

帕金森病脑深部电刺激术安全性长期随访研究

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【摘要】 **目的** 探讨脑深部电刺激术治疗帕金森病的长期安全性,以规范操作步骤。**方法** 采用脑深部电刺激术治疗 362 例帕金森病患者,共植入 613 根电极,记录围手术期和最后一次随访时手术相关和硬件相关并发症。**结果** 围手术期并发症中术后嗜睡和谵妄 21 例(5.80%),颅内出血 4 例(1.10%, 2 例为无症状性皮质少量出血、2 例为基底节穿刺针道周围少量出血),全面性强直-阵挛发作 2 例(0.55%),尿路感染 4 例(1.10%),呼吸系统感染 7 例(1.93%),胸部脉冲发生器囊袋内血肿 11 例(3.04%),脉冲发生器囊袋内血清肿 3 例(0.83%),均经治疗后痊愈出院。术后随访 12~146 个月,中位值 34 个月,硬件相关并发症中切口感染和(或)皮肤破溃 9 例(2.49%),脉冲发生器移位致延长线断裂、脉冲发生器固定线断裂致下移至腹部、因摔倒致电极轻度移位、自觉耳后切口肿胀不适各 1 例(0.28%)。**结论** 脑深部电刺激术治疗帕金森病长期安全性良好。

【关键词】 帕金森病; 深部脑刺激法; 随访研究

Long-term follow-up study on the safety of deep brain stimulation for treating Parkinson's disease

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【Abstract】 **Objective** To evaluate the safety of deep brain stimulation (DBS) for treating Parkinson's disease (PD) under long-term follow-up and modify the surgical procedure. **Methods** A total of 362 PD patients underwent DBS, and almost 613 electrodes were implanted into these patients. Both surgical and hardware-related complications of DBS were retrospectively analyzed. **Results** Perioperative complications included postoperative confusion or delirium in 21 cases (5.80%), intracranial hemorrhage in 4 cases (1.10%; 2 asymptomatic cortical microhemorrhage and 2 basal ganglia trajectory microhemorrhage), generalized tonic-clonic seizures (GTCS) in 2 cases (0.55%), urinary tract infection in 4 cases (1.10%), pulmonary infection in 7 cases (1.93%), implantable pulse generator (IPG) hematoma in 11 cases (3.04%), IPG seroma in 3 cases (0.83%). All these patients were cured. They were followed-up for 12-146 months (median 34 months). Hardware-related complications included infection of incisional wound and/or skin erosion (9 cases, 2.49%), extension wire fracture caused by IPG displacement (one case, 0.28%), IPG shifting to abdomen due to fixation wire fracture (one case, 0.28%), slightly migrated electrode due to fall (one case, 0.28%), and discomfort about occipital incision (one case, 0.28%). **Conclusions** The overall risk of both surgical and hardware-related adverse events of DBS for treating PD is acceptably low.

【Key words】 Parkinson disease; Deep brain stimulation; Follow-up studies

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脑深部电刺激术(DBS)对帕金森病(PD)患者症状波动和药物所致异动症具有良好疗效^[1-3]。术前严格掌握手术适应证和将电极准确植入预定靶

点,是保证术后良好疗效的关键^[4],对手术相关和硬件相关并发症至关重要^[5-6],亦可减低病死率^[7]。我国应用脑深部电刺激术治疗帕金森病的病例数居世界首位,但缺乏针对术后安全性评价的长期随访研究^[8]。近 10 余年来,第二军医大学长海医院神经外科采用脑深部电刺激术治疗 362 例帕金森病患者,并对手术相关和硬件相关并发症进行随访,现总结报告如下。

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资料与方法

一、临床资料

1. 纳入标准 (1) 帕金森病的诊断符合英国帕金森病学会脑库帕金森病临床诊断标准。(2) 既往复方左旋多巴疗效良好。(3) 抗帕金森病药物疗效明显下降或出现严重症状波动或异动症, 影响生活质量。(4) 本研究经第二军医大学长海医院道德伦理委员会审核批准, 所有患者知情同意并签署知情同意书。

2. 排除标准 (1) 痴呆和严重精神疾病患者。(2) 特发性震颤(ET)、肌张力障碍、扭转痉挛(TD)、抽动秽语综合征(TS)患者。(3) 有明显脑萎缩或颅内肿瘤患者。(4) 有基础疾病且预期寿命不超过 1 年患者。

3. 一般资料 选择 2003 年 1 月-2014 年 2 月在第二军医大学长海医院神经外科采用脑深部电刺激术治疗的帕金森病患者共 362 例(613 根), 男性 193 例, 女性 169 例; 年龄 36~78 岁, 平均(62.31 ± 7.01) 岁; 病程 5~21 年, 中位病程 9 年。脑深部电刺激术以丘脑底核(STN)为靶点植入电极 590 根, 以苍白球内侧部(GPi)为靶点植入电极 19 根, 以丘脑腹中间核(Vim)为靶点植入电极 4 根。

二、研究方法

1. 手术器材 植入电极和可植入脉冲发生器(IPG)均为美国 Medtronic 公司产品, 其中, 3389 型脑深部电极 601 根、3387 型脑深部电极 12 根, KINETRA 7428 型双通道脉冲发生器 251 个、SOLETRA 7426 型单通道脉冲发生器 111 个。

2. 手术方法 采用国际标准化操作流程^[9], 术前 72 h 将患者抗帕金森病药物按左旋多巴等效剂量公式换算为多巴丝肼, 直至手术当日清晨停药。术中于局部麻醉下固定在 Cosman-Roberts-Wells 立体定位头架, 行 MRI 扫描, 通过 T₂WI 所示的神经核团形态或解剖学坐标进行刺激靶点定位, 并计算靶点坐标。然后植入颅内电极, 先予粗刺激观察患者运动症状改善情况和不良反应, 确定电极在预定靶点后, 将电极线埋置头皮下。复查 MRI 以确定电极位置是否准确。最后于全身麻醉下植入胸部脉冲发生器并将整个电路系统连接, 其中脉冲发生器固定于锁骨下, 延长线接头固定于颞顶部磨钻磨出的颅骨凹槽内。可吸收缝线连续缝合帽状腱膜和皮下组织, 间断缝合皮肤。术后恢复用药类型和剂

量。术后 1 个月, 启动脉冲发生器并设置刺激参数, 逐渐减少并停用苯海索, 多巴丝肼、卡比多巴/左旋多巴自然减量, 并逐渐以非麦角类多巴胺能受体激动剂替代左旋多巴, 使抗帕金森病药物与电刺激协同作用, 逐渐调整刺激参数, 以获得最佳综合治疗效果。

3. 围手术期并发症评价 记录患者围手术期和最后一次随访时手术相关并发症和硬件相关并发症。手术相关并发症指围手术期和术后 14 d 内发生的嗜睡或谵妄、颅内电极位置错误、颅内出血、脑缺血、硬膜下积液、皮下出血或血肿、脑脊液漏等; 硬件相关并发症指术后 14 d 发生的切口感染、皮肤破溃、颅内电极移位、电极线或延长线断裂、脉冲发生器突然失用等^[6]。术后嗜睡和谵妄的评价采用 Richmond 躁动-镇静量表(RASS)和重症监护病房意识障碍评价量表(CAM-ICU)。

结 果

手术相关并发症中术后嗜睡和谵妄发生率最高, 达 5.80%(21/362), CT 检查均未见颅内出血、脑缺血和张力性气颅, 其中 17 例于术后 3 d 内意识恢复、4 例于术后 2 周内完全恢复清醒; 颅内出血发生率约为 1.10%(4/362), 其中 2 例为无症状性皮质微小出血、2 例为基底节穿刺针道少量出血, 均出现短暂性肌力下降, 经保守治疗后恢复良好; 全面性强直-阵挛发作(GTCS)发生率约为 0.55%(2/362), 发作时无先兆, 其中 1 例仅发作 1 次, 予以丙戊酸钠 400 mg 静脉注射和 1200 mg 微量泵(2 ml/h), 持续 72 h 后改为丙戊酸钠缓释片 500 mg(2 次/d)口服, 未再发作; 1 例术中植入单侧电极, 术后出现癫痫持续状态(SE), CT 检查未见颅内出血, 予丙泊酚镇静以及丙戊酸钠注射液微量泵和卡马西平胃管注入联合抗癫痫治疗 2 d 后, 意识恢复, 此后长期服用丙戊酸钠缓释片, 未再发作; 尿路感染发生率约为 1.10%(4/362); 呼吸系统感染发生率约为 1.93%(7/362); 脉冲发生器囊袋内血肿发生率约为 3.04%(11/362)、脉冲发生器囊袋内血清肿发生率约为 0.83%(3/362), 经沙袋(500 g)压迫止血和穿刺抽吸后血肿自行吸收(表 1)。

本组患者随访 12~146 个月, 中位值 34 个月。硬件相关并发症中切口感染和(或)皮肤破溃发生率最高, 达 2.49%(9/362), 最早发生于术后 6 周、最晚为术后 31 个月, 其中 6 例经抗生素治疗、局部换

表 1 脑深部电刺激术治疗帕金森病的手术相关并发症发生率[例(%)]

Table 1. Occurrence rate of surgical complications of DBS for treating PD [case (%)]

Surgical complication (< 14 d)	N	No. of patients
Delayed wound healing	362	1 (0.28)
Incision infection	362	0 (0.00)
Cerebrospinal fluid fistula	362	0 (0.00)
Intracranial infection	362	0 (0.00)
Epilepsy	362	2 (0.55)
Postoperative confusion or delirium	362	21 (5.80)
Asymptomatic cortical hemorrhage	362	2 (0.55)
Symptomatic cortical hemorrhage	362	0 (0.00)
Subdural hematoma	362	0 (0.00)
Epidural hematoma	362	0 (0.00)
Basal ganglia trajectory hemorrhage	362	2 (0.55)
Subarachnoid hemorrhage	362	0 (0.00)
Pulmonary infection	362	7 (1.93)
Urinary tract infection	362	4 (1.10)
Extension wire hemorrhage	362	0 (0.00)
Lead malposition	362	0 (0.00)
IPG hematoma	362	11 (3.04)
IPG seroma	362	3 (0.83)

IPG, implantable pulse generator, 脉冲发生器。The same for the table below

表 2 脑深部电刺激术治疗帕金森病的硬件相关并发症发生率[例(%)]

Table 2. Occurrence rate of hardware - related complications of DBS for treating PD [case (%)]

Hardware-related complication	N	No. of patients
Electrode malfunction	362	0 (0.00)
Electrode migration	362	1 (0.28)
Electrode fracture	362	0 (0.00)
Lead extension wire migration	362	1 (0.28)
Lead extension wire fracture	362	1 (0.28)
IPG malfunction (except battery depletion)	362	0 (0.00)
Incision infection or erosion not requiring debridement	362	6 (1.66)
Incision infection or erosion requiring debridement	362	3 (0.83)
Discomfort about occipital incision	362	1 (0.28)

药和缝合获得痊愈,2例需手术取出感染部件待感染控制后6个月再次植入相关部件,1例(0.28%)发生电极线周围感染,取出电路系统后感染治愈,未再植入电路系统;脉冲发生器移位致延长线断裂和脉冲发生器固定线断裂致下移至腹部各1例(0.28%),重新植入或复位;1例(0.28%)摔倒后出现右侧肢体电刺激效果减退,经头部CT显示左侧颅内

电极位置较前浅1~2mm,但无明显异位,重新调整刺激参数后,电刺激效果恢复;1例(0.28%)自觉耳后切口肿胀不适,随访7年无感染破溃征象(表2)。

讨 论

研究显示,脑深部电刺激术具有良好安全性,标准化的手术操作流程可在一定程度上减少并发症的发生^[10]。但手术相关并发症发生率在不同医疗中心、不同手术专业组之间有较大差异,与手术医师的经验和技巧密切相关^[11]。

本研究结果显示,脑深部电刺激术围手术期并发症发生率最高的是术后嗜睡和谵妄,与既往研究结果相似^[12-14]。术后嗜睡和谵妄是老年患者的常见并发症,发生率约为14.70%^[15],而本研究术后嗜睡和谵妄发生率仅为5.80%(21/362)。术后嗜睡和谵妄的影响因素较多,如双侧电极是否同时植入、术前有无认知功能障碍^[9]、是否为高龄患者^[16]、电极轨迹是否穿过脑室^[17]等。为了预防或减少术后嗜睡和谵妄的发生,临床工作中须严格掌握以下几点:(1)严格掌握手术禁忌证,对于智力下降或伴脑萎缩的患者婉拒手术要求。(2)尽可能术前不应用苯二氮草类镇静药。(3)采用脑电双频指数(BIS)检测麻醉深度,予最低剂量的麻醉药物并缩短麻醉时间。(4)存在高危风险的患者予分期手术,先于局部麻醉下植入双侧脑深部电极,3天后再于全身麻醉下植入胸部脉冲发生器。

本研究颅内出血发生率约为1.10%(4/362),远低于早期文献报道^[7,18-23],略低于近期发表的大样本临床研究^[13],究其原因,可能是采取了以下措施:(1)围手术期血压平稳^[24]。(2)尽可能使用可视化神经核团定位以减少微电极穿刺^[25]。(3)切开皮质前先行局部皮质电凝,使软脑膜与蛛网膜粘连,从而使拟穿刺皮质的局部蛛网膜下隙消失,而后切开软脑膜和皮质,电凝止血后再缓慢旋转插入湿润过的套管针,尽可能使穿刺轨迹避开侧脑室,从而减少侧脑室开放和穿刺过程中对皮质内血管产生的牵拉作用。

本研究有3例早期行脑深部电刺激术治疗的患者,均发生脉冲发生器囊袋内血清肿,予以沙袋(500g)压迫12小时后未再出现,也未出现压迫引起的切口愈合不良。提示术后予以切口短时间的局部沙袋压迫,可以在一定程度上预防此类并发症的发生^[11]。

有文献报道,术后电极线断裂发生率高达 15.20%^[19],随着手术医师经验的提高,这一并发症发生率逐步下降至 2%^[20,22-23,26-27],延长线断裂发生率为 1%~3%^[11,18,22],本研究仅为 0.28%(1/362)。推测延长线和脉冲发生器移位可能来自脉冲发生器的重力,但并未导致线路断裂。因此,我们将脉冲发生器固定于锁骨下以减少线路张力,并在颞顶部颅骨上磨钻磨出骨槽以固定延长线,进一步降低线路张力^[9]。自此,电极线断裂和延长线断裂的发生率明显降低,并被清华大学研究团队经临床试验所证实^[28]。

切口感染和(或)皮肤破溃的发生率在不同医疗中心差异较大,与随访时间有关,因为很多皮肤破溃发生于术后数年。有文献报道其发生率高达 15.20%^[20],也有 5%~10%的报道^[19,22,27-28],目前大多数医疗中心可将其控制在 5%以内^[5,7,12,18,21,23,28-29]。本研究切口感染和(或)皮肤破溃发生率约为 2.49%(9/362)。若发生切口感染,应尽早处理,若感染扩散应取出植入物,待感染完全控制后 6 个月再次植入^[5]。影响切口感染的因素较为复杂,全身因素包括年龄、营养状况、血糖控制情况等,局部因素包括切口的准备与消毒、术后切口管理、皮下植入物对皮肤的压迫、切口张力和血供等。因此,需全面妥善的管理才能降低感染发生率。

综上所述,脑深部电刺激术具有良好的安全性,严格按照规范化操作,可显著降低手术相关和硬件相关并发症的发生。

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· 小词典 ·

中英文对照名词词汇(三)

- 巨细胞血管纤维瘤 giant cell angiofibroma(GCA)
 聚合酶链反应 polymerase chain reaction(PCR)
 抗癫痫药物 anti-epileptic drugs(AEDs)
 抗核抗体 anti-nuclear antibody(ANA)
 抗神经节苷脂抗体 anti-ganglioside antibody(AGA)
 抗双链 DNA 抗体 anti-double stranded DNA antibody(dsDNA)
 抗中性粒细胞胞质抗体 anti-neutrophil cytoplasmic antibody(ANCA)
 可提取性核抗原 extractable nuclear antigen(ENA)
 快速眼动睡眠期 rapideye movement(REM)
 快速自旋回波 turbo spin echo(TSE)
 扩散张量成像 diffusion tensor imaging(DTI)
 利钠肽受体 C natriuretic peptide receptor C(NPR-C)
 磷酸肌酸 phosphocreatine(PCr)
 颅脑创伤 traumatic brain injury(TBI)
 路易体痴呆 dementia with Lewy bodies(DLB)
 路易小体 Lewy body(LB)
 卵泡刺激素 follicle stimulating hormone(FSH)
 脉冲发生器 implantable pulse generator(IPG)
 毛黏液样型星形细胞瘤 pilomyxoid astrocytoma(PMA)
 毛细胞型星形细胞瘤 pilocytic astrocytoma(PA)
 梅毒螺旋体 treponema pallidum(TP)
 酶联免疫吸附试验 enzyme-linked immunosorbent assay(ELISA)
 美国国立卫生研究院 National Institutes of Health(NIH)
 美国脑肿瘤登记数据库 Central Brain Tumor Registry of the United States (CBTRUS)
 美国神经病学学会 American Academy of Neurology(AAN)
 美国食品与药品管理局 Food and Drug Administration(FDA)
 蒙特利尔认知评价量表 Montreal Cognitive Assessment(MoCA)
 迷走神经刺激术 vagus nerve stimulation(VNS)
 免疫固定电泳 immunofixation electrophoresis(IFE)
 Hidden Markov 模型 Hidden Markov Model(HMM)
 南非麻醉医师协会 South African Society of Anaesthesiologists(SASA)
 脑电双频指数 bispectral index(BIS)
 脑干听觉诱发电位 brainstem auditory-evoked potential(BAEP)
 脑桥小脑角 cerebellar pontine angle(CPA)
 脑深部电刺激术 deep brain stimulation(DBS)
 内侧前额叶皮质 medial prefrontal cortex(mPFC)
 内囊前肢 anterior limb of internal capsule(ALIC)
 扭转痉挛 torsion dystonia(TD)
 欧洲神经病协会联盟 European Federation of Neurological Societies(EFNS)
 帕金森病 Parkinson's disease(PD)
 皮质脑电图 electrocorticoencephalogram(ECoG)
 平滑肌肌动蛋白 smooth muscle actin(SMA)
 前额叶背外侧皮质 dorsolateral prefrontal cortex(DLPFC)
 腔隙性梗死 lacunar infarct(LACI)