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· 临床研究 ·

术后第1天引流液中淀粉酶含量在预测胰瘘中的价值

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摘要

目的: 探讨术后第1天引流液中淀粉酶含量(DFA1)在预测胰瘘(PF)中的价值。

方法: 收集泰山医学院附属医院及肥城矿业中心医院自2011年2月—2016年2月行胰腺切除的患者资料, 选择其中有DFA1资料的患者, 用受试者工作特征(ROC)曲线分析DFA1预测PF的敏感性、特异性、阳性预测值(PPV)及阴性预测值(NPV), 并分析PF的危险因素。

结果: 共125例行胰腺切除术患者中67例(55例胰十二指肠切除术和12例胰体尾切除术)有DFA1资料。此67例中发生PF 15例(22.39%), 其中A级7例(10.45%), B级6例(8.96%), C级2例(2.99%)。ROC曲线分析发现DFA1对PF有明显的预测作用($P < 0.05$), 当截点值为342 U/L时, 其敏感性、特异性、PPV、NPV分别为100%、80.8%、60.0%、100.0%。单因素分析显示, DFA1、胰管直径 ≤ 3 mm及胰腺质地软为PF的危险因素(均 $P < 0.05$), Logistic回归分析表明, DFA1为PF的独立危险因素($P < 0.05$)。
结论: DFA1为PF的独立因素, 对PF具有较好的预测价值, 当患者DFA1 > 340 U/L时应积极预防PF的发生。

关键词

胰腺切除术; 淀粉酶类; 胰瘘
中图分类号: R657.5

Value of drain fluid amylase level obtained on the first postoperative day in prediction of pancreatic fistula

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Abstract

Objective: To investigate the value of drain fluid amylase level obtained on the first postoperative day (DFA1) in predicting pancreatic fistula (PF).

Methods: The clinical data of all patients undergoing pancreatic resection from February 2011 to February 2016 in the Affiliated Hospital of Taishan Medical College and Feicheng Kuangye Central Hospital were reviewed, and those with DFA1 data were selected. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of DFA1 for predicting PF were analyzed by receiver operating characteristic (ROC) curve, and the risk factors for PF were also determined.

Results: A total of 125 patients underwent pancreatic resection and 67 cases (55 cases undergoing pancreaticoduodenectomy and 12 cases undergoing distal pancreatectomy) of them had DFA1 data. Of the 67

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patients, PF occurred in 15 cases, which was classified as grade A in 7 cases (10.45%), grade B in 6 cases (8.96%) as and grade C in 2 cases (2.99%). ROC curve analysis showed that DFA1 had significant predictability on PF ($P < 0.05$), and the sensitivity, specificity, PPV and NPV were 100%, 80.8%, 60.0% and 100.0% respectively at the cutoff value of 340 U/L. Univariate analysis indicated that DFA1, pancreatic duct diameter ≤ 3 mm and soft pancreatic texture were risk factors for PF (all $P < 0.05$), and the Logistic regression analysis identified that DFA1 was an independent risk factor for PF ($P < 0.05$).

Conclusion: DFA1 is an independent risk factor for PF and has better value in predicting PF. Aggressive preventive measures should be made against PF in patients with DFA1 > 340 U/L.

Key words Pancreatectomy; Amylases; Pancreatic Fistula

CLC number: R657.5

胰瘘 (pancreatic fistula, PF) 是胰腺切除术后最为主要的并发症之一, 也是导致胰腺切除术后患者死亡的重要原因。诸多研究致力于通过改善手术方式及围手术期处理等多种方法降低PF发生率, 但其发生率仍达10%~40%^[1-3]。目前研究^[4-6]表明, PF发生风险较低的患者早期拔除引流管可明显减少逆行感染及其他腹腔内并发症的发生。因此, 术后早期通过评估PF危险因素预测其发生概率对于指导患者治疗、促进患者恢复具有重要意义。术后引流液中淀粉酶含量是预测及诊断PF的直接证据, 研究^[7-9]表明术后第1天引流液中淀粉酶含量 (drain fluid amylase obtained on postoperative day 1, DFA1) 可作为预测PF发生的重要指标, 但具体的标准仍有争议。

本研究回顾性分析我院67例胰腺切除术后检测DFA1的患者资料, 并经受试者工作特征 (receiver operating characteristic, ROC) 曲线分析不同截点DFA1值预测PF的敏感性、特异性、阳性预测值 (positive predictive value, PPV) 及阴性预测值 (negative predictive value, NPV), 确定预测PF最为有效的DFA1值。同时, 也对PF发生的危险因素进行了分析。

1 资料与方法

1.1 临床资料

收集泰山医学院附属医院及肥城矿业中心医院2011年2月—2016年2月125例行胰腺切除的患者资料进行回顾性分析, 选择其中检测DFA1的67例患者。经ROC曲线分析DFA1、术后第2天引流液中淀粉酶含量 (DFA2) 及术后第3天引流液中淀

粉酶含量 (DFA3) 在预测PF中的价值及不同截点的DFA1、DFA2及DFA3值预测PF的敏感性、特异性、PPV及NPV。经单因素和多因素Logistic回归分析PF的危险因素。

1.2 围手术期处理

手术由工作15年以上的肝胆胰外科医生完成, 患者行胰十二指肠切除术或胰体尾切除术。胰十二指肠切除术患者胰肠吻合方式采用胰管-黏膜吻合或套入式吻合, 对于胰管直径较小及胰腺质地较软的患者放置胰管外引流管, 胰肠吻合口及胆肠吻合口旁放置引流管; 胰体尾切除的患者横断胰腺后所有胰管断端均予结扎, 胰腺断端放置引流管。

术后每天监测引流量及引流液中淀粉酶含量。无腹胀、恶心及呕吐的患者一般术后第3天开始进流质饮食。引流管中液体 < 20 mL/d且无胰周积液、脓肿、感染及PF表现的患者可拔除引流管; 存在PF的患者要保持通畅引流。

1.3 PF定义及分级

PF的诊断及分级均按照国际胰瘘研究组织 (International Study Group on Pancreatic Fistula, ISGPF) 标准^[10]: 术后第3天开始引流液中淀粉酶含量超过正常血淀粉酶含量的3倍以上。根据胰瘘严重程度及所采取治疗措施的不同, 将胰瘘分为A、B、C级。A级胰瘘患者一般状况良好, 超声或CT检查常无阳性发现, 无继发感染等合并症, 一般不需要特殊治疗。B级胰瘘患者常会出现发热、腹痛等临床症状, 需要口服抗生素、应用生长抑素类似物及营养支持等治疗; 超声或CT检查可能会发现胰周积液, 但可通过调整引流管位置缓解, 不需要有创治疗; 患者住院时间延

长,可能需要再次住院治疗。C级胰痿患者一般状态差,超声或CT检查可见明显的胰周积液,需要引流管持续引流,常会出现感染、脓毒血症、器官功能障碍等继发表现,重症患者会导致死亡;患者需要给予完全肠内或肠外营养,静脉应用抗生素及生长抑素类似物,可能需要再次手术修补漏口、重新进行胰肠吻合或完全胰腺切除;患者住院时间明显延长,再次住院率高。

1.4 统计学处理

采用SPSS 19.0进行统计分析。计量资料采用均数±标准差($\bar{x} \pm s$)表示,计数资料采用百分比(%)表示;计量资料的比较采用Student t检验,计数资料的比较采用 χ^2 检验。多因素分析采用Logistic回归分析。 $P < 0.05$ 为差异具有统计学意义。

2 结果

2.1 患者基本情况及DFA1分析

67例患者包括55例行胰十二指肠切除术患者和12例行胰体尾切除术患者,其中男36例,女31例;年龄45~76岁,平均(60.82 ± 7.12)岁。所有患者手术时间(361.15 ± 76.46)min,术中出血量(329.55 ± 190.60)mL,术后死亡1例(1.49%),发生并发症患者28例(41.79%)。发生PF患者15例(22.39%),其中A级PF 7例(10.45%),B级PF 6例(8.96%),C级PF 2例(2.99%)。术后7例A级PF患者未采取特殊治疗措施;6例B级PF患者通过给予抗感染、应用生长抑素类似物或肠内/外营养支持后好转;2例C级PF患者中1例经再次手术重新行胰肠吻合后好转,另1例患者因继发重症感染及多器官脏器衰竭死亡。患者住院时间(25.64 ± 4.43)d(表1)。

经ROC曲线分析DFA1与PF发生密切相关($P < 0.01$),曲线下面积为0.94(95%CI=0.88~0.99)(图1)。经分析不同截点DFA1值发现,DFA1为342 U/L时具有较好的敏感性(100.0%)、特异性(80.8%)、PPV(60.0%)及NPV(100.0%)(表2)。此外,分析发现DFA2及DFA3与PF发生也有明显关系(均 $P < 0.01$),发现DFA2为282 U/L具有较好的敏感性(100%)、特异性(80.8%)、PPV(60.0%)及NPV(100.0%)(表3);DFA3为210 U/L具有较好的敏感性(93.3%)、特异性(94.2%)、PPV(82.4%)及NPV(98.0%)(表4)。

表1 67例患者临床资料

Table 1 Clinical data of the 67 patients

项目	数据
年龄(岁, $\bar{x} \pm s$)	60.82 ± 7.12
性别[n(%)]	
男	36 (53.7)
女	31 (42.3)
ASA分级[n(%)]	
II	59 (88.1)
III	8 (11.9)
谷丙转氨酶(U/L, $\bar{x} \pm s$)	221.99 ± 224.66
谷草转氨酶(U/L, $\bar{x} \pm s$)	153.23 ± 157.80
总胆红素(μmol/L, $\bar{x} \pm s$)	395.59 ± 74.75
总白蛋白(g/L, $\bar{x} \pm s$)	64.08 ± 6.87
合并症[n(%)]	24 (35.8)
糖尿病	5 (7.5)
肺部疾病	5 (7.5)
高血压	18 (26.8)
术前引流[n(%)]	34 (50.7)
手术时间(min, $\bar{x} \pm s$)	361.15 ± 76.46
术中出血量(mL, $\bar{x} \pm s$)	329.55 ± 190.60
死亡[n(%)]	1 (1.49)
并发症[n(%)]	28 (41.79)
住院时间(d, $\bar{x} \pm s$)	25.64 ± 4.43

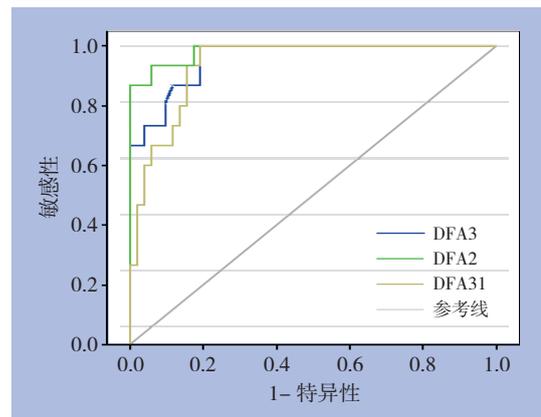


图1 DFA1预测PF的ROC曲线

Figure 1 ROC curve of DFA1 for predicting PF

表2 不同截点DFA1值分析

Table 2 Analysis of DFA1 of different cut-off values

DFA1值(U/L)	敏感性(%)	特异性(%)	PPV(%)	NPV(%)
217	100.0	71.2	50.0	100.0
233	100.0	73.1	51.7	100.0
236	100.0	75.0	53.6	100.0
307	100.0	76.9	55.6	100.0
328	100.0	78.8	57.7	100.0
342	100.0	80.8	60.0	100.0
422	93.3	80.8	58.3	97.7
431	93.3	82.7	60.9	97.7
477	93.3	84.6	63.6	97.8
480	86.7	84.6	61.9	95.7
485	80.0	84.6	60.0	93.6
534	80.0	86.5	63.2	93.7
561	73.3	86.5	61.1	91.8

表 3 不同截点 DFA2 值分析

Table 3 Analysis of DFA2 of different cut-off values

DFA2 值 (U/L)	敏感性 (%)	特异性 (%)	PPV (%)	NPV (%)
197	100.0	73.1	51.7	100.0
209	100.0	75.0	53.6	100.0
216	100.0	76.9	55.6	100.0
223	100.0	78.9	57.7	100.0
282	100.0	80.8	60.0	100.0
322	93.3	80.8	58.3	97.7
380	86.7	80.8	56.5	95.5
396	86.7	82.7	59.1	95.6
397	86.7	84.6	61.9	95.7
409	86.7	86.5	65.0	95.7
457	86.7	88.5	68.4	95.8
489	80.0	90.4	70.6	94.0
521	73.3	92.3	68.7	92.2
532	73.3	94.2	73.3	92.3

表 4 不同截点 DFA3 值分析

Table 4 Analysis of DFA3 of different cut-off values

DFA3 值 (U/L)	敏感性 (%)	特异性 (%)	PPV (%)	NPV (%)
199	93.3	82.7	60.9	97.7
202	93.3	84.6	63.6	97.8
204	93.3	86.5	66.7	97.8
207	93.3	90.4	73.7	97.9
209	93.3	92.3	77.8	98.0
210	93.3	94.2	82.4	98.0
249	86.7	96.2	81.2	96.1
254	86.7	98.1	86.7	96.2
255	86.7	100.0	92.9	96.2
288	86.7	100.0	100.0	96.3
397	80.0	100.0	100.0	94.5
487	73.3	100.0	100.0	92.9
598	66.7	100.0	100.0	91.2

2.2 PF 危险因素分析

PF 患者 DFA1 值 422.00~12872.00 U/L, 平均 (2448.33 ± 3504.88) U/L 明显高于非 PF 患者 DFA1 值, 后者为 19.00~1515.00 U/L, 平均 (242.67 ± 298.20) U/L, 差异有统计学意义 ($P < 0.01$) (表 5)。经单因素分析胰 PF 组及非 PF 组患者一般资料、术前检查、合并症、手术因素、胰腺因素及 DFA1 发现胰管直径 ≤ 3 mm、胰腺质地软及 DFA1 为 PF 的危险因素 (均 $P < 0.05$), 将此 3 种因素进一步经 Logistic 回归进行多因素分析, 结果显示, DFA1 为 PF 的独立危险因素 ($P < 0.05$)。

表 5 PF 危险因素的单因素分析

Table 5 Univariate analysis of the risk factors for PF

因素	非 PF 组 (n=52)	PF 组 (n=15)	P
年龄 (岁, $\bar{x} \pm s$)	61.37 ± 7.28	58.93 ± 6.40	0.25
性别 [n (%)]			
男	28 (53.8)	8 (53.3)	0.97
女	24 (46.2)	7 (46.7)	
主要症状 [n (%)]			
黄疸	33 (63.5)	8 (53.3)	0.23
腹痛	17 (32.7)	5 (33.3)	1.00
ASA 分级 [n (%)]			
II	47 (90.4)	12 (80.0)	0.52
III	5 (9.6)	3 (20.0)	
谷丙转氨酶 (U/L, $\bar{x} \pm s$)	210.98 ± 189.54	260.13 ± 324.13	0.46
谷草转氨酶 (U/L, $\bar{x} \pm s$)	145.96 ± 120.63	178.47 ± 251.99	0.49
术前总胆红素 (μmol/L, $\bar{x} \pm s$)	395.48 ± 76.88	395.99 ± 69.33	0.98
术前白蛋白 (g/L, $\bar{x} \pm s$)	63.51 ± 6.86	66.04 ± 6.76	0.21
合并症 [n (%)]			
糖尿病 [n (%)]	4 (7.7)	1 (6.7)	1.00
肺部疾病 [n (%)]	4 (7.7)	1 (6.7)	1.00
高血压 [n (%)]	12 (23.1)	6 (40.0)	0.33
术前引流 [n (%)]			
是	25 (48.1)	9 (60.0)	0.42
否	27 (51.9)	6 (40.0)	
吸烟 [n (%)]	12 (23.1)	6 (40.0)	0.33
手术因素			
血管切除 [n (%)]	1 (1.9)	0 (0)	1.00
手术时间 (min, $\bar{x} \pm s$)	354.27 ± 75.66	385.00 ± 76.97	0.17
术中出血 (mL, $\bar{x} \pm s$)	307.69 ± 151.38	405.33 ± 282.59	0.08
输血例数 [n (%)]	16 (30.8)	3 (20.0)	0.62
胰腺因素			
胰管直径 (mm, $\bar{x} \pm s$)			
≤ 3	20 (38.5)	13 (86.7)	<0.01
> 3	32 (61.5)	2 (13.3)	
胰腺质地 [n (%)]			
软	24 (46.2)	13 (86.7)	<0.01
硬	28 (53.8)	2 (13.3)	

3 讨论

3.1 PF 是胰腺切除术后重要的并发症

PF 是胰腺切除术后的重要并发症之一, 可明显增加患者术后应用抗生素、生长抑素类似物、肠内/外营养甚至再次手术的可能性, 并且 PF 会导致其他合并症, C 级胰痿患者并发重症感染及多器官功能障碍的可能性很高, 病死率高达 38.8%^[11-14]。以往研究致力于探索 PF 危险因素及降低 PF 发生率的措

施,目前胰管直径 ≤ 3 mm及胰腺质地软作为PF的危险因素已经得到了较为广泛的认可^[15-17];尽管有研究^[18-19]认为通过改变手术方式,如胰胃吻合、胰管结扎等,或通过术后应用生长抑素类似物等方式可降低PF发生率,但这些措施未能得到广泛认可,临床应用也较为局限。目前,不同医学中心报道PF发生率仍达10%~40%^[1,20]。

根据快速康复外科理念,术后早期拔除引流管是减少术后并发症、改善患者预后的重要措施^[21]。Kawai等^[6]报道术后第4天拔除引流管是降低术后感染等并发症独立因素,长期放置引流管可明显增加术后感染及PF的发生。因此,术后早期评估术后PF发生的危险因素,预测PF发生概率,PF风险较低的患者早期拔除引流管对患者术后恢复具有重要意义。

3.2 当前 DFA1 在评估 PF 中的研究进展

术后引流液中淀粉酶含量受到多种因素的影响,主要包括胰腺断面胰液渗透及吻合口胰液漏出。按照ISGPF标准^[10]将DAF3超过正常血淀粉酶含量3倍作为PF诊断标准,但目前多个研究^[8,22-26]表明,术后第1天引流液中淀粉酶含量可作为预测PF的重要指标,并可用于指导引流管拔除等术后治疗。Molinari等^[24]报道术后DFA1 $>5\ 000$ U/L是预测PF的唯一指标,具有较好的敏感性(92.6%)及NPV(98%)。也有报道^[8]认为DFA1 $<1\ 200$ U/L的患者DAF3可出现明显下降,此类患者可早期拔除引流管。Lee等^[22]认为DFA1 <190 U/L的患者可早期拔除引流管。此外,也有将350 U/L或100 U/L作为DFA1预测PF发生概率的报道^[7,9]。由此可见,当前应用DFA1作为预测PF指标的具体标准尚存在较大争议。

3.3 本研究主要结果探讨

本研究收集了67例具有DFA1值的胰腺切除患者资料,经ROC曲线分析DFA1与PF发生密切相关($P<0.05$);PF患者DFA1明显高于非PF患者 $[(2\ 448.33 \pm 3\ 504.88)$ U/L *vs.* (242.67 ± 298.20) U/L, $P<0.01$]。分析DFA1不同截点的特异性、敏感性、PPV及NPV发现DFA1为340 U/L时具有较好的敏感性(100%)及NPV(100%)。因此,笔者认为对于DFA1 <340 U/L的患者可术后早期进食、早期拔除引流管,以减少感染性并发症发生,缩短患者住院时间。经单因素分析发现

DFA1、胰管直径 ≤ 3 mm及胰腺质地软为PF的危险因素($P<0.05$)。此结果与前期报道^[27-28]相同。将此3种因素进一步经Logistic回归进行多因素分析发现DFA1为PF的独立危险因素($P<0.05$)。这进一步说明了DFA1在预测PF中的价值。但本研究为回顾性分析,且病例数较少,研究结果尚待多中心的大样本随机对照研究进一步验证。本研究中还检测了DFA2和DFA3预测PF的截点值,但DFA1较DFA2和DFA3可术后更早的评估患者PF风险,对于风险较低的患者可早起行肠内营养及拔除引流管,对于风险较高的患者可预防性应用生长抑素,保持通畅引流等。

综上所述,经单因素及多因素分析发现DFA1是PF的独立危险因素,经ROC曲线分析不同DFA1截点的敏感性、特异性、PPV及NPV发现DFA1为340 U/L可作为预测PF的良好指标。DFA1 <340 U/L的患者发生PF的风险较低,此类患者术后可早期拔除引流管,否则应积极预防PF的发生。

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