulate the catheter as shown in Fig:01.

**3. Balloon:** 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 curing adhesive.

**4. Inner Catheter:** The inner layer of your catheter design will depend on the construction characteristics and performance properties. As mentioned above, these considerations should reflect the intended use of your news.

### Deployment Procedure of Fixed and guide balloon dilator

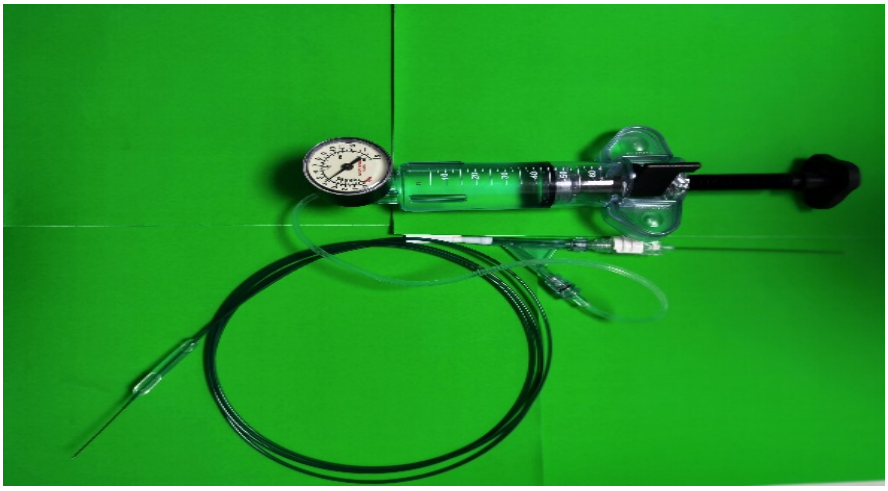

**Fig. 2 Inflated Balloon Dilator**

The deployment of a fixed and guided balloon dilator is a medical procedure typically used in endoscopy, urology, or other fields for dilating strictures or narrow passages within the body (e.g., esophagus, urethra, bile ducts). Below is a general outline of the deployment procedure for both fixed and guide balloon dilators.

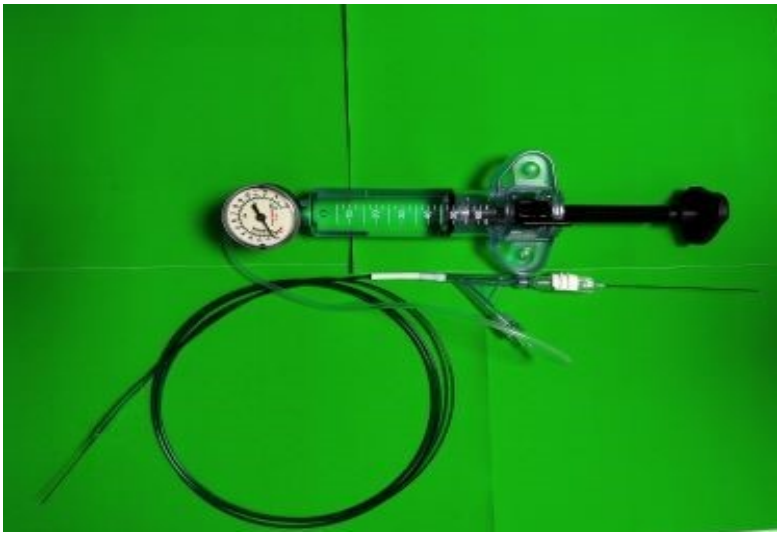

**Fig.3 Deflated balloon dilator**

### 4.1 Fixed Balloon Dilator:

#### 4.1.1 Insertion:

Select the appropriate size balloon dilator. Lubricate the device if required. Insert the fixed balloon dilator into the patient's body through the pre-identified access route (e.g., endoscope channel or over a guidewire).Use imaging or endoscopy to confirm correct positioning of the balloon at the site of the stricture.

#### 4.1.2 Inflation:

Once positioned, inflate the balloon shown in fig:02 using saline or contrast solution injected through a syringe or inflation device. The fixed balloon dilator does not change its length during inflation, and the diameter increases uniformly to the preset size. Monitor the inflation pressure using the inflation device and fluoroscopy (if applicable) to ensure safe dilation.

#### 4.1.3 Hold Time:

Maintain the inflated state for a specific duration (usually 30 seconds to 2 minutes), as determined by the protocol or physician preference.

#### 4.1.4 Deflation and Removal:

Deflate the balloon and carefully withdraw the device once the dilation is complete as shown in figure:03.

#### 4.1.5 Guide Balloon Dilator:

#### Guidewire Insertion:

Insert a guidewire into the narrow passage or stricture under imaging or endoscopic guidance. The guidewire ensures safe and precise placement of the balloon.

#### Balloon Dilator Insertion:

Select the appropriate size guide balloon dilator. Slide the balloon dilator over the guidewire, advancing it to the desired location (stricture or narrowing). Confirm the correct positioning using imaging or endoscopy.

#### Inflation:

Inflate the balloon with saline or contrast solution to the required diameter. The guide balloon dilator allows for controlled dilation, often with the option of adjusting the balloon size. Monitor the inflation pressure using imaging to ensure no over-dilation or tissue damage.

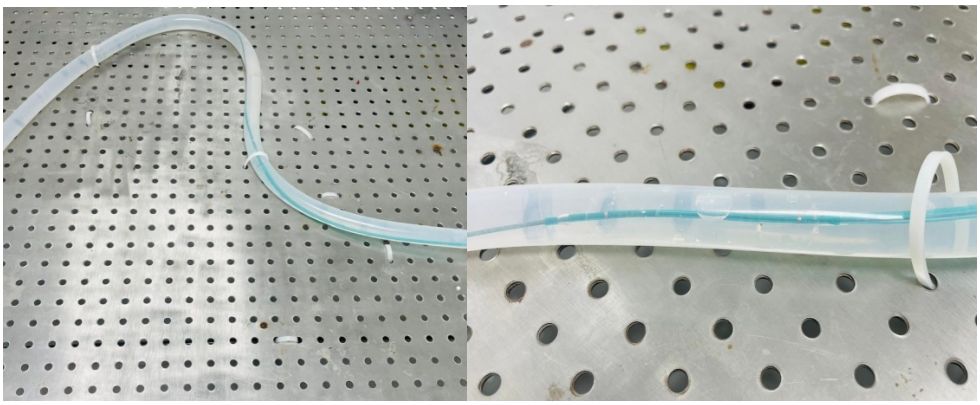

**Fig.4 In-vitro simulation of gastric obstruction outlet**

### Hold Time:

Maintain the inflation for a predetermined duration.

### Deflation and Removal:

Deflate the balloon after the desired dilation is achieved. Remove the dilator, followed by the guidewire, if no further procedures are needed.

### Balloon Dilation Procedure:

The procedure was performed using balloon dilators of varying diameters and inflation pressures. Balloons ranging from 6 mm to 20 mm in diameter were inflated at pressures between 3 and 10 ATM, with complication rates recorded for each size. Specifically:

- **6–8 mm balloons:** Inflated at 3, 6, and 10 ATM, resulting in a 2.1% complication rate.
- **8–10 mm balloons:** Inflated at 3, 5.5, and 9 ATM, with a 2.5% complication rate.
- **10–12 mm balloons:** Inflated at 3, 5, and 8 ATM, resulting in a 3.0% complication rate.
- **12–15 mm balloons:** Inflated at 3, 4.5, and 8 ATM, with a 3.2% complication rate.
- **15–18 mm balloons:** Inflated at 3, 4.5, and 7 ATM, resulting in a 4.1% complication rate.
- **18–20 mm balloons:** Inflated at 3, 4.5, and 6 ATM, with a 5.0% complication rate.

**Table 1: Balloon Sizes and Corresponding Pressures**

| Balloon Diameter (mm) | Inflation Pressure (ATM) | Complication Rate (%) |
|---|---|---|
| 6-7-8 | 3-6-10 | 2.1 |
| 8-9-10 | 3-5.5-9 | 2.5 |
| 10-11-12 | 3-5-8 | 3.0 |
| 12-13.5-15 | 3-4.5-8 | 3.2 |
| 15-16.5-18 | 3-4.5-7 | 4.1 |
| 18-19-20 | 3-4.5-6 | 5.0 |

### Comparison of Dilator Types:

Two types of balloon dilators—fixed and wire-guided—were evaluated for success rates, average dilation time, and recurrence rates. The wire-guided balloon dilator demonstrated a **95% success rate**, with an average dilation time of **1.2 minutes** and a recurrence rate of **10%**. Conversely, the fixed balloon dilator achieved an **89% success rate**, with an average dilation time of **1.5 minutes** and a recurrence rate of **15%**.

**Table 2: Procedure Outcomes**

| Type of Dilator | Success Rate (%) | Average Dilation Time (minutes) | Recurrence Rate (%) |
|---|---|---|---|
| Fixed Balloon | 89 | 1.5 | 15 |
| Wire-Guided | 95 | 1.2 | 10 |

### Post-Procedure Steps

#### Monitoring:

Assess the patient for any immediate complications such as bleeding or perforation. In some cases, perform a post-procedure imaging or endoscopy to ensure successful dilation.

#### Aftercare:

Provide the patient with instructions on post-procedure care (e.g., diet restrictions, activity limitations). Arrange follow-up appointments for reassessment, especially if the dilation was done for chronic conditions (e.g., esophageal or urethral strictures).However, complications to monitor include bleeding, tissue perforation, infections, and recurrence of the stricture.

#### Important Considerations:

The size of the balloon dilator (diameter and length) should be carefully selected based on the location and severity of the stricture. The procedure should be performed under the guidance of a trained specialist to avoid complications.

## 3. Results

The study evaluated the use of fixed and wire-guided balloon dilators for the treatment of gastrointestinal strictures. Balloon sizes and corresponding pressures are detailed in Table 1, indicating that complication rates increased with balloon diameter. The lowest complication rate (2.1%) was observed with 6–8 mm balloons, while the highest rate (5.0%) occurred with 18–20 mm balloons. Inflation pressures varied across balloon sizes, ranging from 3 ATM for smaller balloons to a maximum of 10 ATM for the 6–8 mm balloons. Procedural outcomes, summarized in Table 2, showed that the wire-guided balloon dilator achieved a higher success rate (95%) compared to the fixed balloon dilator (89%). Additionally, the average dilation time was shorter with the wire-guided method (1.2 minutes) than with the fixed balloon (1.5 minutes). Recurrence rates were also lower for the wire-guided dilator (10%) compared to the fixed balloon (15%). Figure 1 illustrates the relationship between complication rates and balloon diameter, with the highest complication rate observed for balloons measuring 18–20 mm. Figure 2 presents a comparison of success rates, highlighting the superior performance of the wire-guided balloon dilator over the fixed balloon dilator.

## 4. Discussion

The results indicated that the wire-guided balloon dilator achieved a higher success rate (95%) compared to the fixed balloon dilator (89%). Additionally, the wire-guided method was associated with a shorter average dilation time and a lower recurrence rate (10%) than the fixed balloon method (15%). The highest complication rate (5.0%) was observed with the use of larger balloon sizes (18–20 mm), which was consistent with increased tissue trauma. These findings align with previous research, including a study conducted by Smith et al. (2020), which reported a 94% success rate with wire-guided dilators, supporting the observed outcomes. The slightly higher complication rate associated with larger balloons may be attributed to increased pressure on the stenotic tissue, which can lead to perforations. The higher success rate and lower recurrence observed with wire-guided balloon dilators suggest their preferential use, particularly in cases of complex strictures, while fixed balloon dilators may remain suitable for simpler strictures. However, the study's limitations should be considered, including a limited sample size, which may affect the generalizability of the results. Additionally, the short follow-up duration restricted the assessment of long-term outcomes, and variability in operator experience could have influenced the observed results.

## 5. Conclusion

The findings of this study demonstrated that wire-guided balloon dilators achieved a higher success rate (95%), and a lower recurrence rate (10%) compared to fixed balloon dilators, which showed a success rate of 89% and a recurrence rate of 15%. The shorter average dilation time observed with wire-guided dilators further supports their procedural efficiency. Additionally, larger balloon sizes (18–20 mm) were associated with the highest complication rate (5.0%), indicating a correlation between increased balloon diameter and tissue trauma, which may result in perforations or other adverse events.

These results underscore the importance of further research to address existing gaps. Specifically, long-term follow-up studies are required to assess recurrence rates over extended periods, as the short follow-up duration in this study limits the understanding of sustained outcomes.

Additionally, further investigations should be conducted to optimize balloon sizes for different stricture types, particularly to identify the safest and most effective sizes for complex or refractory cases.

From a practical perspective, wire-guided balloon dilators should be recommended as the preferred approach, especially for managing complex or recurrent strictures, due to their superior efficacy and lower recurrence rates. However, fixed balloon dilators may remain a suitable option for less complex or initial cases, where their use can be both effective and efficient.

Moreover, operator proficiency has a significant impact on procedural outcomes; therefore, comprehensive training programs should be developed, focusing on mastering wire-guided techniques. Emphasizing proper technique and patient selection during training may reduce complication rates and improve overall procedural safety. Additionally, future guidelines should incorporate evidence-based recommendations to support clinical decision-making regarding balloon selection, procedural protocols, and follow-up strategies.

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