Título del documento	Dispositivo de liberación ecoendoscópica rápida de prótesis de aposición luminal con cistotomo "Hot axios® Boston Scientific"
Tipo de documento	Respuesta Rápida
Fecha	27 de noviembre de 2019
Autoría	Sara González Alonso OETSPA
Revisión	Martín Caicoya Gómez-Morán
Servicio/Organismo solicitante	Subdirección de Atención Sanitaria y Salud Pública Área de Digestivo HUCA

1. INTRODUCCIÓN

El Hot AXIOS es un dispositivo diseñado específicamente para ecoendoscopia digestiva intervencionista que combina en un mismo instrumento un cistotomo con diatermia para penetrar por el tubo digestivo y una prótesis metálica (stent AXIOS) de aposición luminar para mantener la fístula permeable y estanca.

El sistema combina un catéter de acceso habilitado para cauterización con el stent terapéutico AXIOS. Se utiliza bajo guía endoscópica combinada con ultrasonidos y está diseñado para facilitar un acceso suave y eficiente a la estructura objetivo. La vaina del catéter se retrae y se despliega el stent AXIOS.

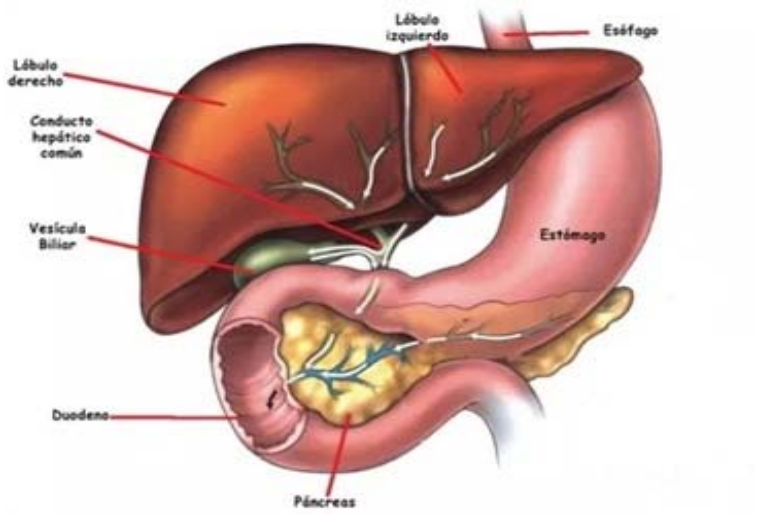
El stent AXIOS es un stent metálico autoexpandible, totalmente cubierto, que se precarga dentro del sistema de suministro. El stent está totalmente cubierto y formado con dos bridas de anclaje bilaterales con un sillín en el medio. El stent AXIOS crea un conducto transluminal entre el tracto gastrointestinal y una cavidad vecina llena de líquido para facilitar el drenaje o crear una derivación alrededor de una estenosis o bloqueo.

Los procedimientos o indicaciones para los que se utilizaría esta nueva tecnología son:

1. Tratamiento de necrosis pancreática y colecciones peripancreáticas por drenaje a cámara gástrica.
2. Drenaje biliar de colédoco a cámara gástrica o duodenal en pacientes oncológicos o con operabilidad limitada.
3. Drenaje de vesícula biliar a cámara gástrica o duodenal en colecistitis aguda.
4. Creación de derivaciones gastro-yeyunales en pacientes oncológicos.
5. Creaciones de derivaciones intragástricas en pacientes con cirugía bariátrica para realizar colangiografía retrógrada endoscópica (CPRE) o que hayan desarrollado el síndrome de sumidero.

Las pancreatitis pueden originar una complicación bastante común, que son las colecciones de líquido pancreático (PFC). La clasificación de las PFC incluye la recolección de líquido peripancreático agudo, el pseudoquiste pancreático, la recolección de necrosis necrótica aguda y la necrosis amurallada (WON). Los tratamientos principales incluyen la extracción del tejido muerto (desbridamiento o necrosectomía), lavado peritoneal (lavado para eliminar el tejido muerto fuera del abdomen), drenaje (inserción de un tubo o "drenaje" para drenar hacia afuera la colección de líquido alrededor del páncreas), o drenaje inicial seguido de necrosectomía si fuera necesario. En la actualidad se realiza drenaje radiológico o cirugía.

En los últimos años, las técnicas endoscópicas mínimamente invasivas se han convertido en una alternativa fiable a los procedimientos quirúrgicos y a su riesgo de morbilidad. El drenaje transmural guiado por ultrasonido endoscópico (EUS) y la necrosectomía han reemplazado cada vez más a la cirugía.



La colecistitis es una inflamación aguda, subaguda o crónica que afecta a la vesícula biliar. La causa más frecuente es la colelitiasis, que es la causante del 95% de los casos de colecistitis aguda. Otras causas de la colecistitis comprenden problemas con el conducto biliar, tumores, enfermedades graves y ciertas infecciones. El mecanismo de la colecistitis aguda es la distensión vesicular, por la obstrucción de la salida de la vesícula por un cálculo, lo que evoluciona a la inflamación con edema de la pared, a la infección de la bilis vesicular e incluso a la perforación vesicular con absceso o peritonitis biliar. La colecistitis aguda es una patología muy frecuente, cuyo mejor tratamiento es la colecistectomía. La obstrucción biliar generalmente se trata con éxito mediante colangiopancreatografía retrógrada endoscópica convencional (CPRE) o drenaje transhepático percutáneo (DTP) con un catéter externo.

La mayoría de los pacientes con obstrucción biliar maligna son diagnosticados en estado avanzado, no siendo candidatos a tratamiento quirúrgico con intención curativa. Independientemente de la etiología, es prioritario el drenaje de la vía biliar como tratamiento paliativo para la resolución de la ictericia y la mejoría en la calidad de vida. En el pasado, el único tratamiento era el quirúrgico, invasivo, con morbimortalidad elevada y mayores estancias hospitalarias. Actualmente, la colangiopancreatografía retrograda endoscópica (CPRE) es el método de elección para el tratamiento de la patología biliopancreática, especialmente en pacientes con obstrucción maligna de la vía biliar, con colocación de prótesis como primera medida paliativa. Sin embargo, en el 5-10% de los casos no es posible por fallo en la canulación del colédoco o por infiltración tumoral (obstrucción duodenal) que limita el acceso a la vía biliar, y se requiere de métodos alternativos de descompresión. El drenaje biliar percutáneo transhepático (CTPH) es una alternativa eficaz, pero con morbimortalidad no desdeñable y un riesgo de complicaciones (fuga biliar, peritonitis, hemorragia, etc.) que se estima hasta del 30%. Otro método alternativo a la CPRE es el drenaje biliar guiado por ecoendoscopia.

La paliación endoscópica de la obstrucción maligna biliar y duodenal concomitante puede plantear problemas debido a la dificultad de acceso a la papila, lo que puede dar lugar a un posible fracaso de la colangiopancreatografía retrógrada endoscópica (CPRE). Además la CPRE en pacientes con un stent duodenal preexistente es particularmente difícil y con una tasa de éxito

baja, siendo una situación frecuente a la que se enfrentan los endoscopistas durante la progresión del cáncer de páncreas avanzado.

El drenaje biliar endoscópico guiado por ultrasonido es una alternativa al drenaje biliar percutáneo en casos de obstrucción biliar maligna y fracaso del drenaje endoscópico clásico por colangiopancreatografía endoscópica (CPRE) debido a canulación fallida o a una ampolla inaccesible (tumor o cirugía previa).

Las obstrucciones gastroduodenales han sido tratadas convencionalmente mediante dos métodos: la cirugía y la colocación de stents o prótesis duodenales. El método quirúrgico se asocia con una alta tasa de complicaciones, mayor morbilidad y más costes. La colocación de prótesis se asocia con menos complicaciones; sin embargo, existe preocupación acerca de la permeabilidad a largo plazo y las tasas de recurrencia que requieren reintervención.

La obstrucción de la salida gástrica y la obstrucción biliar entre los pacientes con anatomía alterada por cirugía bariátrica previa, a menudo requieren una intervención quirúrgica que se asocia con una morbilidad y mortalidad significativas. La dilatación endoscópica para etiologías benignas requiere múltiples sesiones, mientras que los stents metálicos autoexpandibles utilizados para etiologías malignas a menudo fallan debido al crecimiento del tumor. Sin embargo, la colocación endoscópica de stents metálicos con luz, con la intención de crear una anastomosis gastrointestinal de novo en el sitio de la obstrucción, se puede lograr con una eficacia similar y una tasa de complicaciones mucho más baja. La creación de-novo de anastomosis gastro-entérica o entero-entérica con la ayuda de stents metálicos, es una alternativa novedosa y menos invasiva a la cirugía. Se ha utilizado con éxito como tratamiento primario (preferido) o secundario (después del fracaso del tratamiento previo) en el tratamiento de pacientes con etiología maligna o benigna.

El síndrome de asa aferente generalmente se presenta en pacientes que se sometieron a una gastroyeyunostomía quirúrgica o a una reconstrucción en Y de Roux. La extremidad aferente es generalmente parte del duodeno distal o yeyuno proximal que se deja detrás de la gastroyeyunostomía. El síndrome del asa aferente generalmente es causado por una obstrucción mecánica de la extremidad aferente o por una torcedura. Se produce una obstrucción completa que conduce a colangitis, pancreatitis, perforación y necrosis. El síndrome de asa aferente se trata quirúrgicamente de manera convencional. Las modalidades endoscópicas también han ido en aumento, ofreciendo un enfoque menos invasivo para el manejo.

Tradicionalmente, la restauración de la continuidad intestinal normal después de la resección y la derivación de un tracto gastrointestinal enfermo u obstruido sólo puede lograrse a través de la cirugía, que puede ser técnicamente difícil y conlleva un riesgo de eventos adversos. La anastomosis gastrointestinal endoscópica puede ser una técnica segura y factible para restablecer la continuidad del sistema digestivo

2. ¿ES UNA PRESTACIÓN DE LA CARTERA DE SERVICIOS DEL SISTEMA NACIONAL DE SALUD?

Podría considerarse en el siguiente epígrafe, pero no se menciona explícitamente.
Anexo VI Cartera de servicios de prestación protésica:

6. Implantes quirúrgicos
   6.1 Implantes quirúrgicos terapéuticos,
      CD 1 Enterales.

3. ¿HAY INFORME DE EVALUACIÓN REALIZADO POR UNA AGENCIA DE EVALUACIÓN DE TS O REVISIONES SISTEMÁTICAS DE LA LITERATURA?

Se realizaron tres búsquedas en la literatura científica siguiendo la metodología para búsquedas rápidas:

1. NHS Centre for Reviews and Dissemination (CRD) que incluye
   a. -DARE (Database of Abstracts of Reviews of Effects): contiene resúmenes de artículos que valoran y sintetizan RS de efectividad.
   b. -NHS EED: contiene resúmenes de artículos sobre evaluaciones económicas de intervenciones en atención sanitaria.
   c. -HTA (Health Technology Assessment): contiene informes de evaluación de tecnologías sanitarias e información de proyectos en curso realizados por las mismas agencias.
   d. -INAHTA: informes de otras agencias o unidades de Evaluación de Tecnologías Sanitarias. Incluye los informes de la Red Española de Agencias de EvTS.
   e. -EuroScan International Network: informes de tecnologías nuevas y emergentes.
2. Biblioteca Cochrane Plus
3. Embase

Palabras clave: endoscopic ultrasound y hot axios.

Fechas de búsqueda: entre 01/01/2015 al 15/09/2019.

Idiomas: inglés y español.

Tras la búsqueda bibliográfica se obtuvieron los siguientes documentos.

- En NHS Centre for Reviews and Dissemination (CRD): 1 informe de evaluación respecto al tratamiento de necrosis pancreática y drenaje de colecciones peripancráticas por drenaje a cámara gástrica
- En Cochrane: 7 ensayos clínicos, de los cuales 3 están inscritos en la base de datos pero no tienen resultados publicados, 4 tiene resultados preliminares presentados en jornadas de la especialidad, por lo que se descartaron. Sí los hemos incluido en la bibliografía, los que no coinciden con la búsqueda en Embase (4 artículos).
- En Embase se encontraron 45 resultados, tras cotejar los repetidos y coincidentes con la búsqueda en Cochrane (3), uno se descartó por no referirse al hot axios. Otro se descartó por

ser sólo el resumen en Inglés estando el artículo en Alemán, y otros 20 artículos se descartaron por ser comunicaciones o póster a congresos (*), aunque se mantienen en la bibliografía.

Debido a las diferentes indicaciones de uso de esta nueva tecnología, en este informe se clasificarán los artículos según las diferentes indicaciones.

Indicación 1: Tratamiento de necrosis pancreática y colecciones peri pancreáticas por drenaje a cámara gástrica

El informe de evaluación: ***Lumen-apposing metal stents (Axios Stent and Delivery System; Boston Scientific.) for management of pancreatic pseudocysts and walled-off necrosis.Report, HAYES, 2016 (1)***

A los informes de evaluación de HAYES solo se puede acceder al resumen, ya que su coste de adquisición excede considerablemente los precios que desde el sector público se pueden pagar. Por esta razón no aparecen las conclusiones o recomendaciones y es necesario aportar la información del resto de artículos.

Authors' objectives

Pancreatic fluid collections (PFCs) commonly arise in acute pancreatitis episodes and are most commonly due to gallstones, alcohol or drug abuse, pancreatic malignancy or surgery, chronic obstruction of the pancreatic duct, or abdominal trauma. Estimates suggest that of pancreatic episodes, 5% to 15% are complicated by pseudocysts and approximately 15% are complicated by necrosis. Delayed PFCs include pseudocysts and walled-off necrosis (WON) (also referred to as walled-off pancreatic necrosis). Pseudocysts and WON usually occur over 4 weeks after the onset of pancreatitis, differentiating them from acute PFCs.

Description of Technology:
This health technology assessment focuses on the use of the Axios Stent and Delivery System and Axios Stent and Electrocautery Enhanced Delivery System for the treatment of symptomatic pancreatic pseudocysts and WON. The 2-part Axios system is a lumen-apposing metal stent placed via a catheter-based delivery system under endoscopic ultrasound. The stent is anchored to create a transluminal conduit for drainage between the wall of the gastrointestinal tract and the PFC.

Patient Population
The Axios system is indicated for use in patients with symptomatic pancreatic pseudocysts or WON ≥ 6 centimeters in size, with ≥ 70% fluid content, that are adherent to the gastric or bowel wall to facilitate transgastric or transduodenal endoscopic drainage.

Clinical Alternatives:
Clinical alternatives to endoscopic drainage for the management of symptomatic pancreatic pseudocysts include conservative management, surgery, and percutaneous drainage. Clinical alternatives to endoscopic drainage for WON include laparoscopic surgical necrosectomy, or by direct endoscopic necrosectomy and percutaneous drainage.

Comparison of clinical efficacies and safeties of lumen-apposing metal stent and conventional-type metal stent-assisted EUS-guided pancreatic wall-off necrosis drainage: a real-life experience in a tertiary hospital. Surg Endosc. 2018 May;32(5):2448-2453. doi: 10.1007/s00464-017-5946-6. Epub 2017 Nov 3. (2)

Background:
Endoscopic ultrasound (EUS)-guided drainage of pancreatic wall-off necrosis (WON) with transmural stent is regarded as firstline therapy. We aimed at comparing its efficacy and safety with using fully covered self-expandable metal stent (FCSEMS) and lumen-apposing metal stent (LAMS).

Methods:
A retrospective review was performed on all consecutive patients with pancreatic WONs who underwent EUS-guided drainage by either FCSEMS or LAMS. Results: From 2011 to 2016, 68 patients (66.2% male, median age, 66.5 years) underwent WON drainage (22/68 (32.4%) using FCSEMSs of size 10 × 60 mm (14/22, Hanarostent; 8/22 Wallflex); 46/68 (67.6%) using LAMSs (38/46 and 8/46 with AXIOS of size 15 × 10 mm and 10 × 10 mm, respectively). These two groups were matched for age (66 vs. 70 years, p 0.514), APACHE II (11.5 vs. 10, p 0.693), causes [72.7 vs. 80.4% by gallstone pancreatitis (p 0.472); 9.1 vs. 10.9% by alcoholism (p 0.818)], WON size (8.5 vs. 9 cm, p 0.322), location (36.4 vs. 26.1% at pancreatic head, p 0.384; 54.5 vs. 65.2% at body/tail, p 0.395), and enterostomy site [63.6 vs. 76.1% via transgastric (p 0.285); 31.8 vs. 19.6% via transduodenal (p 0.267)] and their number of necrosectomy (p 0.978). The technical (100 vs. 93.5%, p 0.219) and clinical (95.5 vs. 93.5%, p 0.749) success and adverse event (22.7 vs. 39.1%, p 0.180; 9.1 vs. 19.6% with bleeding, p 0.271; 4.5 vs. 13% with spontaneous stent migration, p 0.28; 9.1 vs. 6.5% with dislodgement during necrosectomy, p 0.704) of the two groups were comparable without significant different. However, the LAMS group associated with early stent revision compared with FCSEMS group (log rank p 0.048).

Conclusions:
EUS-guided drainage of WON using FCSEMSs and LAMSs are comparable in efficacy and safety; however, the latter is associated with early stent revision.

Safety of lumen-apposing stent with or without coaxial plastic stent for endoscopic ultrasound-guided drainage of pancreatic fluid collections: A retrospective study. Endoscopy 2018 Oct;50 (10):1022-1026. (3)

Background
The aim of this study was to evaluate whether the placement of a coaxial double-pigtail plastic stent (DPS) within a lumen-apposing metal stent (LAMS) may improve the safety of endoscopic ultrasound (EUS)-guided drainage of pancreatic fluid collections (PFCs).

Methods
This was a retrospective cohort study including patients with PFCs and an indication for transmural drainage. Two strategies (LAMS alone or LAMS plus DPS) were used at the endoscopist's discretion.

Results
A total of 41 patients were treated (21 LAMS alone; 20 LAMS plus DPS). The characteristics of the PFCs, and the technical and clinical success rates did not differ between groups. The LAMS alone group had a significantly higher rate of adverse events than the LAMS plus DPS group (42.9% vs. 10.0%; P =0.04). Bleeding was the most frequent adverse event observed.

Conclusions
The addition of a coaxial DPS to LAMS was associated with a lower rate of adverse events in EUS-guided drainage of PFCs.

Fluoroscopy-assisted vs fluoroless endoscopic ultrasound-guided transmural drainage of pancreatic fluid collections: A comparative study. Gastroenterologia y Hepatologia 2018 41:1 (12-21) (4)

Introduction:
The need for fluoroscopy guidance in patients undergoing endoscopic ultrasound-guided transmural drainage (EUS-TMD) of peripancreatic fluid collections (PFCs) remains unclear.

Aims:
The aim of this study was to compare general outcomes of EUS-TMD of PFCs under fluoroscopy (F) vs fluoroless (FL). Methods: This is a comparative study with a retrospective analysis of a prospective and consecutive inclusion database at a tertiary centre, from 2009 to 2015. All patients were symptomatic pseudocyst (PSC) and walled-off pancreatic necrosis (WON). Two groups were assigned depending on availability of fluoroscopy. The groups were heterogeneous in terms of their demographic characteristics, PFCs and procedure. The main outcome measures included technical and clinical success, incidences, adverse events (AEs), and follow-up.

Results:

Fifty EUS-TMD of PFCs from 86 EUS-guided drainages were included during the study period. Group F included 26 procedures, PSC 69.2%, WON 30.8%, metal stents 61.5% (46.1% lumen-apposing stent) and plastic stents 38.5%. Group FL included 24 procedures, PSC 37.5%, WON 62.5%, and metal stents 95.8% (lumen-apposing stents). Technical success was 100% in both groups, and clinical success was similar (F 88.5%, FL 87.5%). Technical incidences and intra-procedure AEs were only described in group F (7.6% and 11.5%, respectively) and none in group FL. Procedure time was less in group FL (8 min, p = 0.0341).

Conclusions:
Fluoroless in the EUS-TMD of PFCs does not involve more technical incidences or intra-procedure AEs. Technical and clinical success was similar in the two groups

A comparison of outcomes between a lumen-apposing metal stent with electrocautery-enhanced delivery system and a bi-flanged metal stent for drainage of walled-off pancreatic necrosis. Endoscopy International Open 2017 5:12 (E1189-E1196) (5)

Background and study aims:
Bi-flanged metal stents (BFMS) have shown promise in the drainage of walled-off pancreatic necrosis (WON), but their placement requires multiple steps and the use of other devices. More recently, a novel device consisting of a combined lumen-apposing metal stent (LAMS) and electrocautery-enhanced delivery system has been introduced. The aim of this study was to compare the placement and outcomes of the two devices.

Patients and methods:
This was a retrospective review of consecutive patients undergoing endoscopic ultrasound-guided placement of BFMS or LAMS for drainage of symptomatic WON. Data from procedures between October 2012 and December 2016 were taken from a prospectively maintained database. We compared technical

and clinical success, procedure time, costs, and composite end point of significant events (adverse events, stent migration, additional percutaneous drainage) between BFMS and LAMS. Results, 72 consecutive patients underwent placement of BFMS (40 patients, 44 stents) or LAMS (32 patients, 33 stents). Technical success was 91 % for BFMS and 97 % for LAMS. Clinical success was 65 % vs. 78 %, respectively. Median in-room procedure time was significantly shorter in the LAMS group (45 minutes [range 30 - 80]) than in the BFMS group (62.5 minutes [range 35 - 135]; P < 0.001) and fewer direct endoscopic necrosectomies (DEN) were performed (median 1 [0 - 2.0] vs. 2 [0 - 3.7], respectively; P = 0.005). If only inpatients were considered (35 BFMS and 19 LAMS), there was no significant difference in DEN 2 (range 0 - 11) and 2 (range 0 - 8), respectively. The composite end point of 32 % vs. 24 % was not significantly different. Median procedural costs for all patients with successful stent placement for WON treatment was €4427 (range 1630 - 12 926) for BFMS vs. €3500 (range 2509 - 13-393) for LAMS (P = 0.10).

Conclusion:
LAMS was superior to BFMS in terms of procedure time, with comparable adverse events, success, and costs.

A retrospective study evaluating endoscopic ultrasound-guided drainage of pancreatic fluid collections using a novel lumen-apposing metal stent on an electrocautery enhanced delivery system. Endoscopic Ultrasound 2017, 6:6 (389-393) (6)

Objectives:
To report the safety and clinical efficacy with the novel lumen-apposing metal stent (LAMS) with an electrocautery enhanced delivery system for the drainage of pancreatic fluid collections (PFCs).

Methods:
This was a retrospective analysis of all consecutive patients with PFCs who underwent endoscopic ultrasound (EUS)-guided drainage using the LAMS with an electrocautery enhanced delivery system in 2 US centers.

Results:
Thirteen patients with PFCs (69% with walled-off necrosis [WON]) underwent drainage using the study device. Successful stent placement was accomplished in all patients. Direct endoscopicnecrosectomy was carried out in all nine patients with WON complete resolution of the PFC was obtained in all 13 cases, with no recurrence during follow-up. There was one procedure-related adverse event. In one patient, the LAMS was dislodged immediately after deployment, falling into the stomach where it was removed. A second electrocautery enhanced LAMS was placed in this patient immediately afterward.

Conclusions:
EUS-guided drainage using the LAMS with the electrocautery-enhanced delivery system is a safe, easily performed, and a highly effective for the drainage of PFCs.

Lumen-apposing metal stents for drainage of pancreatic fluid collections: When and for whom? Digestive Endoscopy 2017 29:1 (83-90) (7)

Background and Aim:
Although lumen-apposing metal stents (LAMS) are increasingly being used for drainage of pancreatic fluid collections (PFC), their advantage over plastic stents is unclear.

Methods:
In this retrospective case–control study, 20 patients who underwent PFC drainage using LAMS were matched with 40 patients treated with plastic stents according to PFC type (walled-off necrosis [WON] vs pseudocyst) and procedural technique (conventional vs multi-gate). Main outcome measures were treatment success, reintervention, clinical and stent-related adverse events, procedural duration, length of hospital stay (LOS) and hospital costs.

Results:
At median follow up of 570 days, except for median procedural duration (8.5 vs 25 min, P < 0.001), there was no significant difference in treatment success (95.0 vs 92.5%, P = 0.99), reintervention (25.0 vs 30.0 %, P = 0.77), clinical (10.0 vs 12.5 %, P = 0.99) and stent-related adverse events (10.0 vs 2.5 %, P = 0.26) or median LOS (2 [IQR 1–5] vs 2 [IQR 1–7] days, P = 0.58) between patients treated with LAMS versus plastic stents. Although there was no difference for WON ($16 708 for LAMS vs $17 221 for plastic stents, P = 0.90), mean hospital costs were significantly lower for pseudocysts using plastic stents ($18 996 vs $58 649, P = 0.03).

Conclusions:
Although there is no difference in clinical outcomes, treating pseudocysts using plastic stents is less expensive. It is also possible that the short procedural duration is a surrogate marker for procedural complexity and this may drive the use of LAMS in sicker patients.

EUS-guided drainage of pancreatic fluid collections using a novel lumen-apposing metal stent on an electrocautery-enhanced delivery system: a large retrospective study (with video). A. Gastrointestinal Endoscopy 2015 82:6 (1039-1046) (8)

Background and Aims
A lumen-apposing, self-expanding metal stent incorporated in an electrocautery-enhanced delivery system for EUS-guided drainage of pancreatic fluid collections (PFCs) recently has become available. The aim of this study was to analyze the safety and clinical effectiveness of this newly developed device in this clinical setting.

Methods
This was a retrospective analysis of all consecutive patients with PFCs who underwent EUS-guided drainage using the study device in 13 European centers. Results Ninety-three patients with PFCs (80% with complex collections) underwent drainage using the study device. Penetration of the PFC was accomplished directly with the study device in 74.2% of patients, and successful stent placement was accomplished in all but 1 patient, mostly without fluoroscopic assistance. Direct endoscopic necrosectomy (DEN) was carried out in 31 of 52 cases (59.6%) of walled-off necrosis and in 2 of 4 cases (50%) of acute peripancreatic fluid collection. Complete resolution of the PFC was obtained in 86 cases (92.5%), with no recurrence during follow-up. Treatment failure occurred in 6 patients because of persistent infection requiring surgery (n = 3), perforation and massive bleeding caused by the nasocystic drainage catheter (NCDC) (n = 2), and the need for a larger opening to extract large necrotic tissue pieces (n = 1). Major adverse events occurred in 5 patients (perforation and massive bleeding caused by the NCDC in 2 patients, 1 pneumoperitoneum and 1 stent dislodgement during DEN, and 1 postdrainage infection) and were mostly not related to the drainage procedure.

Conclusions
EUS-guided drainage with the electrocautery-enhanced delivery system is a safe, easy to perform, and a highly effective minimally invasive treatment modality for PFCs.

Comparison of clinical efficacies and safeties of lumen-apposing metal stent and conventional-type metal stent-assisted EUS-guided pancreatic wall-off necrosis drainage: a real-life experience in a tertiary hospital. Surg Endosc. 2018 May; 32(5):2448-2453. (9)

Background:
Endoscopic ultrasound (EUS)-guided drainage of pancreatic wall-off necrosis (WON) with transmural stent is regarded as firstline therapy. We aimed at comparing its efficacy and safety with using fully covered self-expandable metal stent (FCSEMS) and lumen-apposing metal stent (LAMS).

Methods:
A retrospective review was performed on all consecutive patients with pancreatic WONs who underwent EUS-guided drainage by either FCSEMS or LAMS.

Results:
From 2011 to 2016, 68 patients (66.2% male, median age, 66.5 years) underwent WON drainage (22/68 (32.4%) using FCSEMSs of size 10 × 60 mm (14/22, Hanarostent; 8/22 Wallflex); 46/68 (67.6%) using LAMSs (38/46 and 8/46 with AXIOS of size 15 × 10 mm and 10 × 10 mm, respectively). These two groups were matched for age (66 vs. 70 years, p 0.514), APACHE II (11.5 vs. 10, p 0.693), causes [72.7 vs. 80.4% by gallstone pancreatitis (p 0.472); 9.1 vs. 10.9% by alcoholism (p 0.818)], WON size (8.5 vs. 9 cm, p 0.322), location (36.4 vs. 26.1% at pancreatic head, p 0.384; 54.5 vs. 65.2% at body/tail, p 0.395), and enterostomy site [63.6 vs. 76.1% via transgastric (p 0.285); 31.8 vs. 19.6% via transduodenal (p 0.267)] and their number of necrosectomy (p 0.978). The technical (100 vs. 93.5%, p 0.219) and clinical (95.5 vs. 93.5%, p 0.749) success and adverse event (22.7 vs. 39.1%, p 0.180; 9.1 vs. 19.6% with bleeding, p 0.271; 4.5 vs. 13% with spontaneous stent migration, p 0.28; 9.1 vs. 6.5% with dislodgement during necrosectomy, p 0.704) of the two groups were comparable without significant different. However, the LAMS group associated with early stent revision compared with FCSEMS group (log rank p 0.048).

Conclusions:
EUS-guided drainage of WON using FCSEMSs and LAMSs are comparable in efficacy and safety; however, the latter is associated with early stent revision.

Los siguientes documentos (*) como se explica en la metodología, se recogen en la bibliografía:

Lumen Apposing Metal Stents vs Double Pigtail Stents. Cochrane Central Register of Controlled Trials, 2019 (10)

Endoscopic ultrasonography-guided drainage of pancreatic fluid collections using a novel lumen-apposing metal stent: a multi-center Australian, New Zealand and Asian experience. Gastrointestinal Endoscopy 2019 89:6 Supplement (AB592-AB593) (11)

EUS-guided drainage of peripancreatic fluid collections: Hot axios experience from a tertiary referral centre. Gut 2019 68 Supplement 2 (A161-) (12)

Management of pancreatic fluid collections by lams: Large series from a tertiary referral HPB centre. Gut 2019 68 Supplement 2 (A159-) (13)

Comparative analysis of eus-guided pseudocyst and walled-off necrosis drainage between different metal (Hot-AXIOS™, NAGI™, SPAXUS™) and plastic (double pigtail) stents: A single

center-experience. United European Gastroenterology Journal 2018 6:8 Supplement (A17-) (14)

Endoscopic ultrasound-guided drainage of peripancreatic fluid collection using luminal-apposing metal stents. Journal of Gastroenterology and Hepatology 2018 33, Supplement 2 (3-4) (15)

Safety and efficacy of the new 20 mm lumen apposing metal stent (LAMS) for endoscopic treatment of pancreatic and peripancreatic fluid collectios: A large, international, multicenter study. Gastrointestinal Endoscopy 2018 87:6 Supplement 1 (AB353-) (16)

Ultrasound-guided endoscopic transgastric drainage of pancreatic fluid collections. United European Gastroenterology Journal 2017 5:5 Supplement 1 (A249-) (17)

Safety and efficacy of endoscopic ultrasound guided drainage of walled-off pancreatic necrosis using lumen apposing metal stents (hot axios). American Journal of Gastroenterology 2016 111 Supplement 1 (S147-) (18)

Feasibility, safety and outcomes of a single-step endoscopic ultrasonography-guided drainage of pancreatic fluid collections without fluoroscopy using a novel lumen-apposing, self-expanding metal stent. Gastrointestinal Endoscopy 2016 83:5 SUPPL. 1 (AB505-) (19)

Technical issues (TI) during EUS-guided interventions with lumen apposing metal stents (LAMS): Incidence, management and impact on procedural outcomes Gastrointestinal Endoscopy 2018 87:6 Supplement 1 (AB324-AB325) (20)

Direct endoscopic necrosectomy in superinfected fluid collections in necrotizing pancreatitis using lumen-apposing metal stents: Better outcome with early intervention. United European Gastroenterology Journal 2018 6:8, Supplement (A613-) (21)

Lumen-apposing metal stents (LAMS) for pancreatic fluid collection (PFC) drainage: May not be business as usual. Digestive Endoscopy 2017 29 Supplement 1 (22)

Indicación 2: Drenaje biliar de colédoco a cámara gástrica o duodenal en pacientes oncológicos o con operabilidad limitada

Endoscopic ultrasound-guided choledochoduodenostomy with electrocautery-enhanced lumen-apposing stents: A retrospective analysis. Endoscopy 2019 51:6 (540-547) (23)

Background

Endoscopic ultrasound-guided biliary drainage is an alternative to percutaneous biliary drainage in cases of malignant biliary obstruction and failure of classic endoscopic drainage by endoscopicretrograde cholangiopancreatography (ERCP). Recently, a new electrocautery-enhanced lumen-apposing metal stent (ECE-LAMS) that allows for endoscopic anastomosis (apposition stent) has become available for use in EUS-choledochoduodenostomy (EUS-CDS) and facilitates the procedure.

Methods

This was a retrospective study of all EUS-CDS procedures performed in France between April 2016 and August 2017. The primary end point was the technical and clinical success rates of EUS-CDS using an ECE-LAMS. Results 52 consecutive patients were included in the study. The etiology of distal bile duct obstruction was distal pancreatic adenocarcinoma in 43 patients (82.7%). The technical success rate was 88.5% (46/52 patients), and the clinical success rate was 100% (46/46 patients). The mean duration of the procedure was 10.2 minutes (range 1-90). Two patients (3.8%) presented with short-term complications after EUS-CDS and before discharge from hospital. In univariate analyses, a small diameter of the common bile duct and not following the recommended procedure technique were significant risk factors for technical failure. Over a mean follow-up of 157 days, the median survival time without biliary complications was 135 days.

Conclusion

EUS-CDS with an ECE-LAMS is efficacious and safe in distal malignant obstruction of the common bile duct and could be proposed as the first option in cases of ERCP failure.

Outcomes of an international multicenter registry on EUS-guided gallbladder drainage in patients at high risk for cholecystectomy. Endoscopy International Open 2019 7:8 (E964-E973) (24)

Background and study aims

The aim of the current study was to review the outcomes of a large-scale international registry on endoscopic ultrasound-guided gallbladder drainage (EGBD) that encompasses different stent systems in patients who are at high-risk for cholecystectomy.

Patients and methods

This was a retrospective international multicenter registry on EGBD created by 13 institutions around the world. Consecutive patients who received EGBD for several indications were included. Outcomes include technical and clinical success, unplanned procedural events (UPE), adverse events (AEs), mortality, recurrent cholecystitis and learning curve of the procedure.

Results

Between June 2011 and November 2017, 379 patients were recruited to the study. Technical and clinical success were achieved in 95.3% and 90.8% of the patients, respectively. The 30-day AE rate was 15.3% and 30-day mortality was 9.2%. UPEs were significantly more common in patients with EGBD performed for conversion of cholecystostomy and symptomatic gallstones (P <0.001); and by endoscopists with experience of fewer than 25 procedures (P =0.033). Both presence of clinical failure (P =0.014; RR 8.69 95%CI [1.56-48.47]) and endoscopist experience with fewer than 25 procedures (P =0.002; RR 4.68 95%CI [1.79-12.26]) were significant predictors of 30-day AEs. Presence of 30-day AEs was a significant predictor of mortality (P <0.001; RR 103 95%CI [11.24-944.04]).

Conclusion

EGBD was associated with high success rates in this large-scale study. EGBD performed for indications other than acute cholecystitis was associated with higher UPEs. The number of cases required to gain competency with the technique by experienced interventional endosonographers was 25 procedures.

EUS-guided choledochoduodenostomy for malignant distal biliary obstruction using a lumen-apposing fully covered metal stent after failed ERCP. Surgical Endoscopy 2016 30:11 (5002-5008) (25)

Background:
A novel lumen-apposing, self-expanding metal stent to perform EUS-guided drainage procedures has been recently developed. The aim of this study was to analyze the safety, technical and clinical effectiveness of this device for EUS-guided choledochoduodenostomy (EUS-CD) with palliative intent.

Methods:
Retrospective analysis of all consecutive patients with unresectable malignant distal bile duct obstruction who, between March 2012 and September 2014, underwent EUS-CD using the study devices (AXIOS™ and Hot AXIOS™, Xlumena Inc., Mountain View, CA, USA) after unsuccessful ERCP in seven European centers was carried out.

Results:
Fifty-seven patients (M/F 31/26; median age 73) underwent EUS-CD using the AXIOS™ stent or the Hot AXIOS™ delivery system. ERCP failure was due to duodenal obstruction in 41 patients (71.9 %) and to inability to cannulate the papilla in the remaining 16 patients (28.1 %). The procedure was technically successful in 56/57 patients (98.2 %), with a mean procedural time of 22.4 min (range 11–65). Clinical success was achieved in 54 of these 56 patients (96.4 %; 94.7 % of the entire cohort). Overall major procedural complication rate was 7 % (two duodenal perforations, one bleeding and one transient cholangitis). During follow-up, 5 out of 54 (9.3 %) patients with clinica success required re-intervention for stent migration in one case and a sump syndrome with transient increase in serum bilirubin concentrations with sludge in the distal duct reservoir in the remaining four patients.

Conclusions:
Our study shows that EUS-CD using the AXIOS™ and the Hot AXIOS™ devices is a safe procedure, with high technical and clinical success rates.

Los siguientes documentos (*) como se explica en la metodología, se recogen en la bibliografía:

Endoscopic ultrasound-guided transduodenal biliary drainage may be a safe and effective alternative option for failed endoscopic retrograde cholangiopancreaticography for malignant biliary obstruction. Journal of Gastroenterology and Hepatology 2018 33 Supplement 2 (6-7) (26)

Eus-guided choledochoduodenostomy using a lumen apposing metal stent for malignant distal biliary obstruction: A retrospective analysis of a single center experience. Digestive and Liver Disease 2018 50:2 Supplement 1 (e205-) (27)

Single-session double-stent placement in concomitant malignant biliary and duodenal obstruction with a cautery-tipped lumen apposing metal stent. Digestive and Liver Disease 2017, 49 Supplement 2 (e172-) (28)

Wireless EUS-guided choledochoduodenostomy by a cautery-tipped lumen apposing metal stent followed by duodenal metal stent placement: A single session sequential approach for

concomitant malignant biliary and duodenal obstruction. United European Gastroenterology Journal 2016 4:5 Supplement 1 (A417-). (29)

Eus-guided biliodigestive anastomosis for drainage of malignant distal biliary obstruction using a novel cautery-tipped lumen-apposing stent delivery system: A large retrospective multicenter European study. United European Gastroenterology Journal 2015 3:5 SUPPL. 1 (A129-) (30)

Indicación 3 Drenaje de vesícula biliar a cámara gástrica o duodenal en colecistitis aguda

Recent advances in endoscopic ultrasound-guided biliary drainage. Dig Endosc. 2018 Jan; 30(1):38-47. (31)

Endoscopic ultrasound-guided biliary drainage (EUS-BD) is increasingly used as an alternative in patients with biliary obstruction who fail standard endoscopic retrograde cholangiopancreatography (ERCP). The two major endoscopic approach routes for EUS-BD are the transgastric intrahepatic and the transduodenal extrahepatic approaches. Biliary drainage can be achieved by three different methods, transluminal biliary stenting, transpapillary rendezvous technique, and antegrade biliary stenting. Choice of approach route and drainage method depends on individual anatomy, underlying disease, and location of the biliary stricture. Recent meta-analyses have revealed that cumulative technical success and adverse event rates were 90–94% and 16–23%, respectively. Development of new dedicated devices for EUS-BD would help refine the technical aspects and minimize the possibility of complications, making it a more promising procedure.

Feasibility of per-oral cholecystoscopy and advanced gallbladder interventions after EUS-guided gallbladder stenting (with video). Gastrointestinal Endoscopy 2017 85:6 (1225-1232) (32)

Background and Aims

The recent development of EUS-guided gallbladder drainage (EGBD) with a lumen-apposing stent has made endoscopic assessment and advanced gallbladder interventions via the stent possible. The aim of this study was to assess the feasibility and safety of per-oral cholecystoscopy and the types of gallbladder interventions that can be performed.

Methods

This was a retrospective review conducted in the Prince of Wales Hospital from June 2012 to March 2016. All patients who had acute cholecystitis with EGBD were included. Cholecystoscopy was performed 1 to 3 months after stent insertion. Patients' demographic data, technical success, types of intervention, and adverse events were recorded.

Results

Twenty-nine cholecystoscopies were performed in 25 patients. Twenty-seven of 29 cholecystoscopies were successful (93.1%). Magnifying endoscopy was performed in 10 patients, confocal endomicroscopy and EUS in 1 patient, and endocytoscopy in another patient. Fourteen patients (56%) had spontaneous stone passage. Eleven patients (44%) had residual gallstones on cholecystoscopy, and removed in 8. Overall stone clearance rate was 88% after a mean (standard deviation) number of 1.25 (0.46) sessions of cholecystoscopy.

Conclusions
Per-oral cholecystoscopy and advanced gallbladder interventions were feasible and safe. This opens up exciting possibilities for endoscopic treatment of gallbladder pathologies.

Endoscopic Management of Gallbladder Stones: Can We Eliminate Cholecystectomy?. Current Gastroenterology Reports 2016 18:8 Article Number 42 (33)

The gold standard for the management of acute cholecystitis is laparoscopic cholecystectomy. In patients that are not fit for surgery, percutaneous cholecystostomy is the standard treatment. However, the procedure is only a temporary measure for controlling gallbladder symptoms and it is frequently associated with morbidities. Recently, endoscopic options for management of acute cholecystitis have been developed. The approach avoids the need for a percutaneous drain and may allow endoscopic treatment of the gallstone. The aim of this article is to provide an overview on the current status of endoscopicmanagement of acute cholecystitis.

Los siguientes documentos (*) como se explica en la metodología, se recogen en la bibliografía:

Endoscopic ultrasound-guided biliary drainage with lumen-apposing metal stents for biliary obstruction. Journal of Gastroenterology and Hepatology 2018 33 Supplement 2 (3-) (34)

Eus-guided gallbladder drainage in high surgical risk acute cholecystitis using a lumen-apposing metal stent on an electrocautery enhanced delivery system: A retrospective multicenter study. Digestive and Liver Disease 2017 49 Supplement 2 (e124-) (35)

Documentos encontrados en la búsqueda bibliográfica para varias indicaciones

Endoscopic ultrasound-guided transmural drainage by cautery-tipped lumen-apposing metal stent: Exploring the possible indications. Annals of Gastroenterology 2018 31:6 (735-741) (36)

Background:
The recently introduced Hot AXIOS™ system for endoscopic ultrasound (EUS)-guided transenteric drainage has the potential to change interventional endoscopy significantly. The aim of our study was to assess the effectiveness and safety of this new type of lumen-apposing metal stent (LAMS) with cautery system for pancreatic collection, and gallbladder and biliary tree drainage.

Methods:
We retrospectively reviewed consecutive patients undergoing EUS-guided drainage by LAMS with cautery system in a tertiary-care academic medical center between March 2014 and March 2017. All patients were included in our prospectively maintained institutional EUS database. The main outcome measures were technical success, clinical effectiveness, and adverse events.

Results:
A total of 45 patients (20 men, mean age 69.6 years) underwent LAMS placement. Indications were pancreatic fluid collections (19 patients, 42.2%), acute cholecystitis (10 patients, 22.2%), and biliary drainage (16 patients, 35.5%). Technical success was achieved in all patients except one (97.7%). Clinical success was achieved in 86.4% (38/44) of cases and adverse events occurred in 5 (11.4%) of patients.

Conclusions:
In our experience, EUS-guided LAMS placement performed by expert endoscopists was feasible and effective in the endoscopic management of pancreatic fluid collection, and biliary and gallbladder drainage. Optimization of transmural drainage by new dedicated devices could improve efficacy and safety in appropriately selected patients.

EUS guided drainages with novel electrocautery-enhanced apposing metal stents (stent Hot AXIOS) in a cohort of 20 patients. Gastroenterologie a Hepatologie 2018 72:4 (309-316) (37)

Background:
The recently introduced Hot AXIOS™ system for endoscopic ultrasound (EUS)-guided transenteric drainage has the potential to change interventional endoscopy significantly. The aim of our study was to assess the effectiveness and safety of this new type of lumen-apposing metal stent (LAMS) with cautery system for pancreatic collection, and gallbladder and biliary tree drainage.

Methods:
We retrospectively reviewed consecutive patients undergoing EUS-guided drainage by LAMS with cautery system in a tertiary-care academic medical center between March 2014 and March 2017. All patients were included in our prospectively maintained institutional EUS database. The main outcome measures were technical success, clinical effectiveness, and adverse events.

Results:
A total of 45 patients (20 men, mean age 69.6 years) underwent LAMS placement. Indications were pancreatic fluid collections (19 patients, 42.2%), acute cholecystitis (10 patients, 22.2%), and biliary drainage (16 patients, 35.5%). Technical success was achieved in all patients except one (97.7%). Clinical success was achieved in 86.4% (38/44) of cases and adverse events occurred in 5 (11.4%) of patients.

Conclusions:
In our experience, EUS-guided LAMS placement performed by expert endoscopists was feasible and effective in the endoscopic management of pancreatic fluid collection, and biliary and gallbladder drainage. Optimization of transmural drainage by new dedicated devices could improve efficacy and safety in appropriately selected patients.

Los siguientes documentos (*) como se explica en la metodología, se recogen en la bibliografía:

The intra-channel stent release technique for fluoroless endoscopic ultrasound-guided lumen-apposing metal stent placement: Changing the paradigm. Digestive and Liver Disease 2017 49 Supplement 2 (e123-) (38)

A novel lumen-apposing metal stent for endoscopic ultrasound-guided drainage: A single center experience. United European Gastroenterology Journal 2016 4:5 Supplement 1 (A416-) (39)

Indicación 4: Creación de derivaciones gastro-yeyunales en pacientes oncológicos

Sólo se encontró un documento con esta indicación pero se trata de una comunicación a un congreso por lo que aparece en la bibliografía:

EUS-guided, minimally invasive enteroanastomosis in cholestasis due to malignant tumor growth and afferent-loop syndrome replacing surgical intervention (e.g., in malignant tumor lesions of the pancreas and the papilla of vater as well as periampullary malignomas)-an interims analysis of the clinical inauguration of the appraoch using an axios stent. Gastrointestinal Endoscopy 2018 87:6 Supplement 1 (AB311-) (40)

Indicación 5: Creaciones de derivaciones intragástricas en pacientes con cirugía bariátrica para realizar colangiografía retrógrada endoscópica (CPRE) o que hayan desarrollado el síndrome de sumidero.

EUS-Guided Endoscopic Gastrointestinal Anastomosis with Lumen-Apposing Metal Stent: Feasibility, Safety, and Efficacy. Obesity Surgery 2018 28:5 (1445-1451) (41)

Traditionally, restoration of normal bowel continuity after resection and bypass of a diseased or obstructed gastrointestinal tract can only be achieved through surgery, which can be technically challenging and comes with a risk of adverse events. Here, we describe our institutions' experience with endoscopic-guided gastroenterostomy or enteroenterostomy with lumen-apposing metal stent (LAMS) from March 2015 to August 2016. Ten patients had gastrogastrostomy (gastric pouch to gastric remnant) and three patients had jejunogastrostomy (Roux limb to gastric remnant) for the reversal of Roux-en-Y bariatric surgery. One patient had gastroduodenostomy (stomach to duodenal bulb) post antrectomy and one patient had jejunojejunostomy for distal obstruction following Roux-en-Y reconstruction. Technical and clinical success were achieved in all patients, save for delayed anastomotic stenosis following stent removal in one patient, with a mean follow-up of 126 days (3–318 days) with minimal complications in two patients. Endoscopicgastrointestinal anastomosis therefore may be a safe and feasible technique to re-establish continuity of the digestive system following bypass in the short-term.

4. ¿SE HAN ENCONTRADO OTROS ESTUDIOS DE INVESTIGACIÓN EN ESPAÑA QUE PUEDAN APORTAR INFORMACIÓN RELEVANTE?

Hemos encontrado un estudio de investigación español retrospectivo y multicéntrico *A retrospective, multicenter analysis of incidents associated with Axios™ lumen-apposing stents* de incidencias asociadas a la retirada de las prótesis tipo Axios, así como la posible asociación entre las mismas y el tiempo de permanencia (42).

En el mismo comentan la controversia que existe cuando el dispositivo se inserta con carácter temporal, como en el drenaje de colecciones necróticas encapsuladas, acerca del tiempo que

deben permanecer *in situ* para optimizar por un lado el resultado del drenaje y, por otro, minimizar los posibles efectos adversos. No se ha llegado a establecer de forma precisa el tiempo de retirada. En las colecciones pancreáticas se ha sugerido que no retirar las prótesis podría ser teóricamente beneficioso para el drenaje, aunque, una vez resueltas las colecciones, podría ocasionar la penetración hacia los vasos y órganos adyacentes, causando hemorragias y fijación de la prótesis a la pared. Por lo tanto, se ha recomendado retirar las prótesis antes de alcanzar las cuatro semanas de permanencia para disminuir así el riesgo de hemorragia diferida como ya comentamos en la referencia de Bang (22) que recomendaba obtener una TC de seguimiento para evaluar la respuesta al tratamiento a las 3 (no a las 6) semanas, seguida de la extracción del stent si el PFC se ha resuelto. El estudio muestra que la permanencia *in situ* de las prótesis tipo Axios es segura, incluso a pesar de superar los periodos de permanencia actualmente recomendados. Pero si creen necesario realizar estudios prospectivos multicéntricos para establecer los tiempos de permanencia óptimos, así como para evaluar las complicaciones asociadas a la permanencia a largo plazo de este tipo de prótesis.

5. PRINCIPALES CONCLUSIONES Y RECOMENDACIONES DEL INFORME DE EVALUACIÓN

La prótesis tipo Hot Axios™ insertadas mediante ultrasonografía endoscópica (USE) se ha introducido en la clínica sin una previa evaluación formal de esta tecnología. Aunque hay ensayos clínicos en marcha, su utilización es un hecho. Cabe la posibilidad de esperar a los resultados de estos ensayos, pero dada la experiencia con esta tecnología no parece lo más aconsejable porque debido a la relativa facilidad en su colocación y a la eficacia demostrada, la utilización de prótesis tipo Hot Axios™ insertadas mediante ultrasonografía endoscópica (USE) para el drenaje del conducto biliar, pancreático, espacios retroperitoneales y la creación de anastomosis digestivas se encuentra en auge y tiene el potencial de cambiar significativamente la endoscopia intervencionista.

Los beneficios potenciales pueden ser múltiples, como evitar la radioscopia (menor radiación para paciente y personal y disponibilidad del técnico y equipo de rayos para otra tarea), la rapidez del procedimiento, menos necesidad de sesiones endoscópicas, estancias hospitalarias más cortas y costes más bajos disminuyendo el consumo de recursos (salas, anestesistas, etc). Además el drenaje al ser interno mejora la calidad de vida del paciente. También la estancia media es menor al evitar cirugías o procedimientos radiológicos con mayor morbilidad.

La mayoría de los pacientes con obstrucción biliar maligna son diagnosticados en estado avanzado, por lo que no son candidatos a tratamiento quirúrgico curativo, y presentan ictericia, prurito, anorexia, malnutrición, colangitis y muerte prematura. El alivio de la obstrucción biliar es esencial para la resolución de la ictericia y la mejoría en la calidad de vida, así como para el incremento en la supervivencia.

La elección de la técnica depende fundamentalmente de la experiencia de los facultativos, teniendo en cuenta los inconvenientes y el impacto de cada procedimiento en la calidad de vida del paciente.

Respecto a los riesgos potenciales o problemas técnicos que puedan surgir (20), no son anecdóticos, a pesar de las altas tasas de éxito clínico y técnico en su colocación.

También la aparición del síndrome de sumidero (43) es posible que aumente con la creciente utilización de la colédoco-duodenostomía endoscópica para paliar los síntomas de una doble estenosis (duodenal y biliar) o en CPRE fallidas en pacientes con cáncer periampular.

En esta circunstancia, lo ideal es introducirlo con un protocolo de uso y una evaluación continua de sus resultados y complicaciones. Por tanto debe ir precedido de un consenso que resultará en la elaboración de un formulario en el que se defina bien que la indicación es adecuada y se recoja información para la evaluación. Se podría valorar enviar la solicitud de un informe de evaluación al ministerio para su consideración como estudio de monitorización.

Entre otras cosas, en el protocolo debe definirse por un lado dónde y quién realizará la técnica y a que patologías y paciente,s y por otro se debe elaborar un método para minimizar los riesgos.
Entre otras cosas, conviene definir el número mínimo de procedimientos realizados bajo supervisión antes de certificar al endoscopista para su uso. El número de casos necesarios para la adquisición de competencia con la técnica por ejemplo, en caso de drenaje biliar de colédoco a cámara gástrica o duodenal en pacientes oncológicos o con operabilidad limitada, son 25 procedimientos según el estudio de Teoh (24), pero también se requiere experiencia en otras indicaciones.

Para minimizar el riesgo del síndrome de sumidero, puede resultar recomendable realizar el abordaje de la vía biliar extrahepática, con el acceso más distal/ yuxtapapilar posible durante la colédoco-duodenostomía guiada por ecoendoscopia.

6. CONSIDERACIONES PARA NUESTRA COMUNIDAD

En la actualidad existen endoscopistas que realizan técnicas similares que podrían estar facultados para llevar a cabo esta. Sin embargo, parece prudente que antes de ejecutarla realicen un periodo de entrenamiento en un centro que sea excelente en ese campo.

La realidad es que en algunos centros de la región ya se está empleando. Convendría conocer los resultados.

El coste del dispositivo, es de 3000 euros por unidad, es similar a la compra de los distintos dispositivos (cistotomo, prótesis de aposición, dilatadores, aguja de endoscopia, guía…) por separado.

Se estiman para toda la región unos 25 30 casos al año.

7. BIBLIOGRAFÍA

1. HAYES, Inc. Lumen-apposing metal stents (Axios Stent and Delivery System; Boston Scientific.) for management of pancreatic pseudocysts and walled-off necrosis. Lansdale: HAYES, Inc. Healthcare Technology Brief Publication. 2016

2. Law S.T., De La SernaHiguera C., Simón P.G., Pérez-MirandaCastillo M. Comparison of clinical efficacies and safeties of lumen-apposing metal stent and conventional-type metal stent-assisted EUS-guided pancreatic wall-off necrosis drainage: a real-life experience in a tertiary hospital. Surg Endosc. 2018 May;32(5):2448-2453. doi: 10.1007/s00464-017-5946-6. Epub 2017 Nov 3.
3. Puga M, Consiglieri CF, Busquets J, Pallarès N, Secanella L, Peláez N, Fabregat J, Castellote J, Gornals JB. Safety of lumen-apposing stent with or without coaxial plastic stent for endoscopic ultrasound-guided drainage of pancreatic fluid collections: a retrospective study. Endoscopy. 2018 Oct;50(10):1022-1026. doi: 10.1055/a-0582-9127. Epub 2018 Mar 28
4. Consiglieri C.F., Gornals J.B., Busquets J., Peláez N., Secanella L., De La Hera M.,Sanzol R., Fabregat J., Castellote J.. Fluoroscopy-assisted vs fluoroless endoscopic ultrasound-guided transmural drainage of pancreatic fluid collections: A comparative study. Gastroenterologia y Hepatologia 2018 41:1 (12-21)
5. Bekkali N.L.H., Nayar M.K., Leeds J.S., Charnley R.M., Huggett M.T., Oppong K.W. A comparison of outcomes between a lumen-apposing metal stent with electrocautery-enhanced delivery system and a bi-flanged metal stent for drainage of walled-off pancreatic necrosis. Endoscopy International Open 2017 5:12 (E1189-E1196)
6. Adler D.G., Taylor L.J., Hasan R., Siddiqui A.A. A retrospective study evaluating endoscopic ultrasound- guided drainage of pancreatic fluid collections using a novel lumen-apposing metal setent on an electrocautery enhances delivery system. Endoscopic Ultrasound 2017, 6:6 (389-393)
7. Bang J.Y., Hasan M.K., Navaneethan U., Sutton B., Frandah W., Siddique S., Hawes R.H., Varadarajulu S. Lumen-apposing metal stents for drainage of pancreatic fluid collections: When and for whom?. Digestive Endoscopy 2017 29:1 (83-90)
8. Rinninella E., Kunda R., Dollhopf M., Sanchez-Yague A., Will U., Tarantino I., Gornals Soler J., Ullrich S., Meining A., Esteban J.M., Enz T., Vanbiervliet G., Vleggaar F., Attili F., Larghi. EUS-guided drainage of pancreatic fluid collections using a novel lumen-apposing metal stent on an electrocautery-enhanced delivery system: a large retrospective study (with video). A. Gastrointestinal Endoscopy 2015 82:6 (1039-1046)
9. Law S.T., De La SernaHiguera C., Simón P.G., Pérez-Miranda Castillo M. Comparison of clinical efficacies and safeties of lumen-apposing metal stent and conventional-type metal stent-assisted EUS-guided pancreatic wall-off necrosis drainage: a real-life experience in a tertiary hospital. Surg Endosc. 2018 May; 32(5):2448-2453
10. John Gasdal Karstensen, Principal Investigator. Lumen Apposing Metal Stents vs Double Pigtail Stents. Cochrane Central Register of Controlled Trials, 2019. https://clinicaltrials.gov/show/NCT04057846, 2019 | added to CENTRAL: 31 August 2019 | 2019 Issue 08,NCT04057846Links: ClinicalTrials.gov
11. Khan S.A., Chandran S., Chin J., Karim S., Mangira D., Ermerak G., Trinh A., Kia C.Y., Mules T., Z ad M., Ang T.L., Johns E., Tee D., Kaul A., Fisher L., Cameron R., Welch, Lim G., Metz A.J., Moss A., BassanM.S., StJohn A., Hourigan L.F., Tagkalidis P., Weilert F., Vaughan R., Devereaux B.M . Endoscopic ultrasonography-guided drainage of pancreatic fluid collections using a novel lumen-apposing metal stent: a multi-center Australian, New Zealand and Asian experience. Gastrointestinal Endoscopy 2019 89:6 Supplement (AB592-AB593)
12. Peerally M.F., Goldie F., Savva S., Khan F., Kadri S EUS-guided drainage of peripancreatic fluid collections: Hot axios experience from a tertiary referral centre. Gut 2019 68 Supplement 2 (A161-)

13. Keane M., El-Sherif Y., Warner B., Reffitt D., Harrison P., Joshi D., Devlin J. Management of pancreatic fluid collections by lams: Large series from a tertiary referral HPB centre. Gut 2019 68 Supplement 2 (A159-)
14. Robles-Medranda C., Puga-Tejada M., Oleas R., DelValle R., Ospina-Arboleda J., Alvarado Escobar H., Soria-Alcivar M., Pitanga-Lukashok H. Comparative analysis of eus-guided pseudocyst and walled-off necrosis drainage between different metal (Hot-AXIOS™, NAGI™, SPAXUS™) and plastic (double pigtail) stents: A single center-experience. United European Gastroenterology Journal 2018 6:8 Supplement (A17-)
15. Chin J., Weilert F. Endoscopic ultrasound-guided drainage of peripancreatic fluid collection using luminal-apposing metal stents. Journal of Gastroenterology and Hepatology 2018 33, Supplement 2 (3-4)
16. Anderloni A.A., Uwe W., Dollhopf M., Fabbri C., Perez-Miranda M., Nieto J., Aparicio J.R., Tarantino I., Vleggaar F.P., Vanbiervliet G., Hampe J., Kahaleh M., Vila J.J., Abu Dayyeh B.K., Fugazza A., Binda C., ArltA., Charachon A., Tyberg A., Moran R., Wani S.B., Repici A., Sethi A., Khashab M.A., Kunda R. Safety and efficacy of the new 20 mm lumen apposing metal stent (LAMS) for endoscopic treatment of pancreatic and peripancreatic fluid collectios: A large, international, multicenter study. Gastrointestinal Endoscopy 2018 87:6 Supplement 1 (AB353-)
17. Silva M., Lopes S., Peixoto A., Vilas-Boas F., Moutinho-Ribeiro P., Macedo G. Ultrasound guided endoscopic transgastric drainage of pancreatic fluid collections. United European Gastroenterology Journal 2017 5:5 Supplement 1 (A249-)
18. Cooper C.J., Dawwas M., Mardini H. Safety and efficacy of endoscopic ultrasound guided drainage of walled-off pancreatic necrosis using lumen apposing metal stents (hot axios). American Journal of Gastroenterology 2016 111 Supplement 1 (S147-)
19. Siddiqui A.A., Nieto J . Feasibility, safety, and outcomes of a single-step endoscopic ultrasonography-guided drainage of pancreatic fluid collections without fluoroscopy using a novel lumen-apposing, self-expanding metal stent. Gastrointestinal Endoscopy 2016 83:5 SUPPL. 1 (AB505-)
20. Sevilla-Ribota S., Garcia-Alonso F.J., Sanchez-Ocana R., Penas-Herrero I., Mora N., Becerro-Gonzalez I., Torres-Yuste R., Cimavilla M., De La Serna C., Perez-Miranda M. Technical issues (TI) during EUS-guided interventions with lumen apposing metal stents (LAMS): Incidence, management and impact on procedural outcomes. Gastrointestinal Endoscopy 2018 87:6 Supplement 1 (AB324-AB325)
21. Albers D., Meining A., Seufferlein T., Hann A., Schumacher B. Direct endoscopic necrosectomy in superinfected fluid collections in necrotizing pancreatitis using lumen-apposing metal stents: Better outcome with early intervention. United European Gastroenterology Journal 2018 6:8, Supplement (A613)
22. Bang J.Y., Hasan M., Navaneethan U., Hawes R., Varadarajulu S. Lumen-apposing metal stents (LAMS) for pancreatic fluid collection (PFC) drainage: May not be business as usual. Digestive Endoscopy 2017 29 Supplement 1 (23)
23. Jacques J., Privat J., Pinard F., Fumex F., Valats J.-C., Chaoui A., Cholet F., Godard B., Grandval P., Legros R., Kerever S., Napoleon B. Endoscopic ultrasound-guided choledochoduodenostomy with electrocautery-enhanced lumen-apposing stents: A retrospective analysis. Endoscopy 2019 51:6 (540-547)

24. Teoh A.Y., Perez-Miranda M., Kunda R., Lee S.S., Irani S., Yeaton P., Sun S., Baron T.H., Moon J.H., Holt B., Khor C.J.L., Rerknimitr R., Bapaye A., Chan S.M., Choi H.J., James T.W., Kongkam P., Lee Y.N., Parekh P., Ridtitid W., Serna-Higuera C., Tan D.M.Y., Torres-Yuste R. Outcomes of an international multicenter registry on EUS-guided gallbladder drainage in patients at high risk for cholecystectomy. Endoscopy International Open 2019 7:8 (E964-E973)
25. Kunda R., Pérez-Miranda M., Will U., Ullrich S., Brenke D., Dollhopf M., Meier M., Larghi A. EUS-guided choledochoduodenostomy for malignant distal biliary obstruction using a lumen-apposing fully covered metal stent after failed ERCP. Surgical Endoscopy 2016 30:11 (5002-5008).
26. Mangira D., Opferkuch M., Moss A., Tagkalidis P. Endoscopic ultrasound-guided transduodenal biliary drainage may be a safe and effective alternative option for failed endoscopic retrograde cholangiopancreaticography for malignant biliary obstruction. Journal of Gastroenterology and Hepatology 2018 33 Supplement 2 (6-7).
27. Anderloni A., Fugazza A., Auriemma F., Carrara S., Di Leo M., Maselli R., Troncone E., Ferrara E.C., Galtieri P.A., Semeraro R., D'Amico F., Attardo S., Repici A. Eus-guided choledochoduodenostomy using a lumen apposing metal stent for malignant distal biliary obstruction: A retrospective analysis of a single center experience. Digestive and Liver Disease 2018 50:2 Supplement 1 (e205-)
28. Anderloni A., Buda A., Carrara S., Di Leo M., Fugazza A., Maselli R., Repici A. Single-session double-stent placement in concomitant malignant biliary and duodenal obstruction with a cautery-tipped lumen apposing metal stent. Digestive and Liver Disease 2017 49 Supplement 2 (e172-)
29. Anderloni A., Carrara S., Buda A., Di Leo M., Repici A. Wireless EUS-guided choledochoduodenostomy by a cautery-tipped lumen apposing metal stent followed by duodenal metal stent placement: A single session sequential approach for concomitant malignant biliary and duodenal obstruction. United European Gastroenterology Journal 2016 4:5 Supplement 1 (A417-)
30. Dollhopf M., Kunda R., Will U., Attili F., Tarantino I., Schmitt W., Larghi A. Eus-guided biliodigestive anastomosis for drainage of malignant distal biliary obstruction using a novel cautery-tipped lumen-apposing stent delivery system: A large retrospective multicenter European study. United European Gastroenterology Journal 2015 3:5 SUPPL. 1 (A129-)
31. Minaga K., Kitano M. Recent advances in endoscopic ultrasound-guided biliary drainage. Dig Endosc. 2018 Jan;30(1):38-47. doi: 10.1111/den.12910. Epub 2017 Aug 8.
32. Chan S.M., Teoh A.Y.B., Yip H.C., Wong V.W.Y., Chiu P.W.Y., Ng E.K.W. Feasibility of per-oral cholecystoscopy and advanced gallbladder interventions after EUS-guided gallbladder stenting (with video). Gastrointestinal Endoscopy 2017 85:6 (1225-1232)
33. Yeung B., Teoh A.Y.B. Endoscopic Management of Gallbladder Stones: Can We Eliminate Cholecystectomy?. Current Gastroenterology Reports 2016 18:8 Article Number 42
34. Chin J., Weilert F. Endoscopic ultrasound-guided biliary drainage with lumen-apposing metal stents for biliary obstruction. Journal of Gastroenterology and Hepatology 2018 33 Supplement 2 (3-)
35. Anderloni A., Dollhopf M., Attili F., Will U., Rimbas M., Sanchez-Yague A., Yuen Bun Teoh A., Costamagna G., Kunda R., Larghi A. Eus-guided gallbladder drainage in high surgical risk acute cholecystitis using a lumen-apposing metal stent on an electrocautery enhanced delivery system: A retrospective multicenter study. Digestive and Liver Disease 2017 49 Supplement 2 (e124-)

36. Anderloni A., Di Leo M., Carrara S., Fugazza A., Maselli R., Buda A., Amato A., Auriemma F., Repici A. Endoscopic ultrasound-guided transmural drainage by cautery-tipped lumen-apposing metal stent: Exploring the possible indications. Annals of Gastroenterology 2018 31:6 (735-741)
37. Pintová J., Procházka R., Nosek V. EUS guided drainages with novel electrocautery-enhanced apposing metal stents (stent Hot AXIOS) in a cohort of 20 patients. Gastroenterologie a Hepatologie 2018 72:4 (309-316)
38. Anderloni A., Attili F., Carrara S., Galasso D., Di Leo M., Costamagna G., Repici A., Kunda R., Larghi A. The intra-channel stent release technique for fluoroless endoscopic ultrasound-guided lumen-apposing metal stent placement: Changing the paradigm. Digestive and Liver Disease 2017 49 Supplement 2 (e123-)
39. Anderloni A., Di Leo M., Carrara S., Maselli R., Buda A., Amato A., Repici A. A novel lumen-apposing metal stent for endoscopic ultrasound-guided drainage: A single center experience. United European Gastroenterology Journal 2016 4:5 Supplement 1 (A416-)
40. Will U., Masaryk V., Fueldner F., Meyer F. EUS-guided, minimally invasive enteroanastomosis in cholestasis due to malignant tumor growth and afferent-loop syndrome replacing surgical intervention (e.g., in malignant tumor lesions of the pancreas and the papilla of vater as well as periampullary malignomas)-an interims analysis of the clinical inauguration of the appraoch using an axios stent. Gastrointestinal Endoscopy 2018 87:6 Supplement 1 (AB311-)
41. Amateau S.K., Lim C.H., McDonald N.M., Arain M., Ikramuddin S., Leslie D.B. EUS-Guided Endoscopic Gastrointestinal Anastomosis with Lumen-Apposing Metal Stent: Feasibility, Safety, and Efficacy. Obesity Surgery 2018 28:5 (1445-1451)
42. Sergio Bazaga Pérez de Rozas, Ana Yaiza Carbajo, Francisco Javier Garcia-Alonso, David Martí,Vicente Sánchiz Soler, Belén Martínez Moreno, José Ramón Aparicio Tormo, Rafael Pedraza Sanz, Juan Vila Costas, Enrique Vázquez-Sequeiros, Rosanna Villanueva Hernández, J. Alexander Jordán Castro, Marcos Jiménez Palacios, Carlos de la Serna Higuera y Manuel Perez-Miranda Castillo. Revista Española de enfermedades digestivas 2019:111(6):419-424 DOI: 10.17235/reed.2019.6147/2018
43. Mosquera-Klinger G, De-la-Serna-Higuera C, Pérez-Miranda M. Síndrome de sumidero secundario a colédoco-duodenostomía USE-guiada mediante prótesis de aposición luminal. Rev Esp Enferm Dig 2019;111(1):74-76.DOI: 10.17235/reed.2018.5815/2018

Documentos de búsqueda Cochrane:

Indicación 1:

44. SV Venkatachalapathy, A Makin, SP Pereira, GJ Johnson, N Bekkali, I Penman, KW Oppong, MK Naya, NR Carroll, EM Godfrey, BM Ryan, V Parihar, CJ McKay, MT Huggett. The first multicentre experience from the UK and ireland of the use of the hot axios system for transluminal drainage of pancreatic fluid collections. Gut. Conference: british society of gastroenterology annual general meeting 2016. United kingdom. Conference start: 20160620. Conference end: 20160623, VL: 65, PG: A44
45. Bang JY, Hasan M, Navaneethan U, Hawes R, Varadarajulu S. Randomized trial comparing the lumenapposing metal stents (LAMS) and plastic stents for EUS-guided drainage of walled-off necrosis (WON). United european gastroenterology journal 2017. VL: 5, NO: 5, PG: A248-

Indicación 3:

46. ClinicalTrials.gov Identifier: NCT03870386. Clinical Trial Comparing ERCP vs ERCP and Transmural Gall Bladder Drainage. Https://clinicaltrials.gov/show/nct03921502, 2019

Indicación 4:

47. CN-01824300.AU: JPRN-UMIN000013839. Feasibility and efficacy of novel EUS-guided gastrojejunostomy technique using a new double-balloon enteric tube and lumen-apposing metal stent. http://www.who.int/trialsearch/Trial2.aspx?TrialID=JPRN-UMIN000013839, 2014