

心脏植入电子装置的现状与挑战

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摘要

随着技术的进步和改进, 儿童心脏植入电子装置的应用逐渐普及和成熟。相较成人, 儿童心脏植入电子装置植入量少。为应对儿童生长发育需求, 心脏植入电子装置植入难度大, 适应症相对狭窄, 选择适当的脉冲发生器、起搏位点对儿童来说至关重要。经静脉心内膜电极植入, 是目前主导的起搏植入方式。但需面临起搏系统及囊袋感染、静脉闭塞、三尖瓣返流等并发症。近年新兴的无导线技术、皮下植入技术、远程监测系统持续为临床提供治疗思路。

关键词

心脏植入式电子装置, 儿童

The Current Status and Challenges of Cardiac Implantable Electronic Devices

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Abstract

With the advancement and improvement of technology, the application of electronic devices implanted in pediatric is gradually becoming more widespread and mature. Compared to adults, the implantation of electronic devices in pediatric is less frequent. To meet the needs of children's growth and development, the implantation of cardiac electronic devices presents greater difficulty

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and narrower indications. The selection of appropriate pulse generators and pacing sites is crucial for pediatric patients. Currently, intravenous endocardial electrode implantation is the dominant method for pacemaker implantation. However, this approach is associated with complications such as pacemaker system and pocket infection, venous occlusion, and tricuspid regurgitation. In recent years, emerging technologies including wireless techniques, subcutaneous implantation, and remote monitoring systems have provided continuous therapeutic options for clinical practice.

Keywords

Heart Implantable Electronic Device, Pediatric

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1. 引言

相对于成人儿童植入电子装置(CIED)的植入总量不到成人植入量的 1% [1] [2]。CIED 作为治疗心脏节律异常疾病等的重要手段，在临床应用越来越广泛。随着医疗技术的进步和发展，CIED 在儿童中应用也逐渐增多，本文就儿童 CIED 植入的现状、特点和展望做一系统综述，以期为临床治疗提供指导。

2. 儿童 CIED 临床特点

在心脏结构正常的儿童患者中，心脏传导阻滞可见于母胎抗体遗传或感染[3]，这些患者中大约 10% 将继续进展为心室肌不同步化或扩张性心肌病[4] [5]，在为儿童植入 CIED 时，需考虑入合并心力衰竭(心衰)且需长期起搏者，首先考虑是否需要生理起搏，心脏再同步化治疗的应用也有积极的效果。此外，还需关注儿童体重、长血管通路、是否有终身起搏的必要等[6] [7] [8]。在年轻患儿中，体型、解剖结构、血管尺寸、生长情况和已存在的起搏导线等，都会限制导线的植入。与儿童生长相关的导线问题和导线拔除的潜在风险是儿童人群比成年人群更令人关注的问题。

3. 儿童 CIED 植入途径选择

1) 针对儿童体重的差异，临床治疗在对起搏植入途径和电极植入部位的选择上应做出相应调整，具体方案如下：对于体重小于 10 kg 的儿童，心外膜电极是首选，起搏模式优先考虑 VVIR 模式。电极通常会被放置在左室心尖部。若心外膜植入困难或植入失败时，可以转为植入心内膜电极，并将电极置于右室间隔部。2) 当儿童体重介于 10 kg 至 20 kg 之间时，电极植入途径可以根据患儿的自身条件选择心外膜植入或心内膜植入，此时电极一般会置于左室心尖部。对于体重大于 20 kg 的儿童选择心内膜电极，起搏器电极可被放置在右室间隔部。如若患儿需要同时进行其他手术时，我们会选择心外膜电极，并将其放置在左室心尖部。起搏器电极经静脉穿刺植入，选择腋静脉及锁骨下静脉为穿刺静脉。脉冲发生器一般置于锁骨下区域，对于皮下组织薄的患儿，可将脉冲发生器置于胸大肌下，以防止起搏装置暴露或发生 Twiddler 综合征[9] [10]。

4. 起搏模式的选择

一般按患儿病情所需选择起搏器型号，正常儿童运动较静止时心排量增加 3~5 倍，选择时还要考虑

运动最低频率需求。心室按需起搏(VVI)、VVIR、双腔按需起搏(DDD)、双腔按需频率适应起搏(DDDR)是较为常见的几种起搏模式, 目前临床大多数儿童选择起搏模式为VVI, 实际上 DDDR 更适合儿童, 因为儿童的自我控制能力差。在完全性房室传导阻滞的幼儿中, 与单纯心室起搏相比, 房室同步的优势似乎仍然很小或不存在。因此, 在植入第一或第二台起搏脉冲发生器时, 为患儿植入单腔 VVIR 起搏器以后升级为双腔起搏装置是合理的。对于合并心功能不全的儿童, 应考虑将双腔起搏作为初始起搏模式。对于窦房结功能障碍且房室结传导完整或充分的患者, 应避免不必要的心室起搏, 应采用心房起搏来维持心率, 或者选择使用具备房室传导的起搏模式和算法, 以减少不必要的心室起搏比例。

5. 起搏部位的选择

在最接近正常传导系统的右心室部位(如 His 束区域、流入道区域[11]和间隔区域[12])植入左心室起搏电极(左束支区域和心尖部[13])有望维持或改善心肌收缩力。由于儿童的室间隔相比成人无论是长度和厚度都更小, 流入道或室间隔植入电极导线可接近传导系统起搏。然而, 由于较高的起搏阈值和更频繁的更换 His 束起搏在儿科患者的心脏起搏治疗策略中并非最优选[14]。儿童心室间隔中部和心尖部厚度尺寸与患者体重相关, 5 岁后室间隔厚度通常为 3~12 mm, 已达到经静脉植入起搏电极的年龄。在进行深间隔起搏或左束支区域起搏期间应预先确定室间隔厚度, 可以防止潜在并发症的发生。目前尚没有关于儿童“最佳起搏部位”, 右心室间隔与 His 束支区域或左束支起搏之间的比较研究。因此, 目前儿童传导系统起搏治疗必须考虑风险最小化、益处最大化的个体化治疗。

一项单中心对 14 例扩张性心肌病患儿 5 年长时间随访[15], 另一项多中心(103 个机构)对 16 例先天性心肌病患儿及 13 例先天性完全性房室传导阻滞患儿短时间随访(中位随访时间为 22 个月)[16], 表明升级双心室的 CRT, 可明显改善左心室功能, QRS 时限缩短、左室舒末容积缩小、临床症状改善。然而, CRT 对于 QRS 时限正常的患儿获益较小, 并且需选择激动最延迟部位植入电极, 可能不是先天性心脏病患儿的最佳解决方案[17]。Amanda 等人的一份包含 24 例患儿(先天性心脏病患儿 4 例)的单中心研究表明, 20 例患儿在性希氏束起搏治疗前射血分数正常, 随后所有这些患儿双心室功能继续正常。四例先心病患儿在围手术期观察到的射血分数至少改善了 5%~10%, 并在随后的超声心动图中保持了这种改善[18]。一项多中心横断面研究表明右室起搏部位对左室功能有较高的负面影响风险, 同时伴有明显的机械不同步和 EF 低下。右室侧壁和游离壁起搏最为明显, 对于右室心尖起搏则不那么明显[19]。一项多中心大规模回顾性研究证实, 选择性右室间隔部起搏可预防起搏引起的左室功能障碍, 但研究中出现有患儿在接受右室起搏后出现了在正常范围值内的 EF 值降低情况, 引起了心室电机械不全同步和室间机械延迟[20]。Silvetti 等人对 10 例先天性高度房室传导阻滞起搏器植入婴幼儿进行随访, 证实左心室起搏可以起到保护左心功能的作用[21]。另一项同期对照临床研究表明, 左心室心尖部心外膜起搏和右心室中间隔起搏在短期与中期随访中保持了先天性传导阻滞症患儿的左心室收缩力和同步性, 两组之间没有相关的显着差异[21]。

6. 术后并发症

6.1. 起搏系统感染

起搏系统感染是 CIED 植入最常见的并发症, 对儿童群体是最为严重的并发症之一。针对儿童 CIED 相关感染, 文献报道较少。囊袋感染发生率在一项单中心回顾针对 230 例植入与更换起搏器患儿的研究表明, 临床感染的发生率为 0.9% [22]。另一项纳入 36,104 患者的全国性队列研究表明, 起搏系统的导联特征对于起搏相关感染也有关系, 主动电极固定相较被动式电极固定更能降低相关术后感染[23]。对于导线的特征与起搏系统的相关感染风险由于抗生素的更新换代以及介入手术的愈见成熟, 报道的发病率为

0.9%~2.4% [24] [25]。对于起搏系统的感染, 目前治疗原则为拔除整个起搏系统[26], 需要持续性起搏治疗的则在规律抗菌治疗至三次血培养为阴性后在对侧植入起搏器, 并制作囊袋[27]。如若心内膜电极与心内膜组织粘连严重, 则需要在体外循环下行开胸手术取除起搏系统。

6.2. 静脉闭塞

为植入心内膜导线最主要的并发症, 目前经静脉植入起搏器后发生静脉闭塞的风险及危险因素仍存在争议, 植入患者血管直径大小、多导联放置[28]、左室射血分数(LVEF)≤40% [29]、心房颤动(房颤) [30]是最主要的危险因素。儿童在植入心内膜电极后发生完全静脉闭塞的发生率 13%, 部分性静脉闭塞的发生率为 12%, 并且该队列研究发现幼儿与老年患者静脉闭塞的发生率相似, 且年龄、体型、导线特征并不能明确预测静脉闭塞的发生[31]。Vos 等人针对 7 例植入起搏器患儿为期 14 年的随访研究发现其中 2 例患儿在术后随访过程中发生了左锁骨下静脉闭塞, 研究表明经静脉心内膜导线是患儿发生静脉闭塞的高风险因素[32]。一项针对 63 例经静脉植入心内膜电极患儿的研究中, 静脉闭塞的发生率为 21%, Figa 等认为和 INDEX (导线横断面与体表面积之比)与静脉闭塞存在相关性, 且存在静脉闭塞的儿童 INDEX 明显高于未发生静脉闭塞的儿童[33], 与性别、心胸比、左心房尺寸、左 LVEF、起搏器植入前的基础心脏病、起搏导线数量、体型方面无明显相关性[34]。虽然静脉闭塞主要发生在左无名静脉, 但上腔静脉闭塞仍然是静脉导联放置的严重并发症[35]。

6.3. 三尖瓣反流

在经静脉植入起搏器的患儿中导线通过三尖瓣, 超声心动图显示三尖瓣的反流变化很小, 但具有统计学意义, 检测到的变化很小, 表明经静脉心内膜导线对三尖瓣的影响很小。Webster 等考虑, 为适应儿童生长发育会预留一定导线, 将导线盘绕在心房或腔静脉, 会致三尖瓣功能障碍[36]。有报道称一例因三度房室传导阻滞植入永久起搏器患儿, 置入永久性起搏器导线后, 在收缩晚期出现 3~4/6 级持续性杂音, 随着吸气和直立姿势而增加, 起搏器导线干扰三尖瓣瓣环导致三尖瓣关闭不全, 超声心动图未见三尖瓣脱垂。拔除起搏器导线后听诊杂音立即消失[37]。因此在起搏器植入术中, 起搏导线在心室以及三尖瓣上盘圈时, 术后除了随访起搏器参数外因加强对患儿三尖瓣功能的监测。

6.4. 导线相关并发症

主要包括电极脱位、断裂、接触不良、感知不良、电极穿孔等。既往相关报道较少, 已报道的儿童起搏器植入术后电极相关并发症发病率为 15%~27% [38] [39] [40]。患儿生长发育、早期导线粘连是导致电极脱位的最主要原因。长时间的起搏治疗导致心内膜导线与心肌接触部位纤维化可导致感知不良, 电极导线与心肌或瓣膜间反复碰撞可导致电极脱位、接触不良。应在植入起搏器后定期检查起搏器相关参数, 以避免更换和拔除起搏器导线相关事件的发生。

7. 儿童 CIED 植入新技术

7.1. 无导线起搏植入技术

随着 Medtronic Micra (美敦力)和 Aveir (雅培)等公司无导线起搏器相关技术的发展, 无导线起搏器已有大量成人置入经验。无导线起搏器体积小, 能克服传统起搏技术并发症多等缺点, 已成为儿童起搏器植入的优先考虑。Siddeek 等人成功在 8 例患儿中植入无导线起搏器, 且在术后长达 3 年的随访中, 未见明显并发症, 起搏器工作良好[41]。为进一步挖掘无导线起搏器的潜在适应症, 扩大临床应用范围 Daniel 等人也成功地在动物实验中通过植入两个无导线起搏器, 并试图通过双无导线起搏器之间的无线通讯技

术达到同步起搏治疗的目的[42]。

7.2. 经皮下植入心律转复除颤器

经静脉植入心律转复除颤器(I-ICD)同样面临静脉闭塞, 起搏系统感染等严重并发症。皮下植入心律转复除颤器(S-ICD)目前已成为新型的植入型心律转复除颤技术。临床实验已证实其对心脏性猝死病人的安全性及有效性[43]。S-ICD 无需血管内及心内装置, 不易导致感染, 不易受制于儿童的生长发育, 因此更适用于年轻患者。但 S-ICD 也有其局限性, 即无心脏起搏功能。

7.3. 远程监测系统

相关远程监测系统逐渐进入临床应用, 不像传统起搏器程控需要到相关医院定期进行程控, 无法做到频繁及时地发现起搏器相关电池、阈值、阻抗的异常和起搏器故障并做出及时调整, 提高安全性。远程监控可及时发现起搏器不良事件, 现相关起搏器可支持蓝牙、手机 APP 互联、家长监测模式等, 定时收集相关数据, 及时向医师发送预警[44]。Zartner 等将 45 例植入起搏器的患儿进行了为期 1 年的数据收集与分析。从植入 CIED 日期为起始, 以一周为, 单位将定期发送 CIED 所记录的相关事件, 将收到的 666 项远程起搏器数据进行集中统计分析, 并根据紧急情况优先级筛选, 在为期 1 年的监控过程中, 中心共收到 113 条(17%)紧急事件, 并在 1 天时间内上报医院, 继续相关治疗, 及时发现问题并进行处理, 增加了 CIED 的安全性[45]。

总之, 随着儿童起搏器技术的日益发展与完善, 起搏器趋于体积小、质量轻、寿命长、智能化程度高, 使儿童植入起搏器的成功率高、安全有效、并发症少, 但儿童仍存在电池耗竭、感染、静脉闭塞等并发症。选择适当的电极、脉冲发生器、起搏位点以及术后定期随访对儿童患者仍然非常重要。

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