·临床研究·

Solitaire AB可回收支架在急性缺血性卒中血管内治疗中的应用

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【摘要】 **目的**　探讨Solitaire AB可回收支架治疗颅内前循环大动脉闭塞致急性缺血性卒中的有效性和安全性。**方法**　回顾分析31例采用Solitaire AB支架机械取栓治疗颅内前循环大动脉闭塞致急性缺血性卒中患者的临床资料，采用脑梗死溶栓血流分级（TICI）评价血管再通、美国国立卫生研究院卒中量表（NIHSS）评价神经功能、改良Rankin量表（mRS）评价预后，记录围手术期栓塞事件以及术后3个月内颅内出血或死亡。**结果**　31例患者共使用33枚Solitaire AB支架，其中19例首次机械取栓即实现血管再通；11例进一步行支架植入术，9例实现血管再通，最终总体血管再通率为90.32%（28/31）。术后1周NIHSS评分（8.81±3.40）分，低于术前的（16.06±4.82）分（$t=-7.104$，$P=0.000$）。术后3个月预后良好（mRS评分≤2分）16例（51.61%）。围手术期发生栓塞事件3例，随访期间发生颅内出血4例，共死亡6例。**结论**　Solitaire AB支架用于急性缺血性卒中的机械取栓安全、有效，首次机械取栓血管再通失败可以联合支架植入术作为补充治疗。

【关键词】 卒中；　脑缺血；　血管成形术；　支架；　手术后并发症

Application of Solitaire AB stent in endovascular treatment of acute ischemic stroke

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【**Abstract**】 **Objective**　To evaluate the safety and efficiency of mechnical thrombectomy with Solitaire AB stent in the treatment of acute ischemic stroke caused by large artery occlusion of anterior circulation. **Methods**　Clinical data of 31 patients with acute ischemic stroke caused by large artery occlusion of anterior circulation, who underwent mechnical thrombectomy with Solitaire AB stent, were reviewed retrospectively. Recanalization results were assessed by immediate scale of thrombolysis in cerebral infarction (TICI) after thrombectomy. National Institutes of Health Stroke Scale (NIHSS) was used to evaluate neurological function at one week after operation, and modified Rankin Scale (mRS) was used to evaluate outcomes at 3 months after operation. Complications related to the procedure, such as perioperative embolic events, intracranial hemorrhage or death within 3 months after operation, were recorded. **Results**　A total of 33 Solitaire AB stents were used in 31 patients. The initial success rate of recanalization was 61.29% (19/31). Among the other 12 patients, one patient with TICI Grade 2a and favorable distal blood supply was not further freated, while 11 patients underwent stent implantation as a rescue treatment and 9 of them were successful. The final recanalization rate was 90.32% (28/31). The NIHSS score one week after operation was 8.81±3.40, which was significantly lower than the score 16.06±4.82 on admission ($t=-7.104$, $P=0.000$). Three months after operation, there were 16 patients (51.61%) with good prognosis (mRS score ≤ 2). Perioperative embolization occurred in 3 patients. Intracranial hemorrhage occurred in 4 patients during the 3-month follow-up period, and 6 patients were dead. **Conclusions**　The application of Solitaire AB stent in mechnical thrombectomy for treating acute ischemic stroke is efficient and safe. Stent implantation can be used as adjunctive treatment when initial recanalization with Solitaire AB stent is failed.

【**Key words**】 Stroke;　Brain ischemia;　Angioplasty;　Stents;　Postoperative complications

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脑卒中是全球第3位、我国首位病死原因，且病残率较高，其中60%～80%为急性缺血性卒中。静脉溶栓作为国内外一致推荐的急性缺血性卒中标准治疗方法，其疗效已经多项临床试验证实[1-2]，但静脉溶栓时间窗较短，血管再通率较低，且仍存在较高的病残率和病死率[3]。近年来，各种血管内取栓装置的应用使血管内治疗迅速发展，特别是Solitaire AB可回收支架其治疗效果获得数项大型临床试验的肯定[4-8]。采用支架取栓装置治疗动脉闭塞迅速被国内外指南推荐为急性大动脉闭塞的标准治疗方法[9-10]。本研究回顾分析近2年郑州大学人民医院采用Solitaire AB可回收支架治疗颅内大动脉闭塞致急性缺血性卒中的临床资料，探讨其有效性和安全性。

资料与方法

一、临床资料

1. 纳入标准 （1）均经头部CT和（或）MRI检查排除颅内出血，并经CTA、MRA或数字减影血管造影术（DSA）证实颅内前循环大动脉闭塞。（2）年龄≤80岁。（3）发病至动脉穿刺时间<8 h。（4）入院时美国国立卫生研究院卒中量表（NIHSS）评分6～30分。（5）本研究经郑州大学人民医院道德伦理委员会审核批准，所有患者或其家属均知情同意并签署知情同意书。

2. 排除标准 （1）既往出血性脑血管病病史或出血倾向。（2）近6个月内严重脑卒中病史。（3）合并重要脏器功能障碍或衰竭。（4）基于早期非增强CT的ASPECT（The Alberta Stroke Program Early CT）评分<6分。（5）入院时NIHSS评分>30分。（6）术前收缩压≥185 mm Hg（1 mm Hg = 0.133 kPa）或舒张压≥110 mm Hg。

3. 一般资料 选择2013年6月–2015年6月郑州大学人民医院介入科采用Solitaire AB可回收支架治疗的急性缺血性卒中患者共31例，男性16例，女性15例；年龄31～78岁，平均（55.70±14.56）岁；发病至入院时间1.70～6.20 h，平均（3.86±1.92）h；既往高血压17例（54.84%）、冠心病5例（16.13%）、糖尿病8例（25.81%）、高脂血症7例（22.58%），吸烟7例（22.58%）、饮酒12例（38.71%）；入院时NIHSS评分6～26分，平均（16.06±4.82）分；单纯颈内动脉（ICA）颅内段闭塞12例（38.71%），单纯大脑中动脉（MCA）闭塞14例（45.16%），合并颈内动脉和大脑中动脉串联闭塞5例（16.13%）；根据改良TOAST分型，大动脉粥样硬化（LAA）型15例（48.39%），心源性栓塞（CE）型16例（51.61%）；术前脑梗死溶栓血流分级（TICI）均为0级。

二、研究方法

1. 术前管理 术前行CT检查排除颅内出血，基于早期非增强CT的ASPECT评分评价梗死灶范围，部分患者在时间允许情况下行多模态影像学（多模态MRI和CT）检查明确动脉闭塞部位和缺血-再灌注情况。对于处于静脉溶栓时间窗的患者，先予尿激酶或重组组织型纤溶酶原激活物（rt-PA）静脉溶栓治疗，效果不佳者再行Solitaire AB可回收支架机械取栓治疗。

2. 手术方法 患者仰卧位，全身麻醉或局部麻醉下经股动脉穿刺，导入6F导管鞘，选择6F～8F导引导管，先以0.014英寸微导丝协同造影导管通过闭塞段血管，撤出微导丝后逐步回撤微导管，分段造影以明确闭塞部位远端，将Rebar18微导管（美国Covidien公司）顶端置于闭塞段以远至少5 mm处，经微导管将Solitaire AB支架（美国Covidien公司）远端送至微导管顶端，缓慢回撤微导管并释放支架，植入支架后即刻复查DSA以观察血流灌注情况，留置3～5 min后回撤支架取栓，将微导管逆行向上对Solitaire AB支架的剩余部分回收，关闭导引导管尾端三通连接的灌注水，以50 ml注射器连接三通连接的开放端持续抽吸血栓，取栓过程根据个体情况配合应用抗血小板药物。颈内动脉和大脑中动脉串联闭塞患者一般开通原则为先开通近端血管，再开通远端血管，术后复查DSA，若血管开通不理想或机械取栓后30 min内出现血管再狭窄或闭塞，则决定是否进一步行支架植入术（图1）。对于植入支架的患者，释放支架前先予以替罗非班（欣维宁）静脉注射（8 μg/kg，3 min内注射完毕），术后再予以0.10 μg/（kg·min）维持24 h。术后即刻复查CT观察有无颅内出血，手术全程静脉滴注低分子肝素。

3. 术后管理 术后密切监测血压，维持收缩压110～140 mm Hg；酌情皮下注射低分子肝素；术后48 h内复查影像学，观察有无颅内出血和新发梗死灶。植入支架的患者停用替罗非班后予双联抗血小板药物（阿司匹林100 mg/d和氯吡格雷75 mg/d）治疗，连续3个月后长期服用单联抗血小板药物（阿司匹林100 mg/d）；未植入支架的患者出院后长期服用单联抗血小板药物（阿司匹林100 mg/d）预防脑卒

中复发。

4.疗效和安全性评价 (1)疗效评价:血管再通评价采用TICI分级,TICI分级2b~3级为血管再通;术后1周采用NIHSS量表评价神经功能,NIHSS评分减少≥8分为神经功能改善;术后3个月采用改良Rankin量表(mRS)评价预后,mRS评分≤2分为预后良好。(2)安全性评价:记录围手术期栓塞事件并发症,术后3个月内颅内出血并发症或死亡。症状性颅内出血定义为任何性质的颅内出血且NIHSS评分增加≥4分。

5.统计分析方法 采用SPSS 22.0统计软件进行数据处理与分析。计量资料以均数±标准差($\bar{x}\pm s$)表示,采用配对t检验。以$P\leq 0.05$为差异具有统计学意义。

结 果

本组31例患者共使用33枚Solitaire AB支架,其中1例(3.23%)机械取栓前予尿激酶静脉溶栓。发病至动脉穿刺时间2.50~7.00 h,平均为(4.52±1.98) h;动脉穿刺至血管再通时间32~128 min,平均(77.46±24.33) min;发病至血管再通时间201~486 min,平均为(348.66±105.60) min。19例患者首次机械取栓后即实现血管再通(TICI分级为2b~3级),血管再通率达61.29%(19/31),其中TICI分级3级9例(29.03%)。1例患者虽然首次机械取栓未实现血管再通,但血流达TICI分级2a级,远端血供良好,未予治疗。余11例患者进一步行支架植入术,其中6例采用Solitaire AB支架机械取栓后解脱植入,9例实现血管再通。最终总体血管再通率为90.32%(28/31)。术后1周NIHSS评分2~32分,平均(8.81±3.40)分,低于术前[(16.06±4.82)分]且差异有统计学意义($t=-7.104$, $P=0.000$),其中14例(45.16%)NIHSS评分减少>8分。术后3个月预后良好(mRS评分≤2分)16例(51.61%),9例遗留不同程度神经功能障碍。

围手术期血栓形成3例,2例机械取栓过程中血管远端血栓形成,其中1例予替罗非班动脉溶栓,效果不佳,1例未予特殊处理,余1例支架植入术中穿支动脉闭塞,未予特殊处理。颅内出血4例,2例为症状性颅内出血,2例为非症状性颅内出血;3例为缺血-再灌注区出血性转化,1例为术中导丝戳破血管致蛛网膜下隙出血,予术中紧急降压,注射鱼精蛋白和低分子肝素抗凝,出血自行停止。术后随访3个月,死亡6例(19.35%),住院期间死亡2例,1例死于颅内出血继发脑水肿和脑疝形成,1例死于心功能衰竭;随访期间死亡4例,2例死于脑水肿,2例死于肺部感染致呼吸功能衰竭。

讨 论

近年来,一系列取栓装置的研发和临床应用,使急性缺血性卒中的血管内治疗进入快速发展时期,从早期的Merci取栓装置(美国Stryker公司)、Penumbra血栓抽吸装置(美国Penumbra公司)到后来的Trevo XP ProVue可回收取栓支架装置(美国Stryker公司)、Solitaire AB可回收支架(美国Covidien公司)。Solitaire AB可回收支架是美国食品与药品监督管理局(FDA)于2012年批准用于临床的新一代取栓装置,支架释放时相当于进行血管成形术,通过与外周血管壁挤压栓子以实现血管再通,支架回收时可以取出血栓,具有精确导向和快速再通血管的功能,较其他取栓装置具有更高的血管再通率和良好预后。多项采用可回收支架取栓装置的临床研究均证实其血管内治疗效果优于传统静脉溶栓[4-8]。

本组31例患者首次机械取栓后血管再通率为61.29%(19/31),处于既往研究得出的血管再通率58%~88%的下限[4-8]。大动脉粥样硬化致急性闭塞,单纯机械取栓常无法解除靶血管原位狭窄,对于合并原位狭窄的患者应行支架植入术[11-12]。研究显示,心源性栓塞致大动脉闭塞对可回收支架机械取栓的反应更佳,血管再通率更高[13-14],与本研究结果相一致。亚洲人群急性缺血性卒中病因主要是动脉粥样硬化(30%~50%),远高于欧美等西方国家[15],可能是本研究首次应用Solitaire AB支架血管再通率相对较低的主要原因。对于血管再通不理想或者血管再通后再狭窄或闭塞患者,支架植入术可以作为补救性治疗方法并取得较好疗效。本研究进一步行支架植入术后最终总体血管再通率达90.32%(28/31)。本研究仅1例患者机械取栓前予尿激酶静脉溶栓,与单纯机械取栓相比,静脉溶栓联合机械取栓的桥接治疗可以快速溶栓,有助于提高血管再通率,对于机械取栓装置难以到达的小血管再通效果较好。然而一项比较单纯机械取栓与静脉溶栓联合机械取栓桥接治疗效果的Meta分析显示,桥接治疗最终总体血管再通率($P=0.370$)和预后($P=0.860$)并不优于单纯机械取栓,反而延迟

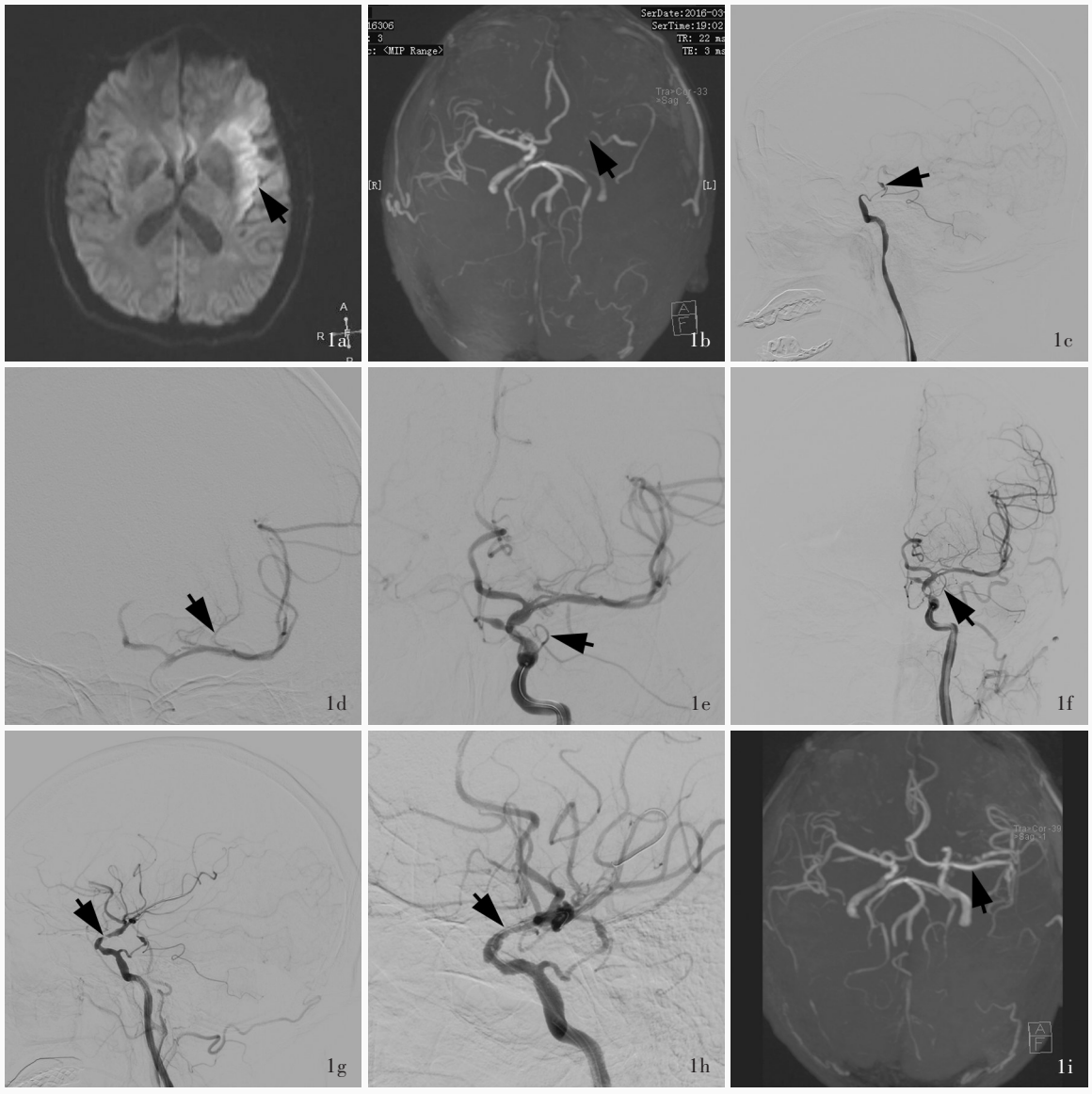

图1 男性患者，51岁，主因右侧肢体无力伴言语不清5 h入院，入院时NIHSS评分18分，临床诊断为急性缺血性卒中、左侧颈内动脉远端闭塞，遂行血管内机械取栓术，术后3个月随访mRS评分2分。手术前后头部影像学检查所见 1a 术前横断面DWI显示，左侧额颞岛叶梗死灶（箭头所示） 1b 术前MRA显示，左侧颈内动脉远端闭塞（箭头所示） 1c 术前DSA显示，左侧颈内动脉远端闭塞（箭头所示） 1d 术前DSA显示，左侧大脑中动脉和大脑前动脉A1段显影尚可（箭头所示） 1e 于颈内动脉闭塞处释放Solitaire AB支架，术中DSA显示左侧颈内动脉远端显影（箭头所示） 1f 于首次机械取栓后5 min复查DSA显示，左侧颈内动脉远端局部显影不良（箭头所示） 1g 予Sprinter Legend球囊扩张病变，DSA仍显示局部充盈缺损（箭头所示） 1h 于狭窄处植入2.50 mm×8.00 mm Apollo支架，复查DSA显示左侧颈内动脉远端原闭塞处显影良好，其远端血流通畅（箭头所示） 1i 术后1周复查MRA显示，左侧颈内动脉血流通畅（箭头所示）

Figure 1 A 51-year-old man presented right limb weakness and speech disorder for 5 h. The baseline NIHSS score was 18. He was diagnosed as acute ischemic stroke and distal occlusion of left internal carotid artery (ICA) and underwent mechnical thrombectomy. The mRS score was 2 after 3-month follow up. Head imaging findings before and after operation Preoperative axial DWI showed infarction of left fronto-temporo-insular lobe (arrow indicates, Panel 1a). Preoperative MRA and DSA showed occlusion of left ICA (arrows indicate; Panel 1b, 1c). Preoperative DSA showed clear A1 segment of left middle cerebral artery (MCA) and anterior cerebral artery (ACA; arrow indicates, Panel 1d). Deploy the Solitaire AB stent in the occlusion site, and intraoperative DSA showed visualization of distal left ICA (arrow indicates, Panel 1e). Five minutes later, DSA showed poor visualization of distal left ICA after the first stent retrieval (arrow indicates, Panel 1f). DSA showed partial filling defect after Sprinter Legend balloon dilatation (arrow indicates, Panel 1g). A 2.50 mm × 8.00 mm Apollo stent was implanted, and DSA showed good visualization of the occulsion site and fluent blood flow of distal left ICA (arrow indicates, Panel 1h). MRA performed one week after procedure showed fluent blood flow of left ICA (arrow indicates, Panel 1i).

血管再通时间（$P=0.010$）[16]。

本组有2例患者首次机械取栓成功实现血管再通，但在术后观察期间发生血管再闭塞，遂行支架植入术。急性期血管再闭塞是机械取栓术后重要

并发症，若早期无法及时解除则影响长期预后，血管再闭塞原因可能与取栓装置损伤血管内皮致血小板聚集有关，因此机械取栓联合应用抗血小板药物有助于减少血管再闭塞的发生。Heo等[17]采用替罗非班动脉溶栓治疗急性期血管再闭塞取得较好效果，他们还证实原位狭窄基础上血栓形成致血管闭塞患者机械取栓后更易发生血管再闭塞。本组有2例患者发生术中血管远端血栓形成，均是手术操作过程中栓子脱落堵塞远端所致，急性血管内再通治疗过程中栓子易破碎并脱落至远端，术中及时应用溶栓药物或抗血小板药物有助于解除血管远端栓塞事件。

急性缺血性卒中机械取栓过程中血管壁损伤、缺血-再灌注损伤、溶栓药物和抗血小板药物等均可能造成围手术期颅内出血。研究显示，性别、入院时NIHSS评分、既往糖尿病和发病至血管再通时间均是颅内出血的危险因素[18]，为减少颅内出血这一并发症，除要求术者经验丰富外，术前准确评价出血风险亦十分重要。本研究围手术期症状性颅内出血均为机械取栓术联合支架植入术患者，有文献报道，与单独机械取栓相比，机械取栓术联合支架植入术增加颅内出血发生率[19]。部分行支架植入术的患者，手术时间延长导致的血管再通延迟也可能增加再灌注出血风险。此外，行支架植入术的患者均应用抗血小板药物，也可能是导致症状性颅内出血的重要原因。

综上所述，Solitaire AB可回收支架用于颅内前循环大动脉闭塞致急性缺血性卒中血管内治疗安全、有效，首次机械取栓后血管再通不理想或者血管再狭窄或闭塞行支架植入术作为补充治疗效果较好。本研究尚存很多不足之处：术前缺少充分的多模态影像学检查，对患者可能存在的缺血半暗带区评价不全面；院内外转运过程不顺畅，使患者发病至血管再通时间相对较长，对于缩短血管再通时间方面仍有潜力改进。尽管多项大样本临床试验证实新型可回收支架在机械取栓中取得可喜成果，但对可回收支架疗效及其在不同发病机制致急性缺血性卒中患者治疗中表现出来的差异，尚待进一步深入研究；此外，新型可回收支架的中远期疗效也要进一步评价。

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The 23rd World Congress of Neurology

Time: September 16–21, 2017

Venue: Kyoto, Japan

Website: www.2017.wcn-neurology.com

The 23rd World Congress of Neurology (WCN 2017) will take place in Kyoto, Japan on September 16–21 2017, cohosted by the Japanese Society of Neurology (JSN), Societas Neurologica Japonica, and Asian and Oceanian Association of Neurology (AOAN). The theme of WCN 2017 will be "Defining the Future of Neurology".

Founded originally in 1902, the JSN has evolved into a large society with 8579 members. Initially a combined neurology and psychiatry association, the current JSN separated in 1959 and continued to flourish ever since. It was the 12th WCN meeting held at Kyoto in 1981 that greatly contributed to the development of JSN and AOAN. Therefore, WCN 2017 which is being held at the very same venue would be a very historic meeting which will again serve as a springboard to strongly advance the Asia Initiative of World Federation of Neurology (WFN) for worldwide advancement of neurology in both scientific and clinical aspects, thus "Defining the Future of Neurology". You can participate in very active discussions and cutting-edge lectures by the world´s top scientists and neurologists including three Nobel laureates as well as hear all the advances of scientific and clinical neurology. Gene therapy and stem/induced pluripotent stem (iPS) cell medicine are such examples on the one hand and brain-machine-interface, information technology and robotics in care and rehabilitation on the other. Neurology related to environmental and disaster medicine will also attract many neurologists particularly in rapidly developing counties.

The Local Organizing Committee of JSN in close collaboration with the WFN looks forward to welcoming you in Kyoto for WCN 2017.