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·专题报道·

全覆膜自膨式金属支架在胆、胰疾病中的应用

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[摘要] **目的** 探讨全覆膜自膨式金属支架(FCSEMS)在胆、胰疾病中的应用价值及其安全性和有效性。**方法** 回顾性分析 2008 年 1 月至 2012 年 6 月接受内镜逆行胆胰管造影(ERCP)置入 FCSEMS 治疗的 56 例胆、胰管疾病患者临床资料,根据病情选择不同长度及类型的 FCSEMS 置入。内镜下择期拔除支架,随访患者终点疗效、支架移除率及相关并发症情况。**结果** 使用 FCSEMS 治疗良性狭窄 49 例,包括肝移植术后吻合口狭窄 32 例、医源性胆管狭窄 12 例、慢性胰腺炎相关胰胆管狭窄 5 例;随访 5~38 个月[平均(15±8.6)个月],支架放置时间 1~15 个月[平均(8.4±5.3)个月],治疗有效率为 89.8%(44/49)。FCSEMS 治疗胆道并发症 7 例,包括内镜下乳头括约肌切开术(EST)术后难治性出血 4 例,EST 术后穿孔 1 例,肝移植术后胆漏 2 例;随访 1~12 个月[平均(5±3.7)个月],支架放置时间 1~8 个月[平均(1.8±0.5)个月],治疗有效率为 100%(7/7)。FCSEMS 回收过程均顺利。与支架相关的不良事件包括:早期并发症 5 例(8.9%),包括 ERCP 术后胰腺炎 2 例、早期胆管炎 2 例、胆囊炎 1 例;远期并发症 7 例(12.5%),包括支架滑脱 2 例、支架移位 3 例、支架相关性胆管炎 2 例。**结论** FCSEMS除了治疗传统意义上的胆、胰良性狭窄外,在处理胆道并发症方面也是潜在可替代手术的方法,且安全、有效。

[关键词] 内镜逆行胆胰管造影术;全覆膜自膨式可回收金属支架;胆道疾病;胰腺疾病
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Application of fully-covered self-expandable metallic stent for treatment of pancreatic-biliary diseases

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[**Abstract**] **Objective** To investigate the value, safety and efficacy of fully-covered self-expandable metallic stent (FCSEMS) in endoscopic retrograde cholangiopancreatography (ERCP) procedures for pancreatic-biliary diseases. **Methods** The clinical data of 56 patients with pancreatic-biliary diseases, who underwent FCSEMS treatment via ERCP from January 2008 to June 2012, were retrospectively analyzed. The stents of different lengths and types were chosen according to the condition of patients. The stents were removed under endoscope. The therapeutic effects at end point, stent removing rate and associated complications were observed. **Results** FCSEMS was placed in 49 patients with benign stricture, including post-liver transplant stricture (32), iatrogenic biliary stricture (12) and chronic pancreatitis-associated stricture (5). The mean follow time was (15±8.6) months (range 5-38 months), the mean stent duration was (8.4±5.3) months (1-15 months), and the effective rate was 89.8% (44/49). FCSEMS was placed in 7 patients with biliary complications, including bleeding after endoscopic sphincterotomy (EST) (4), perforation after EST (1), and bile leakage following liver transplantation (2). The mean follow time was (5±3.7) months (range 1-12 months), the mean stent duration was (1.8±0.5) months (1-8 months), and the effective rate was 100%. All FCSEMS were successfully retrieved. The short-term complication rate associated with stent was 8.9% (5/56), including post-ERCP pancreatitis (2), early cholangitis (2) and cholecystitis (1). The long-term complication rate was 12.5% (7/56), including stent slip (2), stent translocation (3) and stent-associated cholangitis (2). **Conclusion** FCSEMS can not only be used to treat traditional benign pancreatic-biliary strictures, but alto serve as a potential substitute for safe and effective treatment of serious biliary complications.

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[**Key words**] endoscopic retrograde cholangiopancreatography; fully-covered self-expandable metallic stents; biliary tract diseases; pancreatic diseases

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良性胆管狭窄在临床上并不罕见,处理十分棘手。传统的治疗方法是手术治疗,通常需切除狭窄段、胆道整形和(或)行胆肠短路吻合术,手术并发症发生率高达 25%左右,而且术后狭窄复发率亦较高,约为 10%～40%[1-2]。近年来,内镜技术已越来越多地应用于良性胆管狭窄的治疗。常规内镜治疗方法是放置多个大口径塑料支架,操作过程较为烦琐;而且由于支架腔较小,容易发生阻塞,难以维持到既定的支撑期,常需要重复操作和更换;此外,多根支架支撑部位的截面呈"花瓣状"而非"圆形",致使局部胆管不够光整,黏膜面易有损伤,这些不足均会影响内镜治疗的效果[3-5]。

全覆膜自膨式金属支架(fully-covered self-expanding metallic stent,FCSEMS)具有可有效定位于狭窄部位,进行持续的扩张支撑,完全扩张后直径可达 30Fr 大口径,通畅期长及可回收等优势,逐渐替代了多支架支撑引流。因其良好的支撑性能及可回收性,在慢性胰腺炎引起的胆、胰管难治性狭窄及胆道出血及胆漏方面也能发挥其效用。本研究就 FCSEMS 在胆、胰疾病中的应用情况进行回顾性分析,探讨 FCSEMS 治疗胆、胰疾病的安全性和有效性、临床应用范围及价值。

1 资料和方法

1.1 *研究对象* 2008 年 1 月至 2012 年 6 月我院行内镜逆行胆胰管造影(endoscopic retrograde cholangiopancreatography,ERCP)术中选择 FCSEMS 的所有患者,共 56 例,其中男 42 例、女 14 例,年龄 20～78 岁,平均(47.6±13.2)岁。

1.2 *支架类型* 共采用 3 种类型的 FCSEMS,其中 2 种为自行研制并获专利的全覆膜金属支架:带回收线全覆膜金属支架(专利号:ZL 2009 2 0039868.7;长度 4～7 cm,直径 8～10 mm),支架放置于胆管内,支架末端有金属线可收拢支架进行回收,部分改良为短倒锥形(长度 4 cm,直径 10 mm;图 1);全覆膜抗反流金属支架(专利号:ZL 2008 2 0031156.6),末端位于十二指肠乳头外,末端设计有半球形硅胶瓣膜以减少胆肠反流(长度 6 cm 或 8 cm,直径 10 mm)。另外,部分患者选用 Boston 公司生产的 WallFlex® 全覆膜金属支架(长度 6 cm 或 8 cm,直径 8～10 mm),末端有完整回收环。

1.3 *操作方法* 患者俯侧卧位,术中用丙泊酚[3～5 mg/(kg·min)]靶控输注静脉麻醉。采用 Olympus JF-240 或 JF-260V 型电子十二指肠镜,支架放置方式与普通胆道金属支架步骤相同,在胆管内留置导丝,在导丝引导及透视下缓慢释放金属支架,根据病情选择支架末端位于胆总管内或乳头外,末端放置于胆管内的金属支架下端的可回收线留在乳头外,便于支架拔除。根据治疗情况复诊,定期用圈套或鼠齿钳抓取金属线或回收环回收支架。所有患者术前均签署知情同意书,应用自行研制的 FCSEMS 均经医院伦理委员会批准。

1.4 *疗效评价及随访* 根据病情定期回收支架,术后通过电话、门诊随访,记录肝功能、影像学资料及相关并发症等情况。治疗有效定义为:临床症状好转,ERCP、磁共振胆胰管造影(magnetic resonance cholangiopancreatography,MRCP)提示胆、胰管良性狭窄好转或治愈,随诊 6 个月未出现胆管狭窄复发;胆道并发症情况得到有效控制,支架能顺利回收。治疗失败定义为:支架置入后出现明显并发症,支架拔除后狭窄无明显改善;并发症未能得到有效控制或转手术处理。

2 结 果

2.1 *疗效评价* 所有 56 例患者均成功放置 FCSEMS。FCSEMS 治疗良性狭窄共 49 例,包括 32 例肝移植术后吻合口狭窄、12 例腹腔镜胆囊切除(laparoscopic cholecystectomy,LC)术后或胆道探查术后医源性胆管损伤引起的狭窄(图 2)、4 例慢性胰腺炎引起的胰腺段胆管狭窄及 1 例慢性胰腺炎引起的难治性胰管狭窄(图 3)。良性狭窄患者平均随访(15±8.6)个月(5～38 个月),支架平均放置(8.4±5.3)个月(1～15 个月)后均顺利取出。其中 44 例患者狭窄有效缓解,包括 3 例狭窄未消除再次经 FCSEMS 治疗后狭窄解除者。5 例患者FCSEMS 治疗失败,包括:2 例出现早期胆管炎而提前拔除支架;1 例肝门部出现新的狭窄,1 例支架移位支撑无效,此 2 例拔除支架后再给予多根支架支撑引流;1

例胰腺炎胆管狭窄僵硬，治疗后狭窄未能有效解除。FCSEMS 治疗良性狭窄有效率为 89.8%(44/49)。详见表 1。

FCSEMS 治疗胆道并发症共 7 例，包括内镜下乳头括约肌切开术(EST)术后难治性出血 4 例(图 4)、EST 术后穿孔 1 例及肝移植术后胆漏 2 例(图 5)。支架平均放置(1.8±0.5)个月(1～8 个月)，平均随访(5±3.7)个月(1～12 个月)。5 例患者 FCSEMS 顺利取出；2 例患者因恶性肿瘤引起胆道并发症未行支架拔除，其中 1 例患者目前仍存活，支架在位通畅。胆道并发症治疗有效率为 100%。详见表 1。

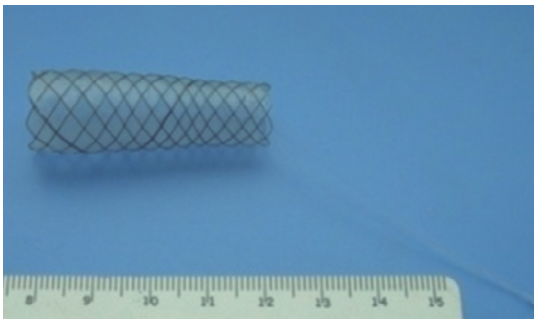

图 1　带回收线的 FCSEMS

Fig 1　Fully-covered self-expanding metallic stent (FCSEMS) with a retrieval suture

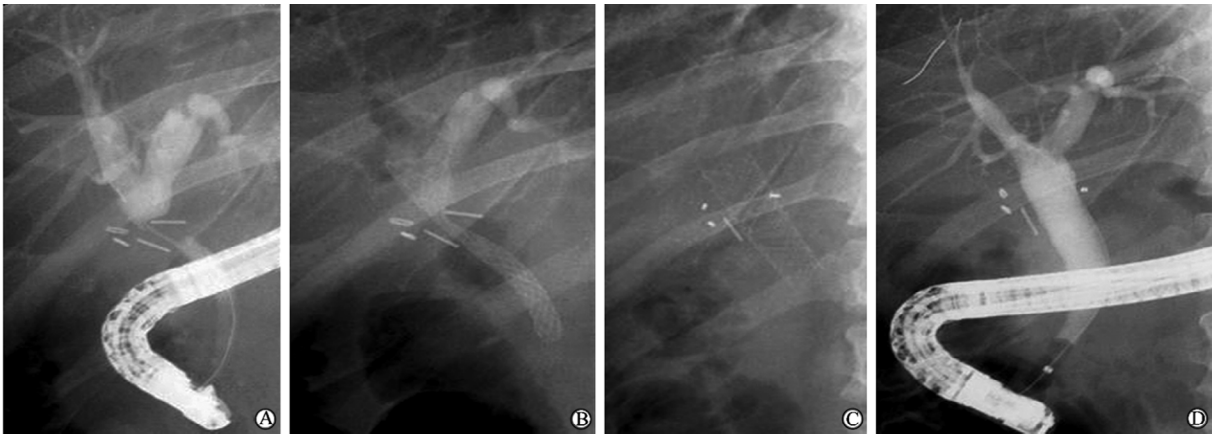

图 2　FCSEMS 治疗 LC 术后胆管狭窄

Fig 2　FCSEMS was used to treat post-LC biliary stricture

FCSEMS: Fully-covered self-expanding metallic stent; LC: Laparoscopic cholecystectomy. A: Inverted cone FCSEMS was placed in the bile duct; B: Post-LC hepatic bile duct stricture, FCSEMS (40 mm×10 mm) was deployed; C: Stent was at the initial position and expanded well after 6 months; D: The hepatic bile duct stricture disappeared after removing the stent

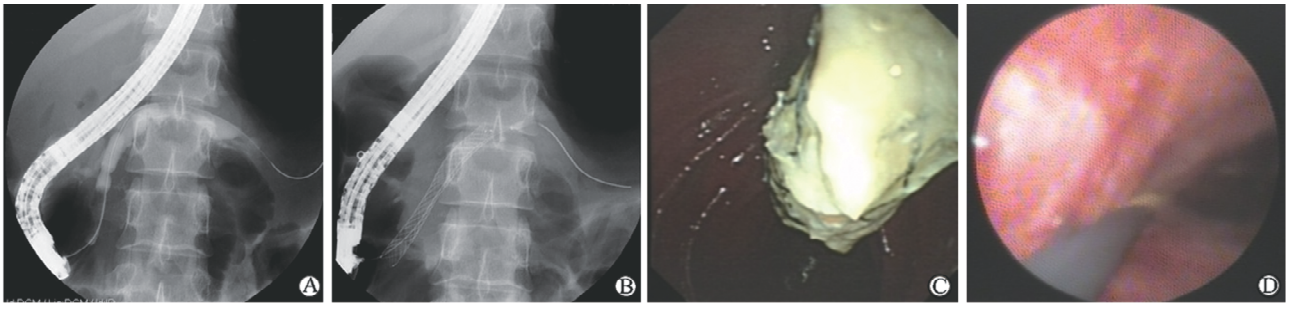

图 3　FCSEMS 治疗慢性胰腺炎引起的难治性胰管狭窄

Fig 3　FCSEMS was used to treat chronic pancreatitis-associated refractory pancreatic duct stricture

FCSEMS: Fully-covered self-expanding metallic stent. A: Expanded the stricture in the pancreas head with 6 mm dilation balloon; B: Deploying the FCSEMS (70 mm×10 mm); C: The stent covered by much protein bolt was retrieved after 5 months; D: 8.5Fr pancreaticoscope could easily pass the relieved stricture in the head of pancreas

2.2　FCSEMS 相关不良事件　FCSEMS 置入术后近期并发症发生率为 8.9%(5/56)，包括 2 例轻度 ERCP 术后胰腺炎(post-ERCP pancreatitis，PEP)、2 例早期胆管炎、1 例胆囊炎，均予对症处理好转。其中 2 例早期胆管炎患者考虑因支架放置位置过高，导致肝门胆管引流受阻，而提前拔除支架。远期

并发症发生率为 12.5%(7/56),包括 2 例支架置入期间出现支架相关性胆管炎,3 例支架出现移位及 2 例支架完全滑脱,均无严重临床后果。详见表 2。

表 1 FCSEMS 治疗良性狭窄及胆道并发症的疗效

Tab 1 Effectiveness of FCSEMS in treatment of benign stricture and biliary complications

Disease	N	Success	
		n	Rate(%)
Benign stricture	49	44	89.8
Post-liver transplant	32	29	90.6
Iatrogenic biliary stricture	12	11	91.7
Chronic pancreatitis	5	4	80.0
Biliary complication	7	7	100
Bleeding after EST	4	4	100
Perforation after EST	1	1	100
Bile leakage after OLT	2	2	100

FCSEMS: Fully-covered self-expanding metallic stents; EST: Endoscopic sphincterotomy; OLT: Orthotopic liver transplantation

3 讨 论

3.1 FCSEMS 治疗胆、胰良性狭窄 本研究采用 FCSEMS 治疗良性胆管狭窄共 49 例,其中 44 例患者狭窄得到有效缓解,FCSEMS 治疗良性狭窄有效率为 89.8%(44/49)。

医源性胆道狭窄及肝移植术后吻合口狭窄位置多位于肝总管,本研究中对于肝总管狭窄放置本院自行研制的带回收线 FCSEMS 处理,远端可回收金属线可收拢支架便于取出。设计为短支架,支撑力更加集中且支架位于胆管内无肠胆反流。Uchida 等[6]也证实支架置于完整的 Oddi 括约肌之上虽然不能完全防止阻塞,但可以延长支架开放时间,降低阻塞率。后经改良的倒锥形支架设计,减少了支架的滑脱移位。本组中因支架移位未有效解除狭窄者再行倒锥形支架支撑,仍能有效解除胆道狭窄。

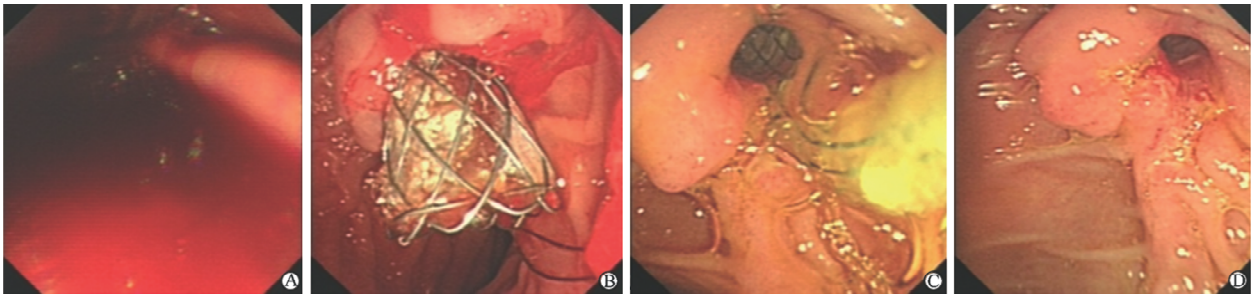

图 4 FCSEMS 治疗 EST 术后难治性出血

Fig 4 FCSEMS was used to treat post-EST refractory bleeding

FCSEMS: Fully-covered self-expanding metallic stent; EST: Endoscopic sphincterotomy. A: Active bleeding at papilla incision; B: The bleeding was controlled instantly after deploying FCSEMS through the papilla orifice; C: The stent was at the initial position after 1 month; D: No bleeding was found after removing stent

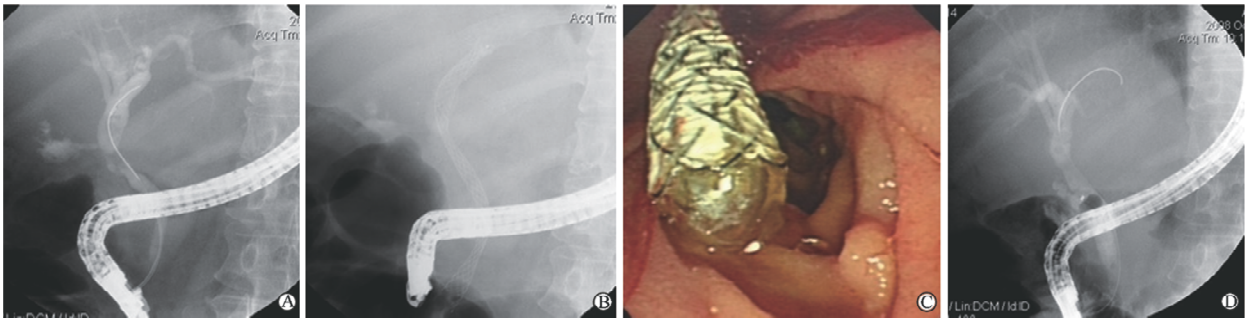

图 5 FCSEMS 治疗肝移植术后吻合口漏

Fig 5 FCSEMS was used to treat post-OLT anastomotic biliary leak

FCSEMS: Fully-covered self-expanding metallic stent; OLT: Orthotopic liver transplantation. A: Biliary stricture and donor bile duct dilation near the anastomotic stoma; B: Deploying the FCSEMS at left hepatic bile duct; C: Stent was at the initial position after 3 months; D: The biliary leak was cured and anastomosis stricture was relieved after removing the stent

表 2　放置 FCSEMS 近期及远期不良事件

Tab 2　Early- and long-term adverse events in patients implanted with FCSEMS

$N=56$

Adverse event	Occurrence	
	n	Rate(%)
Early complication	5	8.9
Post-ERCP pancreatitis	2	3.6
Cholecystitis	1	1.8
Early cholangitis	2	3.6
Long-term complication	7	12.5
Stent slip	2	3.6
Stent translocation	3	5.4
Cholangitis associated with stents	2	3.6

FCSEMS：Fully-covered self-expanding metallic stent；ERCP：Endoscopic retrograde cholangiopancreatography

慢性胰腺炎引起胆、胰管狭窄，普遍采用的方法为同时留置多根塑料支架，以达到充分扩张狭窄段的作用。但临床上慢性胰腺炎引起胆、胰管狭窄僵硬，塑料支架本身无膨胀力，常无法留置足够数量的支架，扩张及支撑效果不理想，而使用 FCSEMS 治疗慢性胰腺炎能取得较好效果，有效率达 58%～90%[7-8]。本组 5 例慢性胰腺炎患者，包括 4 例胆管狭窄及 1 例胰管狭窄，临时性放置 FCSEMS 后，支架均顺利拔除，4 例患者狭窄有效解除，解除率 80%；1 例患者病程较长，胰头部多发钙化，FCSEMS支撑后治疗效果不佳。因此，对于慢性胰腺炎引起的胆管狭窄，特别是早期患者用可回收 FCSEMS代替多根支架的置入进行有效支撑能取得较好效果。

胰管内置入 FCSEMS 目前仍存在争议，主要考虑一些不良事件的发生，包括支架的迁移，特别是支架内移位可能会损伤胰管或胰腺组织。本组 1 例 20 岁男性，外院反复胰管支架置入 6 次，胰头段胰管狭窄段极僵硬，我们用 Soehendra 支架取出器取出原支架并采用直径 6 mm 柱状球囊对狭窄段进行有效扩张，然后置入 FCSEMS，5 个月后回收，胰头段狭窄消失。随访 2 年胰管狭窄未复发，疗效满意(图 3)。Park-do 等[8]认为在难治性良性胰腺导管狭窄患者放置 2 个月的临时 FCSEMS 可能不会加重胰管异常引起相关的胰腺导管的变化，是可行的且比较安全，然而支架移位并不少见。因此，仍需要设计理想的胰管 FCSEMS 来治疗难治性胰腺导管良性狭窄，还需进一步的长期随访研究确定 FCSEMS 治疗难治性良性胰管狭窄的长期疗效、安全性及最佳的支撑时间。

良性胆、胰管狭窄使用 FCSEMS 与放置多个塑料支架相比，在技术上更容易。国外有报道两端不覆膜的半覆膜金属支架对良性狭窄的治疗仅放置 14 周，尽管时间短，但 91%术后引起的狭窄及 80%其他良性狭窄可以得到治愈，包括慢性胰腺炎相关的狭窄，但半覆膜金属支架因需早期拔除，治疗狭窄的标准化时间不够，特别是肝移植术后狭窄[9]。FCSEMS 避免了半覆膜金属支架两端组织增生造成支架取出困难的问题，但同时必须重视预防潜在的肝内胆管闭塞、胆囊炎和胰管流出道梗阻，FCSEMS只适合于狭窄位于肝门部至少 1.5 cm 以下的肝外胆管，胆囊在位应谨慎放置。

3.2　FCSEMS 在胆道并发症的应用

3.2.1　EST 术后难治性出血　采用 FCSEMS 治疗 EST 术后出血是一种新兴的方法，它借助金属支架的自然膨胀力对出血部位进行压迫，以达到止血的目的，全覆膜的金属支架在放置一段时间后，仍可完全回收，该方法主要适用于采用常规方法无法有效止血的病例，尤其是出血部位较为深在及出血量较大的患者。我们采用 FCSEMS 治疗 EST 术后难治性出血，4 例患者均成功止血，术后支架能顺利拔除或自行脱落，放置及拔除支架过程中均未发生并发症。已有 3 项研究报道了共 18 例采用覆膜金属支架进行止血，止血成功率均为 100%，支架放置时间为 5～56 d，放置期间共有 3 例发生支架移位，所有支架均成功拔除，拔除支架后未再次出现出血等并发症，随访期间(30～60 d)未出现相关并发症[10-12]。对于止血后支架留置的时间，目前还没有明确定论，时间过短可能出现再出血，时间过长则有发生支架移位、阻塞、拔除困难和造成继发损伤的风险。Shah 等[12]报道支架在 2～8 周内拔除，且无支架移位、再出血等并发症。由于治疗例数较少，还有待更多的临床验证。放置覆膜金属支架止血与外科手术及血管介入栓塞相比，具有创伤小、恢复快、操作简单等优势，并可直接观察止血效果，疗效较为确实，常规止血方法无效的难治性出血病例可考虑应用。

3.2.2　EST 术后腹膜后穿孔　EST 术及导丝损伤可能会引起腹膜后十二指肠穿孔，据报道有 0.3%～1.3%的发生率及相对高的死亡率(7%～

14%)[13-15]。ERCP 引起的十二指肠侧壁穿孔一般比较大,常因内镜操作不当引起,大多需要外科手术处理。对于腹膜后小穿孔,即使腹膜后有广泛的空气存在,多数情况下胆道支架置入、胃肠减压及抗炎、禁食等保守处理仍是可治愈的。国外有学者建议对于 EST 相关的十二指肠穿孔临时使用 FCSEMS支架,金属支架覆膜的保护作用使得胆汁完全进入十二指肠,而不是流入后腹膜间隙,比塑料胆管支架引流更加安全有效[16-17]。本研究中 1 例胆管结石患者,EST 取石后出现肾周游离气体,考虑后腹膜小穿孔,置入 FCSEMS 及鼻胆管引流,患者未出现明显腹痛、感染等临床症状,6 周后顺利拔除 FCSEMS,黄疸消退后出院。当然,此类患者如临床证据表明仍然存在胆汁泄漏至后腹膜,仍应考虑手术探查,以免延误病情。

3.2.3 肝移植术后胆漏 肝移植术后胆漏较为顽固,且往往漏口愈合后会出现胆管狭窄,需在胆漏完全愈合后再采用激进的狭窄扩张及多根支架长时间支撑治疗,一般遵循"先治胆漏,再治狭窄"的原则。循序地反复实施内镜处置才能取得满意的长期疗效,治疗周期长且花费高。国外有报道 16 例肝移植术后胆漏接受 FCSEMS 放置,12 例(75%)患者胆漏得到控制且并未出现胆管狭窄,放置中位时间为 101 d(56~273 d)[18],认为 FCSEMS 临时放置处理肝移植术后胆漏及预防漏口胆管狭窄有效。本组有 2 例肝移植术后吻合口胆漏患者,胆漏有效愈合后分别于 85 d 及 126 d 拔除 FCSEMS,均未出现胆管吻合口狭窄。提示 FCSEMS 在封闭漏口的同时可预防胆管狭窄,可能会更有效地减少后期繁复的内镜操作,缩短治疗周期。

国外也有学者将 FCSEMS 应用于难治性胰漏的处理[19]。另外,近年也有报道将 FCSEMS 应用于经胃穿刺引流胰腺假性囊肿,为避免 FCSEMS 可能的移位、滑脱,在金属支架腔内再放置 1 根双猪尾支架固定胃内及囊肿腔两端,认为相比于放置多根双猪尾支架引流,置入 FCSEMS 操作相对容易且更有效[20-21]。

综上,FCSEMS 因其定位明确、持续有效扩张、通畅时间长、可回收等特点,应用于胆、胰良性疾病及胆道并发症的治疗确有优势。FCSEMS 替代多支架引流能更有效支撑,避免多次繁杂的内镜处理,缩短治疗周期,从而提高内镜治疗效果。而临时性放置可回收 FCSEMS 在处理 EST 术后难治性出血、EST 术后穿孔、胆漏以及在胰漏、胰腺囊肿引流等方面应根据具体情况个体化处理,应用价值仍有待更多临床病例证实。

4 利益冲突

所有作者声明本文不涉及任何利益冲突。

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