

血管成形术治疗症状性重度颈动脉狭窄的临床研究

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摘要: **目的** 探讨颈动脉内膜剥脱术(carotid endarterectomy, CEA)和颈动脉支架成形术(carotid artery stenting, CAS)治疗症状性重度颈动脉狭窄的近期和中期临床效果。**方法** 回顾性地分析了2016年1月至2018年12月在我院接受CEA或CAS治疗的203例症状性重度颈动脉狭窄患者的临床资料,分析两种术式的围手术期及中期并发症情况。**结果** 共纳入症状性重度颈动脉狭窄患者203人,分为CAS组($n=132$)与CEA组($n=71$),术后随访时间为1y。统计学分析患者在年龄、性别、危险因素、血压等方面均无统计学差异($P>0.05$)。围术期并发症分析中显示,CEA组颈部肿胀3例($P=0.017$);CAS组30d内卒中比例明显高于CEA组($P=0.034$)。1y随访结果分析显示,CAS组再狭窄比例明显高于CEA组($P=0.047$);在心肌梗死、死亡、脑卒中方面两组间无明显统计学差异。**结论** CAS与CEA均可安全有效的治疗症状性重度颈动脉狭窄,围术期并发症方面CEA组颈部肿胀明显高于CAS组,CAS组30d内卒中及1y再狭窄比例明显高于CEA组。

关键词: 症状性重度颈动脉狭窄; 动脉内膜剥脱术; 颈动脉支架植入术

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Treatment of symptomatic severe carotid artery stenosis by angioplasty: clinical trial CHEN Xiao, SU Jing, ZHANG Shizhong, et al. [Shandong First Medical University(Shandong Academy of Medical Sciences), Taian 271000, China]

Abstract: **Objective** To investigate the feasibility and efficacy of carotid endarterectomy and carotid artery stenting in the treatment of symptomatic severe carotid stenosis. **Methods** Retrospectively analyzed 203 patients with symptomatic severe carotid artery stenosis who received CEA or CAS treatment in Taishan Affiliated Hospital of Shandong First Medical University hospital from January 2016 to December 2018, The postoperative complications, and 1 year follow-up outcomes were recorded. Results A total of 203 patients with symptomatic severe carotid stenosis were included, and they were divided into the CAS group ($n=132$) and the CEA group ($n=71$). There were no statistically significant differences in age, gender, risk factors, blood pressure, etc. ($P>0.05$). In the analysis of perioperative complications, there were 3 cases of neck hematoma in CEA group ($P=0.017$). The proportion of stroke within 30 days in the CAS group was significantly higher than that in the CEA group ($P=0.034$). **Results** Of 1-year follow-up showed that the restenosis rate of CAS group was significantly higher than that of CEA group ($P=0.047$). There was no significant difference between the two groups in terms of myocardial infarction, death and stroke. **Conclusion** Both CAS group and CEA group can safely and effectively treat symptomatic severe carotid artery stenosis. In terms of perioperative complications, neck swelling in the CEA group was significantly higher than CAS group, and the proportion of stroke within 30 days and restenosis within 1-year flow up in the CAS group was significantly higher than that in the CEA group.

Key words: Symptomatic severe carotid artery stenosis; Carotid endarterectomy; Carotid artery stenting

颈动脉狭窄是导致缺血性脑卒中的独立危险因素。对于有症状的颈动脉狭窄,早期血运重建可有效预防同侧卒中^[1]。现有血运重建方式分为颈动脉内膜剥脱术(CEA)和颈动脉支架植入术(CAS)。自1951年首例CEA成功以来,已经证明CEA是治疗颈内动脉狭窄及缺血性脑血管疾病的有效手段。随着颈动脉内膜剥脱手术例数不断增多,技术日趋完善,近十年更被誉为治疗颈动脉狭窄的“金标准”。与颈动脉内膜剥脱相比,颈动脉支架植入术的发展历史较短,但同样被证实是治疗颈动脉狭窄的有效手段。因此血运重建方式的选择一直备受关注,但尚存在争议。EVA-3S, SPACE, ICSS, 和

CREST等研究未得出CEA或CAS更有利的证据^[2-7]。但是CAS作为后起之秀在我国应用广泛,技术也不断发展,近几年有研究者提出了分期血管成形术(SAP)^[8,9]、栓塞保护系统^[10],以及各种药物^[11,12]的应用,都是CAS的安全性的到发展。因此

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本研究针对 2016 年以来我院收治的症状性重度颈动脉狭窄患者作出回顾性分析,以探究 CEA 与 CAS 的选择。

1 对象与方法

1.1 研究对象 回顾分析 2016 年 1 月 - 2018 年 12 月于泰安市中心医院收治且完成术后随访 1 y 的症状性重度颈动脉狭窄患者 203 例。所有患者均由神经内科、神经外科及血管外科医生会诊确定均有典型的颈动脉区域缺血性症状包括对侧面部、手臂或腿部无力,或两者兼有;面部、手臂或腿或两者的对侧感觉缺失或感觉异常;或暂时性同侧盲(黑蒙)等症状。由门诊颈动脉彩超、计算机断层扫描血管造影计算机断层扫描血管造影术(Computed Tomographic angiography, CTA)和(或)数字减影血管造影(Digital Subtraction angiography, DSA)证明为重度狭窄(70% ~ 99%),照治疗方法分为 CEA 组和 CAS 组。

1.2 方法 CAS 组患者术前口服阿司匹林(100 mg, qd)和氯吡格雷(75 mg, qd)至少 1 w。手术均行局部麻醉,行股动脉穿刺,肝素华后行患侧颈动脉及脑血管造影,根据狭窄长度及具体位置选择合适角度,给予球囊扩张,在导引导管支撑下导丝顺利通过患侧颈动脉狭窄段,沿导引导管引入保护伞,顺利通过狭窄段,将保护伞置于颈内动脉远端,打开保护伞,置入支架。使用球囊扩张狭窄部位,后再次造影显示患侧颈内动脉近段狭窄情况得到明显改善,回收脑保护装置。术后复查 CT 未见出血,继续服用双抗 + 阿托伐他汀钙 3 m。3 m 后停用氯吡格雷。继续阿司匹林 100 mg, qd。

CEA 组:患者术前口服阿司匹林(100 mg, qd)至少 1 w,全身麻醉。取胸锁乳突肌前缘直切口,沿标记线依次切开皮肤、皮下,颈阔肌,置显微镜,沿胸锁乳突肌前缘钝性分离出颈内静脉,颈动脉鞘,依次暴露颈总动脉、颈外动脉、颈内动脉。全身肝素化后,依次阻断颈内动脉、颈外动脉和颈总动脉,纵行切开颈总动脉末端以及颈内动脉起始端,显微镜下完全剥离、切除颈内动脉内膜及斑块,肝素盐水反复冲洗血管腔,严密缝合动脉切口,依次释放颈外动脉、颈总动脉、颈内动脉,无渗血,缝合颈动脉鞘,鞘外放置引流管 1 根,逐层缝合切口。术后 24 h 内复查 CT,无明显颈部出血,给予每日口服阿司匹林 100 mg。

统计两组患者一般资料,包括:患者年龄、性别、伴随疾病(高血脂、高血压、糖尿病、既往心血管疾病、既往冠状动脉成型术)、吸烟史、术前血压等患者基线资料。其中伴随疾病均有相关会诊医师确诊并指导用药,吸烟史包括已戒烟或正在吸烟。

统计两组围术期及 30 d 并发症,包括脑高灌注综合征(cerebral hyperperfusion syndrome CHS)、切口/穿刺点感染、切口/穿刺点血肿、颅神经损伤、死亡、急性心肌梗死、缺血性脑卒中;统计术后 1 y 内出现的不良反应,包括:死亡、再狭窄、心肌梗死、脑卒中。本研究中 CHS 评价标准为:(1) cea 后 30 d 内;(2)高灌注的证据(TCD、SPECT 或 CT/MR 灌注成像)或 sBP > 180 mmHg;(3)新发头痛、癫痫、偏瘫、格拉斯哥昏迷评分(GCS) < 15 或脑水肿、脑出血等影像学表现;(4)无新发脑缺血、术后颈动脉闭塞及代谢或药理学原因的证据^[13]。

1.3 随访 所有患者术后都会被严密监护各项生命体征,以及术后 30 d, 3 m, 6 m 及 1 y 通过门诊或者电话随访,记录 1 y 内随访资料。复查包括神经系统查体、双侧颈动脉彩色多普勒等。

1.4 统计学结果分析 整理的临床数据资料经 SPSS 22 软件进行统计学分析。计数资料采用百分率(%)表示,行 χ^2 检验;计量数据以 $\bar{x} \pm s$ 表示;行 *t* 检验。 $P < 0.05$ 为差异具有统计学意义。

2 结果

2.1 一般资料 2016 年 1 月 - 2018 年 12 月于泰安市中心医院收治且完成术后随访 1 y 的症状性重度颈动脉狭窄患者 203 例, CAS 组 132 例与 CEA 组 71 例,手术均顺利进行, CEA 组与 CAS 组在年龄、性别、危险因素(高血脂、高血压、糖尿病、吸烟、既往心血管疾病、既往冠状动脉成型术)、术前血压等方面无统计学差异($P > 0.05$)(见表 1)。

2.2 围术期并发症及 30 d 随访结果 其中 CAS 组术后两组共出现 CHS 患者 3 例(2.3%),自诉轻度头痛,对症治疗后恢复满意; CAS 组出现 8 例卒中(6.1%),具体表现为轻度眩晕及手术同侧肢体感觉异常,均为轻症,对症治疗后病情稳定,未出现明显后遗症。

CEA 组 CHS 患者 1 例(1.4%),以头痛为主要症状; CEA 组出现 3 例颈部肿胀患者(4.3%),肿胀程度较轻,给予动态观察,均未行 2 次手术干预,恢复良好; CEA 组出现 1 例颅神经损伤(1.4%),具体表现为声音嘶哑; CEA 组术后因心肌梗死死亡 1 例(1.4%)。

CEA 组在间切口/穿刺点血肿发生率方面明显高于 CAS 组($P = 0.017$),两组间差距有统计学意义; CAS 组 30 d 缺血性脑卒中发生率明显高于 CEA 组($P = 0.034$),两者间有统计学差异;其余 CHS、切口/穿刺点感染、颅神经损伤、死亡、急性心肌梗死发生率均无统计学差异(见表 2)。

2.3 1 y 随访结果 CAS 组术后失访 19 例,其

余随访患者行彩超检查,再狭窄 14 例,心肌梗死 5 例,脑卒中 9 例;CEA 组失访 9 例(围术期死亡 1 例),再狭窄 2 例;心肌梗死 1 例;脑卒中 4 例。再狭

窄患者未诉明显狭窄症状,均予以动态观察,未行二次手术治疗;卒中病例中未见死亡或者严重致残者(见表 3)。

表 1 CEA 与 CAS 组一般情况对比

特征	CAS	CEA	t 值/ χ^2	P 值
性别			0.047	0.829
男	110(83.3%)	60(84.5%)		
女	22(16.7%)	11(15.5%)		
年龄	66.09 ± 7.14	65.48 ± 6.33	0.605	0.546
危险因素				
高血脂	12(9.1%)	9(12.7%)	0.640	0.424
高血压	91(68.9%)	46(64.8%)	0.362	0.547
糖尿病	42(31.8%)	20(28.2%)	0.290	0.590
吸烟	55(41.7%)	37(52.1%)	2.033	0.154
既往心脑血管疾病	72(54.1%)	41(57.7%)	0.244	0.621
既往冠脉成型	9(6.8%)	4(5.6%)	0.100	0.752
术前血压				
收缩压	149.60 ± 16.95	145.39 ± 16.87	2.113	0.090
舒张压	79.74 ± 10.67	79.35 ± 10.312	0.248	0.804

表 2 30 d 内 CAS 组与 CEA 组围术期并发症比较

	CAS(n=132)	CEA(n=71)	χ^2	P 值
CHS	3(2.3%)	1(1.4%)	1.730	0.678
切口/穿刺点感染	0	0	-	-
切口/穿刺点血肿	0	3(4.3%)	5.661	0.017
颅神经损伤	0	1(1.4%)	1.882	0.170
死亡	0	1(1.4%)	1.882	0.170
急性心肌梗死	0	1(1.4%)	1.882	0.170
缺血性脑卒中	8(6.1%)	0(0)	4.480	0.034

表 3 CAS 组与 CEA 组 1 y 随访终点比较

主要终点	CAS(n=113)	CEA(n=61)	χ^2	P 值
死亡	0	0(0)	-	-
再狭窄	14(12.4%)	2(3.3%)	3.938	0.047
心肌梗死	5(4.4%)	1(1.6%)	0.923	0.337
脑卒中	9(8%)	4(6.6%)	0.113	0.736

3 讨论

据有 2015 美国心脏协会统计结果显示^[14],虽然脑卒中的发生率有所下降但是整体负担依然很重,而颈动脉狭窄是造成脑卒中的重要因素之一。虽然早期有大型随机临床试验^[15]发现,CEA 是严重症状性颈动脉狭窄的标准治疗方法,但早期各个临床研究如 CARESS、LEICESTER、SPACE 等^[6,16,17]没有同一标准,如未将纳入心肌梗死作为终点,且没有

常规应用血栓保护装置,但后续研究发现 CAS 后发生围手术期心肌梗死的风险为 0.75%,CEA 后发生围手术期心肌梗死的风险为 1.87%^[18],且 CEA 术后的心肌梗死比 CAS 术后更常见并且与较高的晚期死亡率相关^[19,20],因此各个实验纳入终点及得出结论都不尽相同。ACT 临床试验在包括长达 5 y 随访的分析中,两组之间在非手术相关卒中、所有卒中以及存活率方面的比率上没有显著差异^[21];CREST 实

验中^[22]有症状或无症状颈动脉狭窄的患者中,CAS组和CEA组的卒中、心肌梗死或死亡的综合主要结局的风险没有显著差异,但在围手术期,CAS有较高的卒中风险,CEA有较高的心肌梗死风险。

本研究中CEA组在切口/穿刺点血肿发生率方面明显高于CAS组;CAS组30d缺血性脑卒中发生率明显高于CEA组。CHS、切口/穿刺点感染、颅神经损伤、死亡、急性心肌梗死发生率均无统计学差异。1y随访结果显示CAS组再狭窄发生率明显高于CEA组,而在死亡、再狭窄、心肌梗死、脑卒中方面无明显差异。

急性脑卒中是颈动脉血管重建术中的主要并发症,确定CEA或CAS的术后卒中特征可能减少包括卒中在内的围手术不良事件的发生率^[23,24]。有研究显示在CAS后(24±2)h的MR成像中,27例患者中有6例(22%)在同侧大脑中动脉(middle cerebral artery, MCA)范围内出现了13个新的扩散加权核磁共振成像(diffusion-weighted MR imaging, DWI)病变;27例患者中有1例在对侧半球出现了新的DWI病变,另1例在小脑内^[25]。Karpenko等^[26]的临床研究发现在症状性患者的亚组分析中,CAS组和CEA组30d的卒中率有显著性差异(7.5% vs 2.5%, $P=0.04$),另有大型国际研究的长期随访结果也显示,在有症状的颈动脉狭窄患者中,CAS比CEA术后更容易发生非致残性卒中,而长期随访结果无明显差距^[27-29]。本研究中CAS组术后30d卒中8例(6.1%),CEA组术后30d内卒中患者,两组间有显著差异。而1y随访结果显示无统计学差异。经颅多普勒(TCD)监测显示,脑微栓塞的患病率比内膜切除术时高出8倍以上^[30],因此微栓子的产生或许是CAS30d内卒中发生率较高的原因,但是仍需更多研究。

再狭窄也是血管成型术后并发症之一。颈动脉和椎动脉腔内血管成形术研究(CAVATAS)^[31]显示CAS后再狭窄的发生率是CEA的3倍,并与同侧复发性脑血管症状有关,但是在此研究中大多数患者随机分配到血管内治疗后仅行球囊扩张,并未放入支架,因此此实验结果不足以比较CAS与CEA之间再狭窄的发生率。在EVA-3S研究^[32]中患者行CEA术与CAS的对比显示,在CAS与CEA术后2y超声检查显示颈动脉狭窄复发率显著高于CEA。本研究中1y随访再狭窄患者中无重度(>70%)狭窄患者,但是CAS术后中度狭窄(50%~70%)发生率明显高于CEA组。有研究表明,再狭窄通常发生在术后早期,一般程度较低,很少有症状^[33]。内膜切除术后约2y的再狭窄通常被认为是新生内膜增生所致,而反复发作的动脉粥样硬化则被认为是导致

再狭窄的原因^[34-36],新生内膜增生和平滑肌细胞增生也见于腔内治疗后出现再狭窄症状的患者^[37],而晚期糖酵解的最终产物促进血管壁肌肉细胞的增殖、粘附和迁移,可导致内膜增生再狭窄^[38]。Dakour-Aridi等^[39]研究发现CAS术后再狭窄的预测因素包括颈总动脉病变,而年龄和支架置入后扩张与2y后再狭窄的减少有关。因此糖尿病、狭窄位置、残余狭窄和患者的卒中史也是造成术后在狭窄的可能因素^[40]。本研究随访期1y,两种术式的术后再狭窄情况需更长时间的随访研究。

4 结论

CAS与CEA均可安全有效的治疗症状性重度颈动脉狭窄,围术期并发症方面CEA组颈部肿胀明显高于CAS组,CAS组30d内卒中比例明显高于CEA组。1y随访结果显示CAS组再狭窄比例明显高于CEA组,而在死亡、心肌梗死、脑卒中方面无明显统计学差异。

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