

PRELIMINARY EXPERIENCE WITH BIODEGRADABLE STENTS IN THE TREATMENT OF REFRACTORY BENIGN GASTROINTESTINAL STRICTURE

BARTOLOMÉ L. VIEDMA, RUFO LORENTE, FRANCISCO DOMPER, EVA DE LA SANTA, MANUEL CABANILLAS, ROBERTO PATÓN, CRISTINA VERDEJO, ALICIA HERNÁNDEZ, JOSÉ OLMEDO, EDUARDO RODRÍGUEZ.
GASTROENTEROLOGY UNIT. HOSPITAL GENERAL . CIUDAD REAL. SPAIN.

1. PREMISE

- For gastrointestinal benign strictures, the treatment of choice is balloon dilatation.
- 30-40% strictures may be refractory to conventional endoscopic treatment. Self-expanding stent can be considered, based in continuous dilatation, as better than intermittent dilatation concept.
- Self-expanding plastic or metallic stents involve repeated endoscopic procedures, longer effects of the induction of chronic inflammation, high migration risk (47-64% for plastic stent), mayor complications and disappointing long-term clinical resolution of the stricture rates (less than 50%) (Siersema, Endoscopy 2009).
- Theoretically biodegradable stents (BDS) do not require stent removal and may minimize the development of benign strictures.

2. AIMS

Determine effectiveness and safety of biodegradable self-expanding polydioxanone prosthesis (ELLA-Cs, Kralove, Czech Republic) as treatment of refractory benign gastrointestinal stenosis.

Evaluate: Placing success rate, migration rate, need for re-dilatation, relationship between prosthesis degradation and patient clinical evolution.

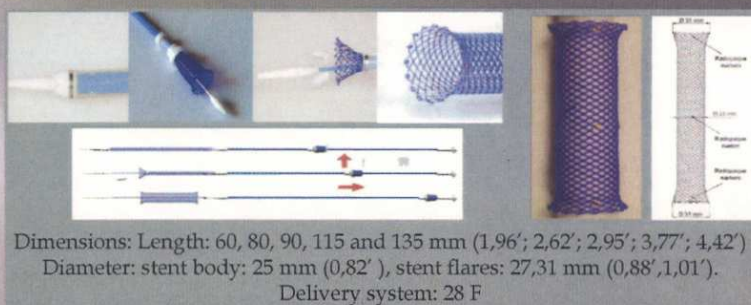
3. METHODS

Five consecutive patients with refractory benign gastrointestinal stenosis (4: esophagus, 1: rectum).

Refractory stenosis definition: stenosis without clinical improvement after at least 5 endoscopic balloon dilatation in 2 preceding months measuring 15 mm diameter at least once.

•ELLA BD[®] Stent: cylindrical uncovered stent of polydioxanone monofilament (used as absorbable surgical suture) with flared ends and radiopaque markers.

•Degradation occurs due to hydrolysis, faster in acid pH, complete after 12 weeks. No need for removal.



ENDOSCOPIC IMAGES



Implant 4 weeks 12 weeks Epithelial hyperplasia 24 weeks

4. RESULTS Success placing rate: 100% . Migration rate: 20% (rectum, no esophagus)

PATIENT	AGE	SEX	LOCATION/ TYPE STRICTURE	DILATATION DURING-BDS INSERTION	COMPLETE ENDOSCOPIC DEGRADATION	HYPERPLASIC TISSUE/ CLINICAL IMPACT	REDILATATION POST-BD	FREE OF SYMPTOMS
1	37	MALE	UPPER ESOPHAGUS/ANASTOMOTIC	YES	12 WEEKS	YES/NO	YES	5 WEEKS
2	70	MALE	UPPER ESOPHAGUS/ANASTOMOTIC	YES	-	-	-	4 WEEKS (lost follow-up)
3	68	MALE	MEDIUM ESOPHAGUS/ANASTOMOTIC	NO	12 WEEKS	YES/NO	NO	12 WEEKS
4	65	MALE	DISTAL ESOPHAGUS/PEPTIC	YES	16 WEEKS	YES/DYSPHAGIA GRADE 3 NO NEED DILATATION	NO	50 WEEKS
5	58	MALE	RECTUM/ANASTOMOTIC	NO	MIGRATED 2 WEEKS	YES (2 WEEKS)/NO	NO	16 WEEKS

5. CONCLUSIONS

- The use of polydioxanone biodegradable prosthesis for refractory benign gastrointestinal stenosis is safe and effective.
- Epithelial hyperplasia is frequent during stent degradation, but with low clinical impact.