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导管引导介入治疗急性中高危肺动脉栓塞临床研究*

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摘要 目的:评估导管引导介入治疗急性中高危肺动脉栓塞的有效性及安全性。**方法:**回顾性分析 2012 年 1 月至 2018 年 6 月在柳州市工人医院血管外科诊治的 112 例急性中高危肺动脉栓塞患者资料。根据治疗方案分单纯抗凝组(共 38 例)、导管介入+抗凝治疗组(共 74 例),对比两组肺动脉压及肺动脉栓塞严重指数降低情况、肺栓塞症状改善率、住院时长和出血并发症发生率;以其随访中肺栓塞复发率和慢性血栓性肺动脉高压发生率。根据介入方案不同,介入治疗组包括 AngioJet 机械吸栓(共 13 例)、猪尾导管碎栓及溶栓(61 例);分别对比两种介入方案术前及术后的动脉血氧分压、指脉氧、心率及肺动脉压、米勒指数评估治疗效果。**结果:**两组术前人口学特征、发病时间、DVT 并发率、肺动脉压、肺动脉栓塞严重指数等无明显差异($P > 0.05$)。介入治疗组在降低肺动脉压及肺动脉严重指数、症状的改善率、缩短住院时间上明显优于单纯抗凝组(P 分别为 0.000、0.001、0.01、0.003);而相关出血并发症发生率无统计学差异($P > 0.05$)。通过分别对比介入治疗两种方案的术前及术后动脉血氧分压、指脉氧、心率及肺动脉压、米勒指数,两种治疗方案在这五个指标均有明显改善(P 值均 < 0.05)。随访 6 月至 7 年,肺栓复发率在单纯抗凝组、导管介入+抗凝治疗组分别为 10.5%、6.8%,统计学差异显著($P=0.004$);慢性血栓性肺动脉高压发生率分别为 5.3%、1.4%,统计学差异显著($P=0.000$)。**结论:**导管引导介入治疗对急性中高危肺动脉栓塞治疗是安全有效的,且可明显降低复发及慢性肺动脉高压的发生率。

关键词:急性肺动脉栓塞;导管;介入治疗;机械吸栓

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Clinical Study of Catheter-directed Interventional Therapy for Acute Intermediate- and High-risk Pulmonary Embolism*

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ABSTRACT Objective: To evaluate the efficacy and safety of catheter-directed interventional therapy for acute intermediate- and high-risk pulmonary embolism. **Methods:** A retrospective analysis of 112 cases with acute intermediate- and high-risk pulmonary embolism diagnosed and treated in vascular surgery of Liuzhou Workers' Hospital from January 2012 to June 2018. According to the therapy, all cases were divided into two groups, the anticoagulation group (38 cases) and the catheter-directed intervention combining with anticoagulation group (74 cases). Five indicators were compared between two groups, which included decrease of the pulmonary arterial pressure and pulmonary embolism severity index, symptomatic improvement rate, length of hospital stay and bleeding complication. According to intervention methods, the catheter-directed intervention group were divided into two groups, including AngioJet mechanical thrombectomy group (13 cases) and pigtail catheter fragmentation and thrombolysis (61 cases). Therapeutic effects of these two interventions were evaluated respectively by comparing the preoperative and postoperative arterial oxygen partial pressure, finger oxygen saturation, heart rate, pulmonary artery pressure, and Miller Index. **Results:** There were no significant differences in preoperative demographic characteristics, onset time, DVT concomitant rate, pulmonary artery pressure, and pulmonary embolism severity index ($P > 0.05$). The CDI group was significantly better than the anticoagulation group in reducing pulmonary arterial pressure and pulmonary artery severity index, symptom improvement, and shortening hospitalization time. There was no significant difference in the incidence of bleeding complications ($P > 0.05$). Comparing the preoperative and postoperative arterial oxygen partial pressure, finger oxygen saturation, heart rate, pulmonary artery pressure, and Miller Index of the two CDI groups, all the five indicators were significantly improved in both the two therapies ($P < 0.05$). During the follow-up period from 6 months to 7 years, the recurrence rate of PE was 10.5 % and 6.8 % in the anticoagulation group and the catheter intervention + anticoagulation group, respectively. The statistical difference was significant ($P=0.004$). And the incidence of chronic thrombotic pulmonary hypertension was respectively 5.3 % and 1.4 %, the statistical difference was significant

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($P=0.000$). **Conclusions:** Catheter-directed interventional therapy is safe and effective for the treatment of acute intermediated- and high-risk pulmonary embolism. CDI can significantly reduce the incidence of recurrence and chronic pulmonary hypertension.

Key words: Acute pulmonary embolism; Catheter; Interventional therapy; Thrombectomy

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前言

急性肺动脉栓塞(acute pulmonary embolism, APE)是血管外科常见的危急疾病,主要继发于下肢深静脉血栓形成(deep venous thrombosis, DVT),并称静脉血栓栓塞性疾病(venous thromboembolism, VTE)。肺动脉的急性大块血栓栓塞会导致血氧交换障碍、右心功能不全甚至血流动力学不稳、意识丧失,严重威胁人类生命。APE是继冠心病、脑血管疾病后位列第三致死的心血管疾病^[1],中高危患者死亡率高达30%,在美国每年因肺动脉栓塞致死的超过10万人^[2]。目前对低危的PE患者,主要以抗凝治疗为主^[3];而对于中高危患者,一些研究已经表明导管引导介入治疗的显著疗效,但在血管外科学界尚无定论。我科室自2012年陆续开展不同的导管引导介入治疗急性中高危肺动脉栓塞,现将相关结果及分析报道如下。

1 资料和方法

1.1 一般资料

回顾性分析2012年1月至2018年6月在柳州市工人医院血管外科收治的PE患者。纳入本研究的标准,同时满足如下因素:1.临床疑诊PE并经肺动脉血管成像(computed tomographic pulmonary arteriography, CTPA)或肺动脉DSA检查明确

确诊;2.发病时间不超过2周;3.血栓累及肺动脉主干和(或)叶动脉;4.APE危险分级属中高危患者^[4]。排除标准:1.存在诸如三尖瓣、肺动脉瓣假体或赘生物、左束支传导阻滞或近期心肌梗死等肺动脉置管禁忌的患者;2.临床资料数据严重缺失、无随访资料者。

共112例纳入本研究。其中男性68例,女性44例;年龄15.2-82.5岁,中位年龄63岁。92例患者入院时经下肢血管彩超明确下肢深静脉血栓形成(左侧52例,右侧19例,双侧21例)。发病时间2小时至12天不等,101例发病时间在72小时内,占90.2%。病人入院主诉主要包括胸闷、气促、呼吸困难、咯血、胸痛、晕厥等症状,临床疑诊PE后经CTPA或肺动脉DSA检查明确(图1);其中3例系全麻术中突发自主心跳呼吸骤停,快速床旁C臂下肺动脉DSA确诊。入院病人均完善的检查,包括动脉血气分析、经胸心脏彩超、心电图等,根据肺动脉栓塞严重指数(pulmonary embolism severity index, PESI)对所有患者进行评分,肺动脉压根据经胸心脏彩超估算。

所有患者均在充分认识各治疗方案优劣势的前提下自主选择治疗方案,并签署手术知情同意书。其中38例选择单纯抗凝治疗,另74例患者选择导管引导介入治疗联合标准化抗凝(13例行AngioJet机械吸栓,61例行猪尾导管碎栓并溶栓)。两组病例人口学特征及术前一般病情详见表1。

表1 两组人口学特征及术前病情比较

Table 1 Comparison of demographic characteristics and preoperative conditions between the two groups

	Age	Gender(M/F)	DVT(%)	Time(hour)	PESI	PAP
Anticoagulation only (n=38)	55.4± 12.5	23 15	31/38 81.6 %	56.5± 10.8	99.2± 13.0	43.3± 1.4
Anticoagulation +CDI (n=74)	52.1± 11.4	45 29	61/74 82.4 %	53.5± 9.5	98.8± 12.3	44.2± 1.6
P value	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

Note: CDI catheter-directed intervention; DVT deep venous thrombosis; PESI pulmonary artery severity index; PAP pulmonary artery pressure.

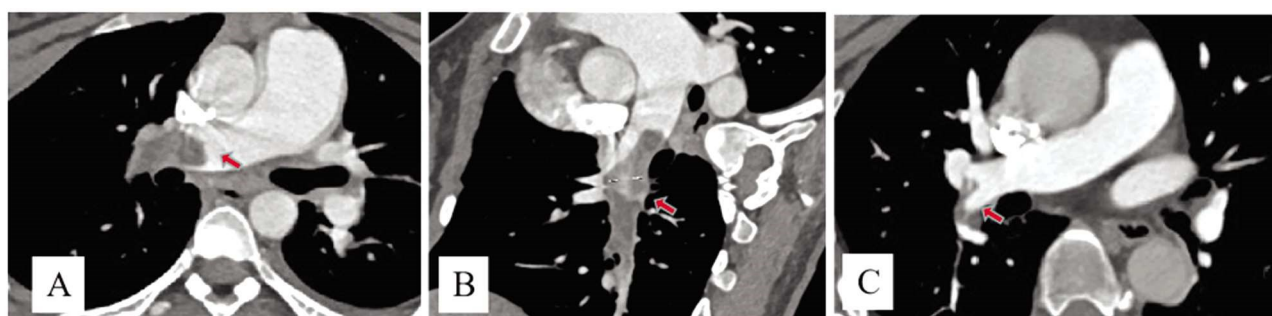


图1 2例典型病例术前CTPA (A、B为同一病例,C为另一病例)

Fig.1 Preoperative CTPA of 2 typical cases (A and B for a case, C for another case)

注:A和B:术前CTPA示右肺动脉主干完全性栓塞(见红色箭头);C:术前CTPA示右下肺动脉栓塞(见红色箭头)。

Note: A and B: Preoperative CTPA showed complete embolization in right pulmonary artery trunk (red arrow); C: Preoperative CTPA showed embolization in lower right pulmonary artery (red arrow).

1.2 方法

1.2.1 一般支持治疗 所有患者入院后均予卧床、心电指脉氧监测、高浓度吸氧,建立外周或中心静脉通路。对昏迷、呼吸衰竭或心肺复苏的病人气管插管呼吸机辅助呼吸。

1.2.2 建立肺动脉导管通道 患者平卧位,心电监测并吸氧;常规消毒穿刺区,Seldinger法穿刺健侧股静脉或右侧颈内静脉(85例右股静脉,20例左侧股静脉,7例右颈内静脉),Stiff导丝与5F猪尾导管(110cm泰尔茂)配合下先后经下腔静脉、右心房、肺动脉主干后分别进入双肺动脉主干进行造影评估血栓累及部位、范围,建立肺动脉导管通道过程中行下腔静脉造影

了解有无血栓。

1.2.3 AngioJet 机械吸栓 猪尾导管分别进入左右肺动脉主干造影评估血栓累及部位、范围(图2A),经Stiff导管置换AngioJet吸栓导管(6F Solent管 波士顿科学)进入肺动脉血栓的远端(图2B),在抽吸模式下缓慢回退导管,通过观察导管吸出的液体颜色间接估计吸栓效果(导管内液体呈暗红色提示血栓清除效果良好)。回退速度控制在0.5-1 cm/s,同时结合患者操作过程中耐受程度及抽吸的液体颜色可重复数次。抽吸结束后再次行肺动脉造影明确吸栓效果(图2C),必要时局部推注10万-20万尿激酶。

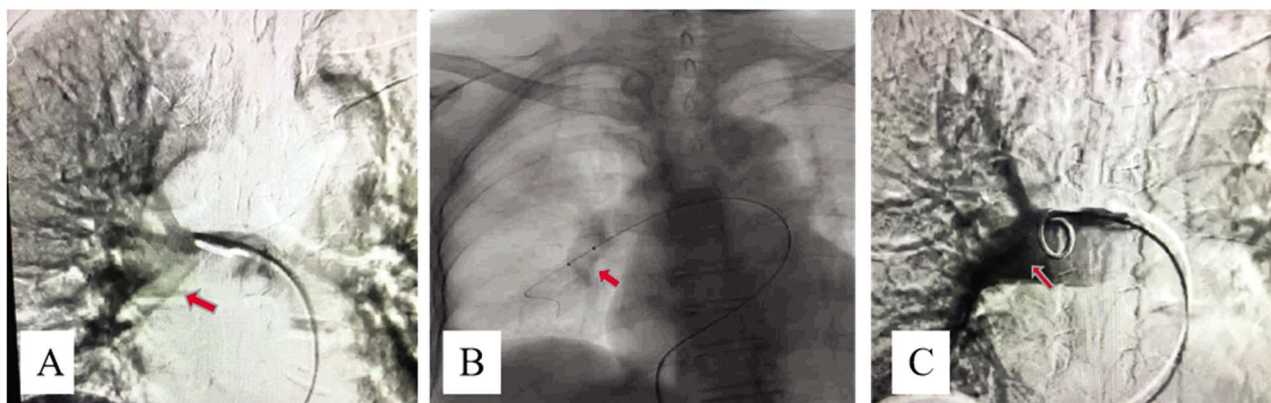


图2 AngioJet机械吸栓术

Fig.2 AngioJet mechanical thrombectomy

注:A:术前肺动脉 DSA 提示右肺动脉主干充盈缺损(见红色箭头);B:术中 AngioJet 导管吸栓(见红色箭头);C:术后肺动脉 DSA 提示右肺动脉主干充盈缺损完全消失(见红色箭头)。

Note: A: Preoperative pulmonary DSA showed filling defect in right pulmonary artery trunk (red arrow); B: AngioJet mechanical thrombectomy (red arrow); C: Postoperative pulmonary DSA showed the thrombus in right pulmonary artery trunk was completely disappeared (red arrow).

1.2.4 猪尾导管碎栓+溶栓 猪尾导管在Stiff导丝的引导下通过肺动脉血栓,回撤导丝使猪尾导管头端保持其记忆形状,同时留置导丝在猪尾导管内提供支撑力,三通阀固定导丝及猪尾导管,一边快速、迅速旋转一边缓慢自血栓远心段(图3A)到近心端(图3B)回撤,这个过程可重复多次,同时注意患者主诉及心电监测的情况适当调整手术进程。碎栓结束后经猪尾导管缓慢注射10-20万单位尿激酶,再次行肺动脉造影了解治疗效果。

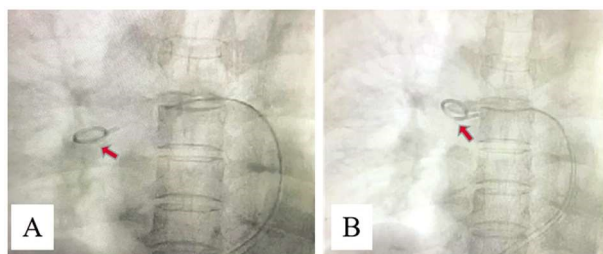


图3 猪尾导管碎栓术

Fig.3 Pigtail catheter fragmentation

注:A:猪尾导管在血栓远心端碎栓(见红色箭头);B:猪尾导管在血栓近心端碎栓(见红色箭头)。

Note: A: Pigtail catheter fragmentation at the distal end of the thrombus (red arrow); B: Pigtail catheter fragmentation at the proximal end of the thrombus (red arrow).

1.2.5 下腔静脉滤器植入 对合并髂股静脉血栓形成并同期行下肢深静脉 CDT 或机械吸栓的患者或术前彩超提示下肢深静脉漂浮血栓的患者予下腔静脉可回收滤器植入。本研究中共78例(其中先建滤器65枚,Cordis滤器13例);所有患者均要求2周内返院取出滤器,其中1例因滤器严重贴壁未取出,另77例均顺利在规定时间内取出。

1.2.6 标准及个体化抗凝方案 根据国内外指南^[3,5],所有患者均接受标准化抗凝,住院期间根据体重予以足量的低分子肝素(100 U/kg q12h)皮下注射或口服利伐沙班(15 mg bid)。出院后根据患者 VTE 的病因制定个体化的抗凝方案,对选择口服华法林抗凝的患者,密切监测凝血功能,保持国际标准值(INR)在2-3;口服利伐沙班者3周后改20 mg 一天一次。

1.3 评价指标和记录方法

比较两组病例住院期间症状缓解率、肺动脉压和 PESI 降低的效果、住院时长和出血发生率。通过随访观察 PE 复发率和慢性血栓性肺动脉高压(chronic thromboembolic pulmonary hypertension,CTPH) 的发生率评估两组病人的远期效果(CTPH 的定义 PE 发病后肺动脉压持续高于25 mmHg 达6个月以上)^[6]。而对于介入治疗组的两种治疗方法,分别对术前动脉血氧分压、指脉氧、心率及肺动脉压、米勒指数的比较评估其治疗效果。

各项指标记录方法:症状缓解指患者主诉症状经治疗后好转或痊愈,肺动脉压由术前和术后的经胸心脏彩超报告获取,

肺栓塞严重指数根据 PESI 量表计算, 出血并发症包括治疗后出现的穿刺处血肿、皮肤或粘膜瘀斑等小出血事件和颅内出血、消化道出血等威胁生命的出血事件。PE 复发是指患者在随访中出现肺栓塞的症状并经 CTPA 明确诊断;CTPH 诊断中的肺动脉压力由病人随访中的经胸心脏彩超报告获取。动脉血氧分压由术前术后动脉血血气分析结果获取, 指脉氧、心率由住院护理单获取, 弥勒指数由介入术中进行的 DSA 造影结果计算, 计算公式: MI= 肺动脉栓塞支数 + 肺灌注分数。

1.4 随访

随访时间表: 按术后第 1 个月、第 3 个月、第 6 个月、第 12 个月及以后每年进行随访。随访方式及项目: 门诊或住院复查凝血功能、心脏彩超、CTPA 及临床资料的采集。随访目的: 主要了解 PE 是否复发和有无 CTPH。

1.5 统计学分析

采用 SPSS22 软件对本研究相关数据进行统计学分析。计数资料采用例数和百分比[例(%)]表示, 计量资料采用均数 $\pm$ 标准差($\bar{x} \pm s$)表示。组间对比, 计数资料采用 χ^2 检验; 计量资料先

经过方差齐性检验, 方差齐者, 用的 t 检验; 方差不齐, 进行非参数检验(秩和检验)。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 两组病例住院期间的疗效和安全性

两组病例在降低肺动脉压和 PESI 评分、缓解临床症状等均有显著效果, 而介入治疗组在这三方面效果优于单纯抗凝组, 且差异有统计学意义(P 值分别为 0.000、0.001、0.01)。抗凝组的平均住院时间为 14.2 天, 介入治疗组平均住院时长为 8.5 天, 明显缩短了住院时间($P=0.003$)。安全性主要考察出血并发症的发生率, 抗凝组有 1 例在治疗期间发生肢体皮下大片瘀斑, 经对症治疗后好转; 介入治疗组在术后发生 1 例穿刺点血肿, 经患肢制动、压迫等处理好转; 另 2 例术前咯血的患者术后咯血一过性加重, 经呼吸道管理、密切观察等处理后好转, 所有出血病例均未输血, 无颅内、消化道大出血等致命性的出血并发症, 无死亡病例。两组在住院期间出血并发症发生率无差异($P > 0.05$), (见表 2)。

表 2 两组病例住院期间疗效和安全性对比

Table 2 Comparison of efficacy and safety between the two groups during hospitalization

	Δ PAP (mmHg)	Δ PESI	Rate of symptom relief	Length of hospital stay (days)	Bleeding complications
Anticoagulation only (n=38)	3.6 $\pm$ 0.8	20.3 $\pm$ 8.6	27/38 71.05 %	14.2 $\pm$ 4.8	1/38 2.6 %
Anticoagulation +CDI (n=74)	14.5 $\pm$ 3.4	48.9 $\pm$ 13.2	65/74 87.8 %	8.5 $\pm$ 3.1	3/74 4.1 %
<i>P</i> value	0.000	0.001	0.01	0.003	>0.05

Note: Δ PAP = Preoperative PAP - Postoperative PAP; Δ PESI = Preoperative PESI - Postoperative PESI.

PESI pulmonary artery severity index; PAP pulmonary artery pressure.

2.2 两组病例随访期间 PE 复发率及 CTPH 发生率

两组病人均进行超过 6 个月的随访, 单纯抗凝治疗组有 4 例出现 PE 复发, 复发率 10.5 %; 2 例出现 CTPH, 发生率 5.3

%; 而介入治疗组 5 例出现 PE 复发, 复发率 6.8 %; 1 例出现 CTPH, 发生率 1.4 %; 介入治疗能明显降低 PE 复发及 CTPH 的发生率(P 分别为 0.002、0.000), (见表 3)。

表 3 两组病例 PE 复发率及 CTPH 发生率

Table 3 PE recurrence rate and incidence of CTPH in both groups

	PE recurrence	CTPH
Anticoagulation only (N=38)	4/38 10.5 %	2/38 5.3 %
Anticoagulation + CDI (N=74)	5/74 6.8 %	1/74 1.4 %
<i>P</i> value	0.002	0.000

Note: PE pulmonary embolism; CTPH chronic thromboembolic pulmonary hypertension.

2.3 AngioJet 吸栓与猪尾导管碎栓溶栓的治疗效果

通过分别对比两种介入治疗方案的术前及术后动脉血氧分压、指脉氧、心率及肺动脉压、弥勒指数等 5 个主要指标, 两组方案显示良好的治疗效果。(P 值均 < 0.05), (见表 4)。

3 讨论

APE 临床表现多样而无特异性, 部分患者无症状或轻度的呼吸困难; 而严重者迅速出现血流动力学不稳定、休克或晕厥等。为了更好的预测 APE 早期死亡率及预后, 临床医师需对确

诊 PE 的患者进行危险分级: 低危、中危和高危。低危患者的治疗方案已在指南和专家共识^[3,5,7]中明确: 规范足量的抗凝是其方案。而中高危患者, 肺动脉血栓负荷重, 右心流出道受阻、右心功能不全、血氧交换障碍, 特别是出现了血流动力学不稳定的高危患者, 早期死亡率极高^[8]。快速有效的减轻血栓负荷, 恢复肺循环是成功救治此类病人的关键^[9]。单纯的抗凝治疗难于达到这个目的; 系统性溶栓对中高危病人已证实有效, 但其严重的出血并发症限制其广泛的应用^[10-13]。

表 4 CDI 组中两种方案的疗效

Table 4 Efficacy of two therapies in CDI group

	AngioJet group(n=13)		Pigtail catheter group(n=61)	
	Preoperative	Postoperative	Preoperative	Postoperative
PaO ₂ (mmHg)	62.8± 6.7	89.8± 10.2	63.1± 6.4	87.8± 8.3
SPO ₂ (100%)	70.7± 11.2	92.0± 7.2	72.3± 10.8	90.4± 7.8
HR/(min)	108.5± 23.5	78± 14.6	110.4± 16.8	82.3± 11.6
Miller Index	22.3± 2.4	9.4± 0.8	23.0± 2.3	12.2± 0.9
PAP(mmHg)	44.8± 1.6	25.2± 1.1	45.2± 1.8	26.2± 1.5

Note: PaO₂ arterial oxygen partial pressure; SPO₂ finger oxygen saturation; HR heart rate; PAP pulmonary artery pressure.

随着腔内技术的不断成熟及血管器械的进步,导管引导介入治疗(catheter-directed intervention, CDI)逐渐成功的应用于APE^[14-16]。CDI包括导管物理碎栓、机械性吸栓和导管局部溶栓等多种技术。猪尾导管旋转碎栓、AngioJet吸栓是在近几年的指南中明确可用于中高危的APE^[17,18]。

猪尾导管特殊的头端设计可在快速旋转中迅速有效的将肺动脉中的血栓打碎,疏通肺动脉主干;而形成小碎片的血栓被血流冲刷至肺血管床内溶解。血栓碎片化不仅恢复了肺循环,同时大大增加了血栓的表面积,增加其与纤溶酶原的接触面,提高了循环中或经导管注射的纤溶酶原激活物的溶栓级联反应。肺叶动脉的截面积总和为主干动脉的截面积2倍,肺循环的这一解剖结构避免了碎落的血栓引起远端栓塞加重病情。本研究结果与很多的研究^[13,19,20]提示了碎栓和局部溶栓的安全性和有效性。Mosafa^[19]等进行CDI和系统性溶栓治疗亚大块型肺栓塞和大块性肺动脉栓塞的对比研究中提示,相对于系统性溶栓的20%左右的出血率,碎栓和局部溶栓的安全性更高,且治疗效果显著。Avgerinos^[13]等对213例APE的研究中,CDI组临床成功率87.8%,出血并发症8%;而系统溶栓组分别为66.3%、19.2%。

AngioJet血栓清除系统利用Bernoulli原理在吸栓导管工作段形成低负压区对血栓形成强大的吸力将血栓吸出体外,已广泛应用于髂股段DVT病人的血栓清除^[21-23],在APE中的应用也有报道^[18]。AngioJet最大的优势是快速的血栓清除能力,快速高效的恢复肺动脉循环,特别适用于肺动脉主干大块栓塞患者。本研究中13例患者中,10例为肺动脉主干的完全栓塞,右心功能不全,经AngioJet导管吸栓后,肺动脉压迅速下降,患者症状明显好转;术后动脉血氧分压、指脉氧、心率及肺动脉压、米勒指数较术前均有明显改善,对比分析差异显著(P 值均 <0.05)。这与国内外的报道结果相似^[18,24]。吸栓过程可能诱导心率失常,红细胞破坏引起的血红蛋白尿、肾功能不全等应进行积极预防,一般的对症处理均能保证操作的顺利进行。本研究中无1例出现严重的心率失常、需透析的肾功能不全病例,相关的研究^[25,26]也未报道严重并发症的发生。

PE复发是APE治疗后的主要远期并发症之一,据统计,1年累计复发率是13%,5年累计复发率为23%,10年为30%^[27]。PE复发的原因和具体机制目前尚无定论,但已有不少研究证实早期血栓清除和规范化抗凝可显著降低其复发率。本研究中,介入治疗组在早期血栓清除中明显优于单纯抗凝组,在超

过半年的随访中,复发率为6.8%,明显低于单纯抗凝组的10.5%,与相关研究结果^[2,29]类似。PE的复发同时会导致严重影响生活质量的栓塞相关肺动脉高压;血栓栓塞后血管壁的纤维化重塑是其主要的病理机制^[30],而重塑后大量减少的血管床是肺动脉高压的成因。据报道^[31,32],急性肺动脉栓塞2年后CTPH发生率为2%-4%;本研究中总体复发率为2.7%,介入治疗组为1.4%,提示早期的血栓清除可降低CTPH的发生率。

综上所述,对于死亡率较高的急性中高危肺动脉栓塞,多种导管引导介入治疗在早期可显著缓解症状、降低肺动脉压和PESI等达到降低早期死亡率的效果。而微创的腔内技术未增加严重并发症,是安全可行的措施。同时在随访中提示可显著降低肺栓塞复发及肺动脉高压等远期并发症。当然,需正视的是本研究也存在一些限制或不足,单中心的回顾性研究、AngioJet吸栓治疗的样本量相对较少,患者的随访时间短等。因此,有待于前瞻性、多中心、大样本的研究进一步证实介入治疗在急性中高危肺动脉栓塞中的安全性和有效性。

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