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CLINICAL SUMMARY

Clinical Outcomes of Magnesium-Based Balloon-Expandable Biodegradable Stenting for Benign Biliary Strictures

Single-Center Retrospective Cohort Study – UNITY-B Percutaneous Balloon-Expandable Biodegradable Biliary Stent

Mariano Eduardo Giménez, Chiara Innocenzi MD, Ignacio Corteggiano, Juliana Maria Racedo,

Lucas Fehlauer, Samantha Robert, Pablo Acquafresca, Eduardo Houghton, and Mariano Palermo

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UNITY-B

Balloon Expandable Biodegradable Biliary Stent System

BIODEGRADABLE

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Main Clinical Outcomes

What the data showed — UNITY-B Biodegradable Biliary Stent

22 stent-placement procedures · 21 patients
Median patient age 58 yrs (IQR 51–70)

100%

Technical success

22/22 procedures — stent deployed successfully across every target stricture.

0%

Stent-related complications

No adverse events within 30 days of stent placement, across all 22 procedures.

90.5%

Freedom from recurrence — 6 months

66%

Freedom from recurrence — 12 months

34.0% cumulative incidence (competing-risk adjusted). Recurrence events stopped after month 10, despite follow-up extending to 27 months.

6/6

Recurrences successfully treated — 100%

Every patient who recurred was retreated without difficulty — no retained device complicating reintervention showing excellent safety profile.

› **76.2% of strictures were anastomotic at the hepaticojejunostomy** — the most technically demanding stricture population in this space.

Giménez, Mariano Eduardo, et al. "Clinical Outcomes of Magnesium-Based Balloon-Expandable Biodegradable Stenting for Benign Biliary Strictures: A Single-Center Retrospective Cohort Study." Journal of Laparoendoscopic & Advanced Surgical Techniques:

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FROM THE PUBLICATION

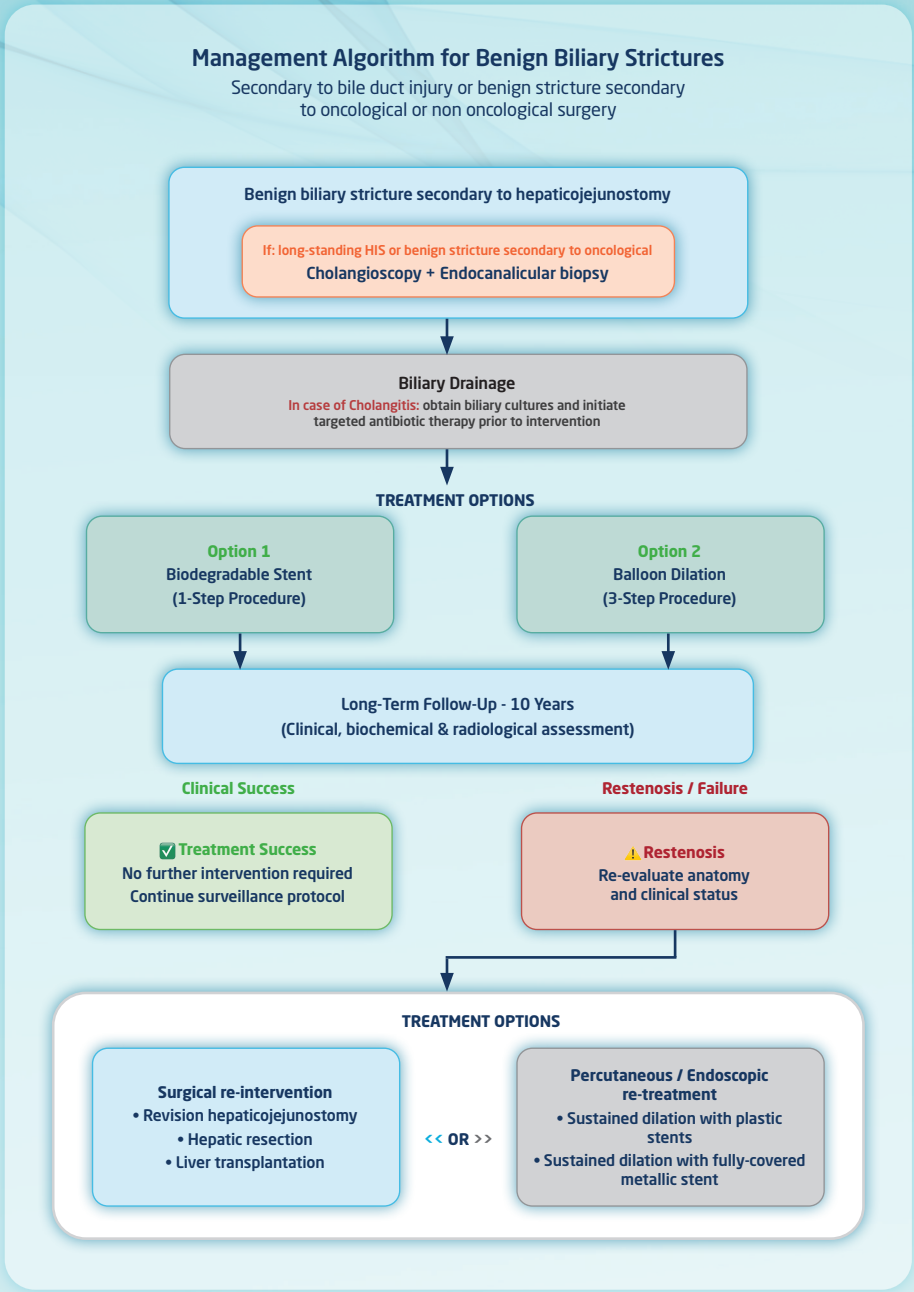
Proposed Management Algorithm

The authors set out a proposed treatment pathway for benign biliary strictures in which biodegradable stenting stands alongside balloon dilation as a first-line option after biliary drainage with comparable outcomes

- **Initial biliary drainage with dilatation and catheterisation**
- **Ensure cholangitis is addressed**

OPTIONS:

- **One-step placement OR three-step balloon dilation as first line treatment dependant on patient selection**



Giménez, Mariano Eduardo, et al. "Clinical Outcomes of Magnesium-Based Balloon-Expandable Biodegradable Stenting for Benign Biliary Strictures: A Single-Center Retrospective Cohort Study." Journal of Laparoendoscopic & Advanced Surgical Techniques.

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Four Pillars Beyond the Primary Data

HYPOTHESIS

Quality of Life

One procedure, not three.

No catheter dwell, no exchanges. Proven QoL up 14-fold by day 90 with Biodegradable Stents in ERCP.

Vasan et al., 2025 – biodegradable bile duct stents after bile leaks

Cost Effectiveness

Nothing to exchange, nothing to retrieve.

Strips out repeat journeys to and from hospital for repeat procedures and removal procedures – as proven in ERCP.

McGarrigle et al., 2026 – cost-effectiveness of biodegradable stents

Hospital Efficiency

Eliminate multiple returns for serial balloon dilatation and catheterisation.

Frees IR and theatre capacity; frees nurse workflows and waiting lists.

Fahrettin et al., 2012 – repeat balloon dilation in HJ strictures

Sustainability

Fewer procedures, less waste and CO2e.

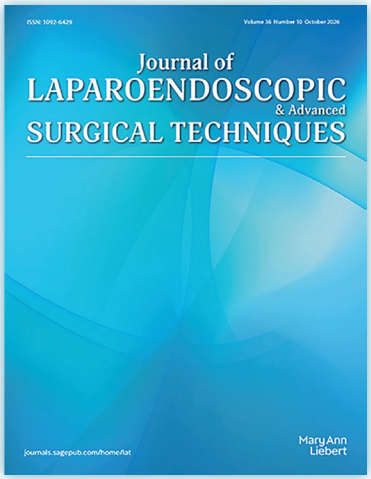
649 kg CO_2e cut; 7.1 kg waste and 138 kg CO_2e saved per bed-day.

Salman et al., 2026 – safety, cost and environmental impact in ERCP

Reasoned hypotheses, not study endpoints – position as expected benefit.

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Clinical Outcomes of Magnesium-Based Balloon-Expandable Biodegradable Stenting for Benign Biliary Strictures: A Single-Center Retrospective Cohort Study

Mariano Eduardo Giménez [1,2], Chiara Innocenzi MD [2-4], Ignacio Corteggiano [1], Juliana Maria Racedo [1], Lucas Fehlauer [1], Samantha Robert [1], Pablo Acquafresca [1], Eduardo Houghton [1], and Mariano Palermo [1]

LINK TO FULL PUBLICATION HERE



UNITY-B Percutaneous Balloon Expandable Biodegradable Biliary Stent System

LINK TO UNITY-B BROCHURE HERE

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