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· 临床研究 ·

早期胰管支架置入治疗急性坏死性胰腺炎的疗效： 附57例报告

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摘要

背景与目的：急性坏死性胰腺炎（ANP）的病情复杂多变，病理进展迥异，继发感染时病死率可达20%~30%。目前对于ANP的治疗主要是早期给予禁食、补液、镇痛、抑酸、抑酶等对症治疗，后期形成并发症时，进行外科干预的阶梯治疗。而ANP后期局部并发症发生率和病死率较高，预后较差。相关研究表明，胰管高压和胰管梗阻在急性胰腺炎（AP）的发病过程中起着重要作用，AP合并胰液渗漏的概率可高达90%以上。因此，本研究探讨早期胰管支架置入治疗ANP的有效性和安全性。

方法：回顾性收集宁夏医科大学总医院2019年6月1日—2021年12月30日期间入院后48 h之内行胰管支架置入术治疗的ANP患者临床资料。

结果：按照纳入标准和排除标准，共纳入57例患者，其中中度重症34例，重症23例。所有患者入院到手术等待时间为8（3~21）h，均成功完成胰管支架置入。18例患者在手术中可见胰管蛋白栓，其中中度重症8例（23.53%）、重症10例（43.48%）。患者手术后腹痛、腹胀等症状均有不同程度的缓解；患者入院48 h后，白细胞、血淀粉酶、血脂肪酶、血糖水平及APACHE II评分均较入院时明显降低（均 $P<0.05$ ）。患者首次经口进食时间和住院时间的中位数分别为72（48~144）h和9（6~16.5）d。进一步分析显示，中度重症转入ICU患者数量、首次经口进食时间、住院时间、住院费用和CT严重程度指数方面均明显优于重症患者（均 $P<0.05$ ）。大部分患者入院时有严重的胰周渗出，胰管支架置入后，胰周渗出都有不同程度的吸收。无严重手术相关不良事件发生，后期形成感染性坏死8例、包裹性坏死7例，其中5例通过胰管支架引流后治愈，其余10例行经皮穿刺置管引流，未进行开腹清创等其他外科干预。

结论：早期胰管支架置入治疗ANP可以快速缓解患者的症状，降低局部并发症的发生率，减少后期反复的外科干预，是临床有效的治疗方法和策略。

关键词

胰腺炎，急性坏死性；支架；引流术；胰胆管造影术，内窥镜逆行

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Efficacy of early pancreatic duct stent placement in treatment of acute necrotizing pancreatitis: a report of 57 cases

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Abstract

Background and Aims: Acute necrotizing pancreatitis (ANP) is a complex and variable condition with diverse pathological progressions, and the mortality rate can reach 20% to 30% when secondary infections occur. Currently, the treatment for ANP mainly involves early symptomatic management, such as fasting, fluid infusion, pain relief, acid suppression, and enzyme inhibition, followed by a step-up approach involving surgical interventions when complications develop in the later stages. Late-stage local complications of ANP are associated with a high incidence complications and poor prognosis. Studies have suggested that pancreatic duct hypertension and obstruction play crucial roles in the pathogenesis of acute pancreatitis (AP), with a probability of pancreatic fluid leakage exceeding 90%. Therefore, this study investigated the efficacy and safety of early pancreatic duct stent placement in treating ANP.

Methods: Clinical data of ANP patients who underwent pancreatic duct stent placement within 48 h of admission at Ningxia Medical University General Hospital from June 1, 2019, to December 30, 2021, were retrospectively collected.

Results: According to the inclusion and exclusion criteria, 57 patients were included, including 34 with moderately severe disease and 23 with severe disease. The median time from admission to surgery for all patients was 8 (3-21) h, and all patients successfully underwent pancreatic duct stent placement. Pancreatic protein plugs were observed in 18 patients during surgery, including 8 cases (23.53%) with moderately severe disease and 10 cases (43.48%) with severe disease. Patients had varying degrees of relief from symptoms such as abdominal pain and bloating after surgery. On 48 h after admission, the white blood cell count, amylase, lipase, blood glucose levels, and APACHE II scores were significantly reduced compared to admission values (all $P < 0.05$). The median time to the first oral intake and length of hospital stay were 72 (48-144) h and 9 (6-16.5) d, respectively. The analysis further revealed that patients with moderately severe disease had significantly better outcomes in terms of ICU admission, time to first oral intake, hospital stay, hospital costs, and CT severity index compared to patients with severe disease (all $P < 0.05$). Most patients had significant peripancreatic fluid collections at admission, and after pancreatic duct stent placement, these collections showed varying degrees of absorption. No severe surgery-related adverse events occurred. Late-stage complications included infected necrosis in 8 cases and walled-off necrosis in 7 cases, of whom 5 cases were cured through pancreatic duct stent drainage, while the remaining 10 cases underwent percutaneous drainage without the need for open surgical debridement or other surgical interventions.

Conclusion: Early pancreatic duct stent placement in the treatment of ANP can rapidly alleviate symptoms, reduce the incidence of local complications, and decrease the need for subsequent surgical interventions. It is an effective clinical treatment strategy.

Key words

Pancreatitis, Acute Necrotizing; Stents; Drainage; Cholangiopancreatography, Endoscopic Retrograde

CLC number: R657.5

急性胰腺炎 (acute pancreatitis, AP) 是常见的消化系统急症之一,多数患者为轻症 AP,病程短,且有自限性,约 15% 的患者可能会出现胰腺与胰腺周围组织的坏死,急性坏死性胰腺炎 (acute necrotizing pancreatitis, ANP) 的病情复杂多变,病理进展迥异,继发感染时病死率可达 20%~30%^[1-2]。其病因大多为胆道结石、酒精、高脂血症引起。目前指南^[3]建议,ANP 患者入院时先以禁食、补液、抑酸、抑酶等保守治疗为主,当出现包裹性坏死或坏死继发感染时,行经皮穿刺置管引流 (percutaneous catheter drainage, PCD)^[4-6] 为主的外科升阶梯治疗模式。然而,ANP 的病情复杂多变^[7-8],患者在疾病早期,即出现全身炎症反应综合征 (systemic inflammatory response syndrome, SIRS),严重者甚至出现全身重要器官功能衰竭 (organ failure, OF),后期若胰腺周围渗出和坏死未及时吸收,可形成包裹性坏死、感染性坏死等并发症^[9]。在临床工作中发现,不论是胆源性、高脂血症性还是酒精性,胰管阻塞、胰管高压的患者病情更重,且当患者胰腺坏死累及胰管形成胰痿时,需要反复行 PCD。基于以上临床观察,本研究采用早期内镜逆行胰胆管造影 (endoscopic

retrograde cholangiopancreatography, ERCP) 胰管支架置入治疗 ANP 的患者,观察其临床疗效和安全性

1 资料与方法

1.1 一般资料

回顾性分析宁夏医科大学总医院 2019 年 6 月 1 日—2021 年 12 月 31 日期间收治的 ANP 患者的临床资料,收治时向患者家属告知治疗方式有胰管支架置入与保守治疗两种方式可供选择,经家属或患者同意后再行 ERCP 术。最后共纳入研究的数据有 57 例 ANP 患者,其中男性 36 例,女性 21 例;年龄 (46±18) 岁。57 例患者中,23 例为重症 AP,34 例为中度重症 AP,不同严重程度患者的一般资料见表 1。纳入标准:(1) 满足 2012 年修订版亚特兰大标准 ANP 诊断^[10];(2) 年龄为 18~80 岁。排除标准:(1) 妊娠及哺乳期妇女;(2) 慢性胰腺炎急性发作者;(3) 入院后 >48 h 行胰管支架置入;(4) 临床资料不完整者;(5) 发病距入院超过 72 h 者。本研究获得宁夏医科大学总医院医院伦理委员会批准 (批号:2019-467),患者均自愿参与本研究并签署知情同意书及 ERCP 术同意书。

表 1 不同严重程度患者的一般信息

Table 1 General information of patients with different degrees of severity

项目	中度重症(n=34)	重症(n=23)	χ^2/Z	P
性别[n(%)]				
男	20(58.82)	16(69.57)	0.68	0.409
女	14(41.18)	7(30.43)		
年龄[岁,M(IQR)]	44(33.75~58.00)	37(33.00~66.00)	-0.651	0.515
病因[n(%)]				
胆结石	19(55.9)	13(56.5)	0.091	0.955
高脂血症	14(41.2)	9(39.1)		
特发性	1(2.9)	1(4.4)		

1.2 治疗方法

患者入院后即给予禁饮食、补液、镇痛、抑酶、抑酸等治疗,对于高脂血症性胰腺炎患者,给予降脂治疗,若降血脂效果不佳,可行血浆置换治疗,出现并发症及器官功能衰竭时给予对应治疗。在保守治疗的基础上,患者于入院后 48 h 之内行胰管支架置入术,所有内镜操作均由操作经验 10 年以上的医师完成,手术医师应用十二指肠镜,通过口腔、胃,到达十二指肠,于十二指肠内侧寻找十二指肠大乳头,采用导丝引导法进

行胰管插管,抽吸胰液,若胰管内存在堵塞物,取出堵塞物,导丝引导法置入胰管支架,若术前或术中造影显示存在胆总管结石,可同期行内镜下胆总管结石取石术。结石过大或乳头水肿时,依据病情情况,决定是否行十二指肠乳头括约肌切开。胰腺炎治愈后 2 个月拔除胰管支架,或复查 CT 示胰周渗出吸收较差,胰管有堵塞可能时,则更换胰管支架。

1.3 观察指标

局部并发症发生率、外科干预情况、病死率、

新发器官功能衰竭发生率、转重症监护室治疗率、首次经口进食时间、住院时间等。对比患者入院时和入院48 h后的白细胞、血淀粉酶、血脂肪酶、血糖及APACHE II评分等。

1.4 进食指征与出院指征

进食指征：患者已经恢复排气、排便、腹痛、腹胀明显缓解，饮水后腹部症状无明显加重且淀粉酶降低，开始进流质饮食，同时检测淀粉酶变化，观察患者有无腹部不适。出院指征：患者恢复进食无需营养支持，无感染症状（发热、白细胞升高），无明显腹痛，淀粉酶恢复正常。

1.5 统计学处理

采用SPSS 25.0软件进行统计分析。正态分布的计量资料以均数 \pm 标准差($\bar{x} \pm s$)表示，组间比较采用独立样本 t 检验、配对样本 t 检验。非正态分布的计量资料以中位数(四分位间距)[$M(IQR)$]表示，组间比较采用符号秩和检验，计数资料以频数(%) [$n(\%)$]表示，组间比较采用 χ^2 检验。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 术中情况

所有患者入院到手术等待时间为8(3~21) h，均成功完成胰管支架置入。18例患者在术中发现胰管内白色黏稠物质(胰管蛋白栓)，其中中度重症8例(23.53%)，重症10例(43.48%)。十二指

肠乳头括约肌切开清理该物质后，可见清亮胰液流出。有3例患者在主胰管行胰管支架置入，副胰管置入鼻胰管加强引流。

2.2 术后情况

57例患者手术后腹痛、腹胀等症状均有不同程度的缓解；患者入院48 h后白细胞、血淀粉酶、血脂肪酶、血糖水平及APACHE II评分均较入院时明显降低(均 $P < 0.05$)(表2)。有23例患者发生器官衰竭，经治疗后，均好转，所有患者于入院72(48~44) h后进食，住院时间中位数为9(6~16.5) d，总住院费用中位数为4.5(3~8.0)万元。大部分患者入院时胰周渗出较多，胰管支架置入后，胰周渗出都有不同程度的吸收(图1)。有9例患者病情较重，转入重症监护室治疗，除3例患者病情较重，自动离院外，其余患者均治愈出院。比较中度重症与重症患者转入ICU患者数量、首次经口进食时间、住院时间、住院费用、CT严重程度指数(CTSI)评分，结果显示，前者上述指标均明显优于后者(均 $P < 0.05$)(表3)。

2.3 并发症与其他干预

5例患者术后血淀粉酶明显增高，其中3例为术中见明显的乳头水肿，可能与插管困难有关。除此之外并未见明显的手术相关并发症。后期形成感染性坏死8例、包裹性坏死7例，其中5例通过胰管支架引流后治愈，并未进行其他外科干预，其余10例行PCD引流，引流后胰周渗出均减少，未进行开腹清创等其他外科干预。

表2 患者相关临床指标的变化

Table 2 Changes in relevant clinical variable of patients

项目	入院时	入院48 h后	$t/\chi^2/Z$	P
白细胞($10^9/L, \bar{x} \pm s$)	16.07 \pm 5.96	10.72 \pm 3.72	6.987	<0.001
血清淀粉酶[U/L, $M(IQR)$]	746.70(449.20~1 413.85)	287.90(157.95~539.80)	-5.486	<0.001
血清脂肪酶[U/L, $M(IQR)$]	5 631.50(3 515.25~9 252.75)	1 365.00(596.00~2 995.25)	-4.689	<0.001
血糖[mmol/L, $M(IQR)$]	8.89(7.53~14.02)	8.03(6.61~11.21)	-3.973	<0.001
APACHE II评分[$M(IQR)$]	10.0(8.0~12.0)	5.0(3.5~7.0)	-6.274	<0.001

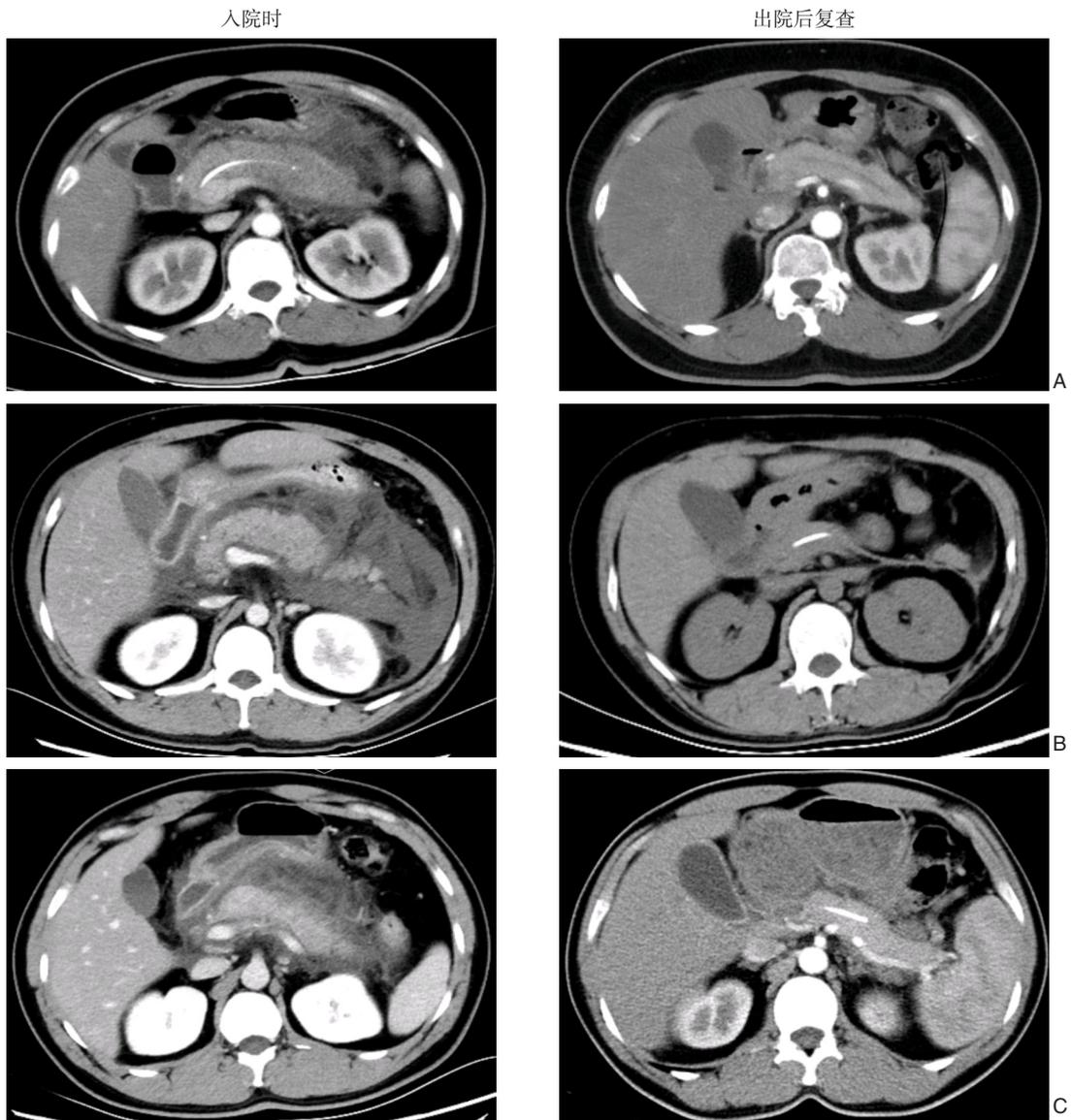


图1 部分患者CT图像 A: 42岁女性患者,发病24 h后入院,入院时CT显示胆囊结石伴胆囊炎,诊断为胆源性胰腺炎,胰腺尾部坏死合并胰管中断,胰周积液,胰管支架未通过坏死区,后期患者渗出伴感染,于入院后17 d行PCD治疗,术后7个月复查CT,显示胰周渗出已吸收,胰管支架已取出; B: 33岁女性患者,发病24 h入院,入院时甘油三酯为30.15 mmol/L,诊断为高脂血症性胰腺炎,腹部CT显示胰腺周围渗出较多,胰管支架置入,通过坏死区,后期因感染行PCD治疗,5个月后复查,CT显示胰腺周围渗出明显减少; C: 36岁男性患者,发病8 h后入院,入院时甘油三酯为12.59 mmol/L,诊断为高脂血症性胰腺炎,腹部CT示胰腺周围大量渗出,出院3个月后复查,CT显示胰周渗出仅存少量积液

Figure 1 CT images of some patients A: A 42-year-old female patient who was admitted 24 h after the onset of symptoms, CT at admission revealed gallstones with concomitant cholecystitis, leading to the diagnosis of biliary pancreatitis, necrosis in the tail of the pancreas with pancreatic duct disruption, peripancreatic fluid collection, and the pancreatic duct stent did not pass through the necrotic area, leakage with an infection in the later stage, PCD was performed after 17 d of hospitalization, and follow-up CT after 7 months showed absorption of the peripancreatic fluid collection, and the pancreatic duct stent had been removed; B: A 33-year-old female patient admitted 24 h after the onset of symptoms, triglycerides were measured at 30.15 mmol/L at admission, leading to the diagnosis of hyperlipidemic pancreatitis, abdominal CT revealed a significant peripancreatic fluid collection, a pancreatic duct stent was inserted, passing through the necrotic area, PCD was performed due to infection in the later stage, and follow-up CT showed a marked reduction in the peripancreatic fluid collection 5 months later; C: A 36-year-old male patient admitted 8 h after the onset of symptoms, triglycerides were measured at 12.59 mmol/L at admission, leading to the diagnosis of hyperlipidemic pancreatitis, abdominal CT revealed a substantial peripancreatic fluid collection, and follow-up CT showed only a small amount of residual peripancreatic fluid 3 months after discharge

表 3 不同严重程度患者治疗后相关指标比较

Table 3 Comparison of relevant variables in patients with different degrees of severity after treatment

项目	中度重症(n=34)	重症(n=23)	χ^2/Z	P
转入ICU [n(%)]	2(5.89)	7(30.43)	4.51	0.034
入院APACHE II评分	9(5.75~11)	11(9~16)	-3.003	0.003
首次经口进食时间[h, M(IQR)]	72(48~102)	144(72~192)	-2.854	0.004
住院时间[d, M(IQR)]	8.5(5~12)	16.0(9~18)	-3.051	0.002
住院费用[万元, M(IQR)]	4.0(3.1~4.8)	7.4(4.6~10.0)	-3.237	0.001
CTSI评分[n(%)]				
4~6	17(50.00)	2(8.70)	10.533	0.001
7~10	17(50.00)	21(91.30)		

3 讨论

AP是一种常见的急腹症,约15%发生胰腺实质或胰周组织的坏死^[1],早期阶段,胰腺炎症激活细胞因子级联反应,主要表现为SIRS,进而诱发OF,后期阶段,胰腺及胰周组织坏死继发感染导致脓毒症、出血、消化道瘘等并发症,是患者死亡的主要原因,现有指南治疗根据升阶梯(step-up)治疗策略^[3-6],早期先禁食、胃肠道功能减压,抑酸及抑制胰酶等,出现感染时,合理应用抗生素,针对高脂血症进行降脂、血浆置换等对症治疗,早期积极液体复苏纠正休克及组织低灌注。病程后期,部分患者病情较重,出现包裹性坏死或坏死继发感染,行PCD引流,若病情进一步进展,行开腹清创治疗等。然而,ANP患者病情复杂多变^[8-9],保守治疗下,患者坏死、渗出吸收缓慢,后期局部并发症发生率较高,且合并胰管断裂时,持续性的胰瘘增加了感染的风险。

Harvey等^[11]在实验中通过模拟胆汁反流、酒精、胰管梗阻等病因,模拟AP的发生,结果表明,3种动物模型均出现AP,且胰管内压力增高明显,胰管对大分子物质通透性增加,Arendt等^[12]也验证了此结论。在高三酰甘油血症性胰腺炎(hypertriglyceridemic pancreatitis, HTGP)中的发病机制并不明确,有学者^[13-14]认为,在HTGP患者中,过高的游离脂肪酸,不仅可以直接损伤胰腺腺泡细胞和血管内皮细胞,还可诱发酸中毒,加速胰蛋白酶原的激活,导致腺泡细胞的自身消化。然而,笔者在临床中发现^[15],在部分HTGP患者中,胰管内存在白色絮状物质(称为胰管蛋白栓),有胰管蛋白栓的患者,症状更重,坏死程度更高。在本研究中,18例患者存在胰管蛋白栓

(16例为高脂血症性,1例为胆源性,1例为特发性),ERCP术取出蛋白栓后,胰液引流通畅,患者症状明显好转。因此,不论是胆源性、高脂血症性,还是酒精性,胰管梗阻和高压导致胰液引流不畅,在AP的发病中起着重要作用。既往研究^[16]中,AP合并胰液渗漏的概率可高达90%以上,在这些患者中,少部分是主胰管的破损,大部分患者存在分支胰管的破损,因此对于ANP患者,我们认为尽早胰管支架置入可缓解胰管压力的同时,也可减少胰液渗漏,从而减少患者局部并发症的发生。近期本项目团队^[17]研究显示,胰管支架治疗重症AP可明显改善患者症状,在这项研究中,胰管支架组中合并胰腺坏死的患者占比是对照组的2倍,但是两组的后期并发症发生率相当,全身并发症发生率明显降低。

基于以上理论,本研究在保守治疗的基础上同时行胰管支架置入,目的是降低胰管压力,通畅胰液引流,减弱胰酶对底物的自身消化作用,进而使患者腹痛症状减轻,对于主胰管破裂的患者也可起到桥接作用。本研究所有患者从入院到手术等待时间为8(3~21)h,首次经口进食时间为72(48~144)h,住院时间为9(6~16.5)d,与同期其他保守治疗^[18-19]相比,住院时间和首次经口进食时间明显缩短。相比于单一的保守治疗,早期放置胰管支架置入有以下优点,可维持胰管支架的完整性,减少局部并发症的发生。本研究中,大部分患者入院时胰周有大量渗出,最后有8例患者出现感染性坏死,7例患者出现包裹性坏死,5例患者只通过胰管支架引流后治愈,并未进行其他外科干预,其余10例患者进行了PCD,通过胰管支架内引流联合穿刺外引流,患者胰周渗出逐渐吸收,所有患者未进行开腹手术治疗,有效降低

了局部并发症的发生与后期反复穿刺引流等外科干预。

ERCP术相关并发症为出血、穿孔、感染及ERCP术后胰腺炎等相关并发症^[20-23],本研究中有3例患者自动离院,其中2例患者入院时就有严重的多器官衰竭,并伴有脓毒症,1例伴有腹腔间隔室综合征,患者全身并发症严重,最终家属决定自动离院。5例患者术后血淀粉酶明显增高,其中3例为术中见明显的乳头水肿,可能与插管困难有关。除此之外并未见明显的手术相关并发症。相反, Karjula等^[24]为ANP患者行胰管支架置入,从症状发作到内镜下支架置入的时间为4.6(2~9)d,所有成功放置支架的患者均发生了感染。ERCP相关并发症,与内镜医师的经验密不可分^[25],本单位内镜操作均由操作经验10年以上的医师完成,每年完成ERCP术的例数>900例,本研究中未见严重的ERCP手术相关并发症。总之,ERCP作为一种侵入性且难度高的操作,发展和普及仍受限,预防ERCP术相关并发症的发生,还需要大量的临床医生培训和研究来避免和改进。有研究^[26-30]表明,放置胰管支架可以逆转炎症过程和ERCP术后胰腺炎的发生。在本研究中,由于所有患者在入院48h内行胰管支架置入,因此,比较了入院时和入院48h后的白细胞,血淀粉酶,血脂肪酶,血糖,APACHE II评分,结果显示,患者置入胰管支架后,这些指标明显下降,提示胰管支架置入可有效控制ANP的炎症反应。

综上所述,早期胰管支架置入治疗ANP,可以降低患者住院时间和首次经口进食时间,降低局部并发症的发生率,减少后期外科干预,有效控制ANP的炎症反应。因此,早期胰管支架置入是一种有效的治疗方式,能有效改善患者的病情。本研究属于单中心回顾性研究,样本量少且缺乏对照,因此有一定的局限性,需后期多中心对照试验进一步验证。

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