**EAU****男性性功能障碍指南之勃起功能障碍**

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# 1.介绍

## 1.1 目标

 本准则包括四个部分。前两节的目的是介绍勃起功能障碍（ED）和早泄（PE）患者诊断和治疗的当前证据。勃起功能障碍和PE是男性性药物的两个主要主诉[1,2]。药理学治疗完全改变了ED的诊断和治疗方法。

第三部分的目的是为执业泌尿科医生提供关于阴茎曲率诊断和治疗的最新证据，来协助他们做出决策。阴茎弯曲是一种常见的泌尿系统疾病，分为先天性和后天性两种。本指南简要讨论了下先天性弯曲，这种弯曲没有任何其他伴随的异常存在（如尿道异常），在成年人群中有明显的病理特征。对于儿科先天性阴茎弯曲，请参阅“儿科泌尿外科学指南”，先天性阴茎弯曲分析[3]。后天性弯曲主要是由于佩罗尼氏病引起，但也可能是由于阴茎骨折后纤维化的产生引起。

第四部分的目的是介绍患有阴茎异常勃起患者诊断和治疗的当前证据。阴茎异常勃起是一种病理状态，持续超过四个小时以上，或与性兴趣或性刺激无关，代表真正的阴茎勃起障碍[4]。总的来说，长达四个小时的勃起是被一致定义为“持续很久”的。异常勃起可发生在所有的年龄段。 一般人群中阴茎异常勃起的发生率较低（每10万人年0.5-0.9例）[5,6]。在有镰状细胞病的男性中，18岁以下男性的阴茎异常勃起的患病率高达3.6％[7]，18岁以上男性的增长率高达42％[8-11]。

 欧洲泌尿学协会的准则办公室（EAU）已任命了一个专家小组，来更新以前出版的ED，PE，阴茎弯曲以及阴茎异常的EAU指南。

 必须强调的是本临床指南为专家提供了最佳证据。但是，遵循指导方针的指导不一定会产生最佳的结果。在为个别患者做出治疗决定时，指南永远不能取代临床专业知识，而是可以帮助做出最佳决策，同时应考虑患者的个人价值观和偏好/个人情况。指南不是强制使用的，也不应该被视为法律的参照标准。

## 1.2 出版史

 第一个关于勃起功能障碍的EAU指南于2000年发布，随后在2001年，2002年，2004年，2005年，2009年，2013年和2014年进行了更新。特别是2009年文件对以前的出版物进行了重大更新，其中包括“ 早泄“，案文更名为”EAU男性性功能障碍指南“[12]。2011年，小组决定制定解决阴茎弯曲的新指南，并于2012年出版[13]。随后2014年的指南中，加入阴茎异常勃起部分[14]。

## 1.3 参考的文献

 除了在EAU科学杂志“欧洲泌尿学杂志”[16-20]中发表的几篇科学综述之外，还提供了一份快速参考文献（Pocket Guidelines），包括印刷版和许多移动设备版本，介绍了男性性功能障碍指南。 这些是缩写版本，可能需要与全文版本进行协商。所有可用的材料可以在EAU网站上查看和下载，该网站还包括由国家泌尿协会制作的一系列翻译：http://www.uroweb.org/guidelines/online-guidelines/。

## 1.4 参编者构成

 男性性功能障碍的EAU指南小组由泌尿科医师组成。 这个小组的成员是根据他们的专长选出的，代表着从事ED，PE，阴茎弯曲和阴茎异常勃起的的专业人员。

# 2.方法

## 2.1 介绍

 本文中使用的参考根据其证据级别（LE）和指南中给出建议的等级（GR）根据从牛津中心修改证据[21]的循证医学水平的分类系统评估。 其他方法信息可以在本文件的一般方法部分中可以找到，并在EAU网站<http://www.uroweb.org/guidelines/>查询。 也可以在上述地址在网上查看背书的EAU指南协会的名单。

 关于2016版，对涵盖2015年5月至2016年6月期间的指导方针的所有领域进行了范围界定进行了搜索。检索了Embase，Medline和Cochrane对照试验中心登记册（RCT）数据库，局限性的系统评估，荟萃分析或随机对照试验。 共查明了2783条独特记录，检索并筛选出相关性，其中56份被选中列入。 详细的搜索策略可在线获取：http://www.uroweb.org/guideline/male-sexualdysfunction/。

## 2.2 评审

 本文件在2015年出版之前进行同行评审。

## 2.3 未来目标

 正在进行和新的系统性回顾的结果将更新在2018年版的男性性功能障碍指南部分。

 正在进行的系统评包括：

1.非手术治疗的阴茎硬结症的效果如何（有效性和安全性）？

2.手术治疗的阴茎硬结症的效果如何（有效性和安全性）？

3. 用于男性性功能障碍的睾酮治疗的好处和的危害？[22]。

# 3. 男性性功能障碍

## 3.1 勃起功能障碍

### 3.1.1 流行病学/病因学/病理生理学

 阴茎勃起是一种复杂的现象，意味着神经系统，血管和组织隔室之间的微妙和协调的平衡。 它包括动脉扩张，小梁平滑肌松弛和活体静脉闭塞机制[23]。阴茎持续不能达到和（或）维持足够的勃起以获得满意的性生活（性交）[24]。 勃起功能障碍可能会影响身体和社会心理健康，并可能对患者及其伴侣的生活质量（QoL）产生重大影响[25-27]。 越来越多的证据表明，ED可能是冠状动脉和外周血管疾病的早期表现。 勃起功能障碍不应仅被视为影响生活质量（QoL）的因素，而且也可作为心血管疾病（CVD）的潜在警告标志[28-30]。

#### 3.1.1.1 流行病学

流行病学数据显示， ED在世界各地具有高发病率与患病率。其中，马萨诸塞州男性老龄化研究（MMAS）[25]报道波士顿地区40至70岁的非制度化男性患者的总发病率达52％；对于轻度，中度和重度的ED的具体患病率为分别为17.2％，25.2％和9.6％。在科隆30-80岁男子研究中，ED的患病率为19.2％，年龄相关性由2.3％上升至53.4％[31]。根据MMAS研究的长期数据，ED发病率（每年每1000名男性中新发病例）为26例[32]，而一项荷兰研究是19.2例（平均随访4.2年）。在一项寻求首次医疗帮助的新发ED男性的横断面现实生活研究中，四分之一的患者年龄小于40岁，近50％的年轻人主诉患有重度ED[34]。这些研究之间的差异可以通过被研究人群所使用的方法，年龄和社会经济以及文化状况的差异来解释。

#### 3.1.1.2 危险因素

勃起功能障碍与CVD共享于诸多不可改变和可改变的常见危险因素（例如肥胖，糖尿病，血脂异常，代谢综合征，运动缺乏症和吸烟）[27,35-37]。 最近的报道证实了ED状态与年龄，糖尿病持续时间，血糖控制差和体重指数（BMI）之间的关系[38]。

 大量的研究表明一些证据表明，改变生活方式[29，39]和针对CVD危险因素的药物疗法[39，40]可能在改善ED患者的性功能有帮助。 然而，应该强调的是，需要更多的控制前瞻性研究来确定运动或其他生活方式变化对预防或治疗ED的影响[30]。

 流行病学研究也证明了下尿路症状（LUTS）/良性前列腺增生（BPH）与性功能障碍之间的关系，不分年龄，其他并发症和各种生活方式因素之间的联系[41]。 在美国，法国，德国，意大利，荷兰，西班牙和英国进行的老龄男性跨国调查（MSAM-7）研究系统地调查了50-80岁之间的>12,000名男性的LUTS与性功能障碍之间的关系。83％的自我报告为性活跃的男性中，LUTS的总体发病率为90％，ED的总发病率为49％，10％的患者完全无法勃起。此外，射精障碍的总患病率是46％[42]。

 最近的流行病学数据集还强调了与ED有潜在关联的其他意想不到的风险因素，包括牛皮癣[43]，强直性脊柱炎[44]，非酒精性脂肪肝[45]和经直肠超声（TRUS）指导的前列腺活检[46]。

#### 3.1.1.3病理生理学

 ED的病理生理学可能是血管源性的，神经源性的，解剖学，激素，药物诱导和/或心理因素（表1）[23]。

**表1: ED的病理生理学**

|  |
| --- |
| * **血管源性的**
 |
| 心血管疾病（高血压，冠状动脉疾病，外周血管病变等） |
| 糖尿病 |
| 高脂血症 |
| 吸烟 |
| 主要骨盆手术（根治性前列腺切除术（RP））或放射治疗（骨盆或腹膜后） |
| **神经源性的** |
| 中枢原因 |
| 退行性疾病（多发性硬化，帕金森病，多发性萎缩等） |
| 脊髓损伤或脊髓相关疾病 |
| 中风 |
| 中枢神经系统肿瘤 |
| 外围原因 |
| I、 II型糖尿病 |
| 慢性肾衰竭 |
| 多发性神经病 |
| 外科手术（（骨盆/腹膜后手术） |
| 尿道手术（尿道狭窄，尿道成形术等） |
| **解剖的或者结构上的** |
| 尿道下裂，尿道上裂 |
| 小阴茎 |
| 阴茎硬结症 |
| 阴茎癌 |
| 包茎 |
| **激素的** |
| 性腺机能减退 |
| 高泌乳素血症 |
| 超甲状腺功能减退症 |
| 超和低皮质醇（库兴氏病等） |
| 全垂体功能减退和多发性内分泌失调 |
| **药物引起的** |
| 抗高血压药（噻嗪类利尿剂等） |
| 抗抑郁药（选择性5-羟色胺再摄取抑制剂，三环类） |
| 抗精神病药（精神安定药等） |
| 抗雄激素（GnRH类似物和拮抗剂） |
| 消遣药物（酒精，海洛因，可卡因，大麻，美沙酮，合成药物，合成代谢类固醇等） |
| **精神性的** |
| 广泛类型（例如性唤起缺乏和性亲密关系的障碍） |
| 情境类型（例如，性伴侣相关的，发生过程中的问题或者由于悲痛） |
| **外伤** |
| 阴茎折断 |
|  骨盆骨折 |

##### 3.1.1.3.1根治性前列腺切除术后ED，放射治疗后ED和近距离放疗后ED

 任何形式的前列腺癌根治术（RP）（开放，腹腔镜或机器人）是治疗临床局限性前列腺癌（PCA）和延长至少十年患者生命而被广泛地应用[47]。该过程可能导致影响健康相关的QoL的治疗特异性后遗症。随着越来越多的年轻男性被诊断出前列腺癌，这一结果的影响越来越重要[48，49]。研究表明，男性25-75％的会发生RP后ED [50]。临床相关性大多数研究中无辅助的术后勃起功能恢复率在20％至25％之间; （这些比率在过去十七年出现并没有大幅提高或改变[51]。鉴于机器人辅助RP（RARP）的临床重要性不断增加，这种手术正在成为术后评估功能结果的范例。系统综述（SR）显示，与开放性耻骨上的RP相比，RARP有12个月效能比优势[52]，而腹腔镜RP和RARP无显着性差异。最近有报道证实，与开放式RP相比，RARP的勃起功能恢复的可能性大约是RARP的两倍[53]。最近一项前瞻性，受控制的非随机试验中，14个瑞典中心进行的RARP与耻骨后RP 比较，显示RARP后勃起功能（EF）有比较小的改善[54]。相反，一项3期随机对照研究，显示，这两种技术在12周时产生类似的功能结果[55]。作为一个整体，对于术后ED发生率的影响，RARP是否优于开放性RP，需要进行更多的前瞻性研究及长期随访[56]。总体来说，患者年龄、手术量以及保留神经血管束的能力可能是主要推动保持术后最高性能力效能的主要因素[48,50]。

 术后性能力是术后EF恢复的一个主要因素[49]。考虑保护神经RP（NSRP）的患者理应是术前有性能力的48,49]。总体而言，术后勃起功能恢复时间具有重要的临床意义。已有数据证实术RP后勃起功能恢复需要几年(多达48个月)[57]。

同样地，共同观点认为，术后治疗（任何类型）的时间应尽可能接近外科手术[48,50]。

勃起功能障碍也是使用外束放射治疗和近距离放射治疗Pca后的常见后遗症[58,59]。 前列腺照射后导致ED的机制涉及损伤神经血管束，阴茎脉管系统，和海绵体组织结构[58]。前列腺癌的替代疗法，包括冷冻和高强度聚焦超声（HIFU）与手术或放射治疗相比，具有相等或者更高的ED发生率[60，61]。

##### 3.1.1.3.2 ED的流行病学/病因学/病理生理学证据概况

|  |  |
| --- | --- |
| **证据概况** | **LE** |
| ED是世界范围存在 | 2b |
| ED与心血管疾病有共同的危险因素 | 2b |
| 生活方式改变（经常运动和体重指数下降）可以改善勃起功能。 | 1b |
| ED是一种症状，而不是一种疾病。有些患者没有被准确评估后者潜在的疾病或状况没有得到治疗从而引起ED | 4 |
| ED在RP后是常见的，与所用的手术技术无关。 | 2b |
| ED是外部放射治疗和近距离放射后常见的。 | 2b |
| ED在冷冻治疗和高强度聚焦US之后是常见的。 | 2b |

### 3.1.2 分类

 勃起功能障碍通常根据其病因分为三类。 这些包括器质性，心理性和混合ED。 然而，这种分类应谨慎使用，因为大多数情况实际上是混合病因。 因此建议使用原发器质性或主原发心理性的术语。

### 3.1.3 诊断评估

#### 3.1.3.1 基本的诊断检查

 评估ED的第一步总是患者的详细医疗和性史，同时可能的话询问下他们的性伴侣[62]。在这种情况下，通过全面的医疗史可能会发现与ED有相关性的许多常见的疾病之一[62]。 在病史询问建立轻松的氛围很重要。这将使我更容易问）有关勃起功能和性史的其他方面的问题; 和ii）给患者及其伴侣解释诊断和治疗方法。图1列出了ED患者的最小限度的诊断评估（基本处理）。

##### 3.1.3.1.1 性史

 性史必须包括关于性取向，以前和现在的性关系，当前情绪状态，勃起问题的发作和持续时间以及以前的咨询和治疗的信息。 合作伙伴的性健康状况（如果可用）也是有用的。

 性史必须包括性取向，以往和当前的性关系，目前的情绪状况，发病以及勃起问题的持续时间，和以前的咨询和治疗的信息。性伴侣的性健康状况（如果有的话）也是有用的。

 应详细描述性刺激和早晨勃起的强度和持续时间，以及性欲，唤醒，射精和性高潮问题[63,64]。 经验证的心理测量问卷，如国际勃起功能指数（IIEF）[65]或其缩写版“男性性健康清单”（SHIM）[66]，有助于评估不同的性功能领域（即性欲，勃起功能 ，高潮功能，性交和整体满意度），以及具体治疗方式的潜在影响。

 心理测量分析还支持在实践中和临床试验研究中使用勃起硬度评分来评估阴茎刚度[67]。 在临床抑郁症的情况下，在日常临床实践中建议使用2个问题的抑郁症量表：“在过去一个月中，您有经常感到失望，沮丧或没有希望所困扰吗？ 在过去一个月里，你经常做事感到无趣，没有乐趣而感到烦恼吗？“[68]。 患者应总是筛查可能的性腺机能减退症状（=睾酮缺乏症），包括体力下降，性欲降低，疲劳和认知障碍以及LUTS。 在这方面，虽然LUTS / BPH本身并不代表治疗迟发性性腺功能减退症的患者的禁忌症，但LUTS严重程度的筛查在临床上是相关的[69]。

##### 3.1.3.1.2 体格检查

 每个患者必须给予重点泌尿生殖，内分泌，血管和神经系统[70，71]体检。 体格检查可能揭示没有料到的诊断，如佩罗尼氏病，恶变前或恶性生殖器病变，前列腺肥大或不规则/结节，或体征和症状暗示性腺机能减退（小睾丸，第二性征的改变等）。 如果在过去三到六个月没有评估血压和心率，应进行测量。 同样，病人的患者的BMI计算或腰围测量也应考虑进去作为参考。

##### 3.1.3.1.3 实验室诊断

实验室测试必须根据患者的投诉和风险因素进行调整。 如果最近没有评估，患者可能需要空腹血糖或HbA1c和脂质分布。激素试验包括空腹总睾酮。 如果有必要，可能需要生物可利用的或计算的游离睾酮来证实总睾酮测量。 然而，维持勃起所需的睾酮阈值较低，ED通常是更严重的性腺机能减退症状的症状[35,72-74]。 对于水平> 8nmol/l，循环睾酮和性功能之间的关联性是非常低的[35，72-74]。另外的实验室试验可以在选定的患者进性检查（例如，前列腺特异性抗原（PSA）[75];催乳素和黄体生成素[76]。虽然大多数男性ED体格检查和实验室评估可能提示准确诊断，但给确定疾病关键提供了机会，不应该错过。

**图一：ED患者的最小诊断评估（基本处理）**



ED =勃起功能障碍; IIEF =国际勃起功能指数。

##### 3.1.3.1.4心血管系统和性活动：处于危险中的病人

寻求治疗性功能障碍的病人患有心血管病的发病率较高。流行病学调查强调了男性[77]和女性[78]中心血管危险因素、代谢危险因素与性功能障碍之间的关联。总体而言，ED可以提高筛查无症状糖尿病男性CVD的敏感性[79,80]。ED显著增加患导致死亡的CVD，冠心病，中风的风险，并且这种增加可能独立于常规心血管危险因素之外引起的[28,29,81]。来自基于人群的965名非CVD心脏病患者的纵向数据显示，持续性患有ED的年轻男性（<50岁）的Framingham风险增加显著增加，这个指数是独立于传统CVD风险因素之外的。

关于诊断和治疗男性ED的EAU指南已从以前公布的普林斯顿共识会议中关于性功能障碍和心脏风险的建议进行了改编[83]。普林斯顿共识（专家小组）会议致力于性功能的优化和心血管健康的保护[83-85]。 因此，ED患者可以分为三个心血管风险类别（表2），可用作启动或恢复性活动的治疗算法的基础（图2）。 临床医生也可以从大多数患者的运动耐力水平估计性活动的风险，这可以在询问患者病史时确定[40]。

**表2：心脏危险分层在（based on 2nd and 3rd Princeton Consensus [83, 85]）**

|  |  |  |
| --- | --- | --- |
| **低风险类别** | **中度风险类别** | **高风险类别** |
| 无症状，<3个CAD的危险因素（不包括性别） | > 3个CAD风险因素（不包括性别） | 高风险心律失常 |
| 轻度，稳定的心绞痛（评估和/或正在治疗） | 中度，稳定的心绞痛 | 不稳定或难治性心绞痛 |
| 简单以前发生的MI | 最近发生的MI(> 2, < 6 周) | 最近发生的MI(< 2 周) |
| LVD/CHF (NYHA class I or II) | LVD/CHF (NYHA class III) | LVD/CHF (NYHA class IV) |
| 冠状动脉血运重建后成功 | 动脉粥样硬化疾病的非心脏后遗症（例如，中风，周围性血管疾病） | 肥厚性梗阻型和其他型心肌病 |
| 高血压控制稳定 |  | 控制差的高血压 |
| 轻度血管疾病 |  | 中度至重度的瓣膜病 |

CAD =冠状动脉疾病; CHF =充血性心力衰竭; LVD =左心室功能障碍; MI =心肌梗塞; NYHA =纽约心脏协会。

**图二：用于确定根据在勃起功能障碍的心脏风险性行为水平治疗的算法（第三普林斯顿共识[83]**



a 性活动相当于在20分钟内平路行走1英里，或者在10秒钟内快速爬上两层楼梯。

b 性活动相当于Bruce跑步机程序的四分钟。

##### 3.1.3.1.4.1低风险类别

 低风险类别包括与性活动相关的心脏风险无明显差异的患者。低风险通常表现为有执行适度强度的能力，其定义为静止状态下≥6代谢当量无症状的能量消耗。 根据目前了解与性活动相关的运动需求或情绪压力，低风险患者在性活动开始或恢复或治疗之前不需要心脏测试或评估。

3.1.3.1.4.2中级或不确定定风险类别

 在中期或不确定的风险类别包括患者的不确定的心脏状况或患者的风险需要恢复性生活之前进行测试或评估。 根据测试结果，这些患者可能被移至高危组或低危组。 有些患者可能需要进行心脏病咨询，以帮助主治医师确定性活动的安全性。

##### 3.1.3.1.4.3高风险类别

 高危病人有心脏状况是十分严重和/或不稳定进行性活动会有显著风险。大多数高危患者有中度至重度症状的心脏疾病。 应将高风险个人转介进行心脏评估和治疗。 应该停止性活动，直到患者的心脏状况通过治疗稳定，或由心脏病专家和/或内科医生决定恢复性活动是安全的。

##### 3.1.3.2专业诊断测试

大多数ED患者可以在性保健环境中进行管理; 相反，一些患者可能需要特定的诊断测试（表3和表4）。

##### 3.1.3.2.1夜间阴茎勃起和硬度测试

 在夜间阴茎勃起和硬度评估应进行至少两个单独的夜晚。功能性勃起机制由持续十分钟或更长，阴茎头部记录的至少60％硬度的勃起特征来表示[86]。

##### 3.1.3.2.2海绵体内注射试验

 海绵体内注射试验提供了血管状态的有限信息。阳性测试是在海绵体注射后十分钟内出现的僵硬勃起反应（阴茎不能弯曲），持续30分钟[87]。 总体而言，测试不确定作为诊断程序，如果临床上有需要，应要求对阴茎进行复式多普勒研究。

##### 3.1.3.2.3复式超声检查阴茎

 收缩末峰血流> 30 cm / s，舒张末期速度<3 cm / s，阻力指数> 0.8通常被认为是正常的[88]。 当复式超声（US）检查正常时，进一步进行血管调查是不必要的。

##### 3.1.3.2.4动脉造影术和动态灌注海绵体测量法或海绵体腔摄影术

 动脉造影术和动态灌注海绵体测量法或海绵体造影术应仅在被考虑用于血管重建手术的患者中进行[89]。

##### 3.1.3.2.5精神病学评估

 每当临床指出，精神障碍患者应转介给对性健康特别感兴趣的精神科医生。 在具有长期初级ED的年轻患者（<40岁）[34]中，在进行有机评估之前，精神评估可能是有帮助的。

##### 3.1.3.2.6 阴茎异常

 患有ED和阴茎异常（例如尿道下裂，先天性弯曲或保留硬度的阴茎硬结症）的患者可能需要进行手术矫正。

#### 3.1.3.3患者教育 – 咨询和推荐

与患者协商应包括对患者及其性伴侣的期望和需求的讨论。 还应审查患者和伴侣对ED以及诊断结果的了解，并提供理性选择治疗方案[90]。 患者和伴侣的教育是ED管理的重要组成部分[90，91]。

**表3：特异性诊断试验的适应症**

|  |
| --- |
| 原发性ED（不是由有机疾病或心理疾病引起的）。 |
| 具有盆腔或会阴创伤史的年轻患者，可以从潜在的治愈性血流重建术或血管成形术中受益。 |
| 可能需要手术矫正的阴茎畸形患者（例如，阴茎硬结症，先天性阴茎弯曲）。 |
| 复杂的精神病或心理性疾病患者。 |
| 复发性内分泌障碍患者。 |
| 根据患者或其伴侣的要求指明的具体检查。 |
| 医疗法律原因（例如，植入阴茎假体治疗ED，性虐待）。 |

**表4：具体诊断方法**

|  |
| --- |
| 使用Rigiscan®的夜间阴茎膨胀和刚度（NTPR） |
| 血管研究-海绵体血管活性药物注射-阴茎动态双相超声检查-阴茎动态灌注海绵体测压和海绵体造影-内阴动脉造影 |
| 神经学研究（例如球海绵体反射潜伏期，神经传导研究） |
| 内分泌研究 |
| 专业心理诊断评估 |

#### 3.1.3.4对ED进行诊断评估的建议

|  |  |  |
| --- | --- | --- |
| **建议** | **LE** | **GR** |
| 对每个病人的疾病史和性生活史进行详细全面的了解。 | 3 | Ｂ |
| 使用与勃起功能障碍有关的验证问卷对整体性功能和具体治疗方式的影响进行评估。 | 3 | Ｂ |
| 在对勃起功能障碍（ED）男性进行初步评估时，包括体格检查，以确定与ED有关的潜在疾病。 | 4 | Ｂ |
| 评估常规实验室检查，包括葡萄糖-脂质分布和总睾酮量，以确定和纠正任何可逆的危险因素和生活方式。 | 4 | Ｂ |
| 仅有表3所示情况下，初诊包括具体的诊断方案。 | 4 | Ｂ |

### ３.１.４　疾病处理

#### ３.１.４.１治疗方案

 与勃起功能障碍相关的危险因素可能是多变和可逆的，包括生活方式或药物相关因素[30]。这些因素可以在特定治疗前或治疗中进行改变。同时，ED可能与伴随和潜在疾病（如内分泌紊乱和代谢紊乱，如糖尿病；心血管疾病如高血压）相关，治疗ED总要先控制这些疾病[92]。通常，目前的治疗方案可有效治疗ED，但无法治愈。例外的是精神性ED，年轻患者创伤后动脉性ED和激素原因（例如性腺机能减退和高泌乳素血症）导致的ED[73,76]，这可能通过特异性治疗来治愈。大多数ED患者将选择治疗方案，而这些治疗方案不是特定的，从而导致治疗策略取决于疗效，安全性，创伤性，成本以及患者的偏好[90]，在这种情况下，医患沟通在整个ED的治疗中是必不可少的。评估治疗方案必须根据患者和伴侣满意度，QoL因素以及治疗相关的安全性和有效性进行调整。ED的治疗算法如图3所示。必须根据患者和伴侣满意度，QoL因素，安全性和有效性来进行治疗方案的评估和调整。ED的治疗方法如图3所示。

##### 3.1.4.1.1 ED的治疗与伴随的危险因素

 最基本的是，患者必须确定ED的可逆危险因素。必须在任何药物治疗之前或治疗过程中改掉不良的生活方式和危险因素，生活方式的改变可能带来临床的潜在益处，这主要体现在并发心血管或代谢障碍（如糖尿病或高血压）的男性[30,93]。

##### 3.1.4.1.2 根治性前列腺切除术后勃起功能障碍

 RP术后使用勃起功能药物对术后勃起功能的恢复很重要。几项试验显示，在接受药物治疗或预防治疗的患者中，RP术后勃起功能的恢复率较高。早期治疗与晚期治疗的勃起功能对比，起效时间似乎受影响[48]。目前可行的ED治疗方法如图3所示。

 由于磷酸二酯酶5抑制剂（PDE5Is）的出现，RP-ED的治疗已经发生了革命性变化，因其已证明的疗效，易用性，良好的耐受性，良好的安全性和对QoL的正面影响。必须强调，RP后，ED患者对PDE5Is的反应不良。然而，无论采用什么手术技术，对于实施神经保留（NS）术的患者，PDE5Is均作为其一线药物[48,49]。对于接受RP的患者，已经确定了许多临床参数作为PDE5Is的潜在预测因子。患者年龄和NS手术水平是RP术后保留勃起功能的关键因素[48,49,52]。在不同RP术后试验中，对于接受NSRP治疗的患者，西地那非治疗ED的反应率为35％〜75％，接受非NSRP治疗的患者的反应率为0％〜15％[48,94]。认为RP术后早期使用高剂量西地那非与保护海绵体内平滑肌有关[95]。与行双侧NSRP术后服用安慰剂的患者相比，RP术后每天服用西地那非的患者在自发性正常勃起功能的恢复上优势更大[96]。相反，在最近的一项前瞻性，随机，安慰剂对照研究中，除了采用IIEF-EF外，还通过对夜间阴茎恢复和夜间阴茎勃起情况进行评估，与前脸腺癌术后定量给药对勃起功能恢复相比，夜间服用枸橼酸西地那非对其无改善作用。

 已对按需服用他达拉非和伐地那非治疗RP术后ED的效果进行了评估。欧洲和美国的一项大型多中心试验研究了双侧NS手术后ED患者服用他达拉非的情况。使用20mg他达拉非治疗的患者中，71％的患者勃起功能得到改善，而安慰剂组为24％，而性行为成功率为52％，安慰剂组为26％[98]。类似地，伐地那非的随机，多中心，前瞻性，安慰剂对照研究已经在北美地区NSRP术后ED患者中进行了测试[99]。在双侧NSRP后，服用10mg和20mg伐地那非后勃起功能分别提高了71％和60％。对同一队列患者进行的扩展分析表明，与安慰剂相比，伐地那非与性交满意度，勃起硬度，性高潮以及对性生活的整体满意度有关[100]。此外，与每日一次服用安慰剂相比，在对欧洲和加拿大9个国家50个中心的68岁以下接受NSRP治疗且术前勃起功能正常的男性进行的随机，双盲，双模拟试验中[101]，他达拉非在NSRP术后的ED患者中对于药物辅助勃起功能最有效，数据表明，术后早期每使用天一次他达拉非，对术后早期有潜在疗效，有助于恢复术后勃起功能，并且对阴茎结构变化可能起保护作用[101]。无辅助的勃起功能在停止主动治疗9个月后不会改善[101]。此外，在九个月的双盲治疗中，与安慰剂相比，每天服用他达拉非可明显缩短勃起功能恢复的时间。相反，按需求服用他达拉非却没有[102]。同样地，无论是在双盲治疗还是非盲治疗期间，每日使用一次他达拉非可提高术后的QoL得分[103]。

 在欧洲，加拿大，南非和美国的87个中心的随机，双盲双模拟，多中心，平行研究中，对行双侧NSRP后ED患者按需和夜间服用伐地那非进行了对比[104]。在术前勃起功能评分>26的患者中，伐地那非在按需使用时有效，对RP后ED患者按需服用也起作用[104]。一项双盲，安慰剂对照，平行研究中，298名双侧NSRP后ED患者随机分配到100或200 mg的阿瓦拉非或安慰剂组，在性活动前30分钟服用，持续十二周，其中100和200mg与安慰剂组相比，性交次数的显着增加以及IIEF问卷第三部分即勃起功能部分的平均得分增加。

与安慰剂组相比，给予阿伐那非36.4％（77例中的28例）性行为（）在15分钟或15分钟内完成，而安慰剂组为4.5％（44例）（p <0.01）[105]。最近进行的Ｍｅｔａ分析证实，阿伐那非与西地那非，伐地那非和他达拉非的疗效相当[106]。尽管一些研究者报道，若他达拉非5mg与西地那非长期联合使用，每天一次，勃起功能有所改善[107]，但此方案还需进一步进行安全性分析。

 在ED治疗史上，RP后ED的治疗方案还包括海绵体内注射[108]，尿道微型栓塞[48,109]，真空装置吸引治疗[48,110]和阴茎假体植入[48,111,112]。当口服PDE5Is对于术后患者无效或禁忌时，进行海绵体内注射和阴茎假体植入可作为二线和三线治疗（3.1.4.3和3.1.4.4节）。最近，人类1期试验中，对前列腺切除术ED患者进行抽脂后，将分离的新鲜自体脂肪来源的再生细胞（ADRCs）注入海绵体腔，数据显示其有恢复正常勃起功能的潜在作用[113]。

**图3：勃起功能障碍治疗程序**



##### 3.1.4.1.3　可能治愈ED的有效方法

###### 3.1.4.1.3.1激素原因

 内分泌专家的建议可能有助于治疗荷尔蒙异常的患者[76]。睾酮缺乏症是原发性睾丸衰竭或继发于垂体/下丘脑疾病（例如导致高泌乳素血症的功能性垂体肿瘤）[76,114]。临床表明[115]，雄激素补充疗法（TS）（肌肉注射，口服或皮下注射）是有效的，但只有在睾丸衰竭的其他内分泌原因被排除之后才应使用[35,73,116]。雄激素补充疗法前，应先进行直肠检查（DRE），血清PSA检测，血细胞比容，肝功能检查和血脂检查[35,73,117]。雄激素补充疗法的患者应监测临床反应，血细胞比容升高程度，肝或前列腺疾病的进展[35,73,117]。有前列腺癌（LE：4）病史患者使用雄激素存在争议[118]。有证据表明雄激素补充疗法可能不是PCa复发或进展的风险因素，雄激素补充疗法在未治疗的前列腺癌患者（LE：4）中是禁忌的。

 雄激素补充疗法对不稳定性心脏病患者禁忌[69,119]。相反，睾酮对男性心血管疾病的作用是有争议的。临床试验没有足够证据证明雄激素补充疗法与心血管疾病不良事件相关[120-125]。目前内分泌协会的指导意见对心脏病患者是否应该筛查的性腺机能减退没有给出建议，且不建议在心脏病患者中补充睾酮以提高生活质量[72]。然而，最近关于雄激素补充疗法对心血管相关疾病的影响的所有安慰剂对照综合SR和meta分析，结果均不支持雄激素补充疗法与不良心血管事件之间存在因果关系[119]。

###### 3.1.4.1.3.2年轻患者中的创伤后动脉性ED

 在骨盆或会阴创伤的年轻患者中，阴茎血运重建手术的远期成功率为60％-70％的 [126]。病变须通过阴茎药物动脉造影证实。静脉闭塞障碍是血运重建的禁忌症，必须通过动态阴茎海绵体测压或海绵体造影术排除。由于存在远期不良结果，不再推荐静脉闭塞障碍的血管术[126]。

###### 3.1.4.1.3.3心理咨询与治疗

 对心理问题严重的患者，可给予单独或其它方式的心理治疗，以改善夫妻性满意度和女性性功能[127]。心理治疗需要坚持随访，且结果不同[128]。

#### 3.1.4.2 一线治疗

##### 3.1.4.2.1 口服药物治疗

 磷酸二酯酶5抑制剂可水解海绵体组织中的环鸟苷酸（cGMP）。抑制PDE5导致平滑肌松弛，动脉血流量增加，引起白膜下静脉丛受压迫，导致阴茎勃起[129]。欧洲药物管理局（EMA）批准了四种有效的选择性PDE5I药物治疗ED [130]。这些药物不能诱发勃起，仍需要性刺激以诱导勃起。治疗效果需达到足够硬度的勃起来完成性交。

**西地那非**

 西地那非在1998年推出，是市场上首先可用的PDE5I [131]。可用剂量分为25,50和100mg。推荐的起始剂量为50 mg，应根据患者的反应和副作用进行调整[131]。西地那非在给药后30-60分钟有效[131]。由于延迟吸收，食用高油脂食物可致疗效降低。功效可长达十二小时[132]。西地那非的药代动力学资料列于表5中。自然发生的不良事件（表6）通常是轻度的，连续使用可限制不良事件的发生[133,134]。在剂量反应研究中，普通ED患者服用25ｍｇ，50ｍｇ和100 mg西地那非24周后，勃起功能改善率分别达到56％，77％和84％，而服用安慰剂的改善率为25％[135]。西地那非显着提高IIEF，SEP2，SEP3和普通评估问卷（GAQ）患者评分和治疗满意度。已成功证明西地那非对几乎每个亚组的ED患者有疗效。（LE：1）。最近，50mg剂量的枸橼酸西地那非口含消溶片（ODT）给吞咽固体困难患者带来益处。

**他达拉非**

 他达拉非于2003年2月批准治疗ED，并在给药后30分钟内有效，约2小时后达到最高效力[136]。药效维持长达36小时[136]，且不受食物影响。按需剂量为10mg和20mg，替代日剂量为5mg。推荐按需剂量起始为10mg，然后根据患者的反应和副作用进行调整[136,137]。他达拉非的药代动力学资料列于表5中。自然发生的不良事件（表6）通常是轻度的，且连续用药后不良事件会受限。在前期研究中，经过十二周的治疗和剂量反应研究后，普通ED患者服用10mg和20mg他达拉非的勃起功能改善率分别为67％和81％，相比之下，安慰剂对照组的勃起功能改善率为35％[136]。他达拉非显著提高了IIEF，SEP2，SEP3和GAQ得分和治疗满意度[136]。

 上市后的研究已证实了其疗效[130,138]。他达拉芬在几乎对每个ED亚组患者，包括难治疗亚组（如糖尿病ED）均有疗效[139]。每日服用他达拉非用于治疗良性前列腺增生导致的下尿路症状也已许可。因此，ED伴随LUTS的患者服用他达拉非是有用的[140]。

**伐地那非**

 伐地那非在2003年3月批准上市，给药后30分钟有效[139]。高脂肪饮食（> 57％的脂肪）可降低其疗效。已批准的按需治疗剂量为5,10和20mg。推荐的起始剂量为10mg，应根据患者的反应和副作用进行调整[141]。伐地那非的药代动力学资料列于表5中。自然发生的不良事件（表6）通常是轻度的，连续用药后会自我限制[141]。经过十二周的剂量反应研究中，普通ED患者服用5mg,10mg和20mg伐地那非的勃起功能改善率分别为66％，76％和80％，而服用安慰剂的勃起功能改善率为30％[142]。伐地那非可显着提高IIEF，SEP2，SEP3和GAQ的评分和治疗满意度。上市后研究已证实了其药效[141,142]。已证明伐地那非对几乎每个ED亚组的患者（包括难治性亚组）（如糖尿病ED）均有疗效。最近，伐地那非的ODT形式已经发布[142]。与薄膜包衣制剂相比，可溶解的片剂更方便，可能成为患者优先选择的。吸收与饮食无关，与薄膜包衣片相比，具有更好的生物利用度[143]。伐地那非ODT的疗效已在几项RCT中得到证实，与常规制剂似乎没有差异[143-145]。

**阿伐那非**

阿伐那非是一种高度选择性的PDE5I，在2013年批准上市[146]。与其他PDE亚型相比，阿伐那非对PDE5抑制率高，药物准予治疗ED，同时尽可能的减少不良反应[147]。已批准的按需治疗ED的剂量为50mg，100mg和200mg[146]。推荐的起始剂量是100mg，在性生活前大约15至30分钟服用，并且剂量可以根据药效和耐受性进行调整[146,148,149]。在普通ED患者中，服用阿伐那非50mg，100mg和200mg的性生活成功率分别为47％，58％和59％，而安慰剂为28％[146,148]。数据显示，在服药十五分钟内进行的性尝试，服用阿伐那非50,100和200 mg的成功率分别为在64％，67％和71％。最大推荐给药频率是每天一次。基于肾功能，肝功能，年龄或性别调整剂量[148]。阿伐那非的药代动力学资料列于表5 [146,148]。自然发生的不良事件通常是轻微的（表6）[146,148]。现有的配对ｍｅｔａ分析数据表明，阿伐那非显着提高了IIEF，SEP2，SEP3和GAQ得分，且具有明显的剂量-反应关系[146,150]。与空腹饮食相比，食物可能会延迟药效，但是可以使用或不加食物来服用阿瓦那非。已证明阿伐那非对几乎每个ED亚组的患者（包括难治性亚组）（如糖尿病ED）均有疗效。

**不同PDE5I之间的选择或偏好**

 迄今为止，尚无可用于比较西地那非，他达拉非，伐地那非和阿伐他非的功效和/或患者偏好的双盲或三盲的多中心研究数据。药物的选择取决于性交的频率（偶尔使用或规律治疗，每周三到四次）和患者的个人经验。患者需要了解药物是短效还是长效，其可能的缺点以及如何使用它。最近的ｍｅｔａ分析表明，期待高效力的ED患者必先考虑服用50mg西地那非，而那些考虑耐受性的患者会首先服用10mg他达拉非，如果疗效不佳，再改用优地那非100mg[138]。临床方面，优地那非不是EMEA或FDA批准药物。另一项临床试验结果显示，对按需服用PED5I治疗有部分反应的男性，每日服用一次５ｍｇ他达拉非可能会改善勃起功能[151]。

**连续使用PDE5Is**

 动物试验表明，长期服用PDE5抑制剂可显着改善或预防由于年龄，糖尿病或手术损伤引起的海绵体内结构改变[152-156]，还缺乏对人的相关研究数据。临床研究表明，每日使用一次5毫他达拉非，可治疗不同严重程度的ED，且有良好的耐受性和有效性[157]。2007年，EMA批准2.5和5mg的他达拉非用于ED的日常治疗。根据EMA，患者的选择和医师的判断，他达拉非2.5 mg或5 mg每天一次可能是合适的。在这些患者中，推荐剂量为5 mg，大约每天服用一次。总的来说，与按需服用他达拉非相比，每日服用5mg他达拉非一次，对喜欢自由性生活而不是计划的，或打算性生活频繁的夫妇，其优点是服用剂量无需与时间相关。应该定期重新评估日常用药方案是否合适[157,158]。连续给药也可用于合并患有LUTS和ED的患者。

**表5：目前EMA批准用于治疗ED的四种PDE5Is的关键药代动力学数据摘要\***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **参数** | **西地那非100mg** | **他达拉非，20 mg** | **伐地那非，20 mg** | **阿伐那非200mg** |
| 血药浓度最大值 | 560μg/ L | 378μg/ L | 18.7μg/ L | 5.2μg/ L |
| T max （中位数） | 0.8-1小时 | 2小时 | 0.9小时 | 0.5-0.75小时 |
| T1 / 2 | 2.6-3.7小时 | 17.5小时 | 3.9小时 | 6-17小时 |
| AUC | 1,685μg/ h | 8,066μg·h / L | 56.8μg/ h | 11.6μg.h/ L |
| 蛋白结合 | 96％ | 94％ | 94％ | 99％ |
| 生物利用度 | 41％ | NA | 15％ | 8-10％ |

*\*禁食状态，推荐剂量较高。数据来源于EMA关于产品特性的陈述。C max：最大浓度，T max：到达最大血浆浓度时间;　T1 / 2：血药浓度半衰期; AUC：曲线下面积或血清浓度时间曲线。*

**表6：目前EMA批准用于治疗ED的四种PDE5Is的常见不良事件\***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **不良事件** | **西地那非** | **他达拉非** | **伐地那非** | **Avanafil 200mg** |
| 头痛 | 12.8％ | 14.5％ | 16％ | 9.3％ |
| 法拉盛 | 10.4％ | 4.1％ | 12％ | 3.7％ |
| 消化不良 | 4.6％ | 12.3％ | 4％ | 罕见 |
| 鼻塞 | 1.1％ | 4.3％ | 10％ | 1.9％ |
| 头晕 | 1.2％ | 2.3％ | 2％ | 0.6％ |
| 视力异常 | 1.9％ |  | <2％ | 没有 |
| 背疼 |  | 6.5％ |  | <2％ |
| 肌痛 |  | 5.7％ |  | <2％ |

*\*源自EMA关于产品特性的陈述。*

**PDE5Is的安全问题**

**(i) 心血管安全**

 四种PDE5Is的临床试验结果和西地那非，他达拉非，伐地那非上市后的研究数据表明，作为RCT非盲研究的一部分，或与年龄的预期比较相比，接受PDE5Is的患者的心肌梗死率没有增加匹配的男性人口。在稳定型心绞痛的男性运动测试中，PDE5I均未对总运动时间或时间依赖性缺血造成不良影响。慢性或按需使用具有良好的耐受性，安全性。所有PDE5Is禁止在以下患者中使用：

i）在过去六个月内患有心肌梗死，中风或危及生命的心律失常的患者; ii）患有静息性低血压（血压<90/50 mmHg）或高血压（血压> 170/100 mmHg）的患者; iii）患有不稳定型心绞痛，性交性心绞痛或分类为纽约心脏协会IV类的充血性心力衰竭的患者[83,159-161]。

 **(ii) PDE5i使用时禁止合用硝酸酯类药物**

 PDE5Is使用的绝对禁忌症是使用任何形式的有机硝酸盐类（例如硝酸甘油，硝酸异山梨酯和硝酸异山梨酯）或一氧化氮（NO）供体（例如其他用于治疗心绞痛的硝酸盐制剂，以及亚硝酸戊酯或硝酸异戊酯--“poppers”）。 它们导致cGMP积聚和不可预测的血压下降和相关症状。有机硝酸盐和PDE5I之间的相互作用持续时间取决于PDE5I和使用的硝酸盐 如果服用PDE5I的患者出现胸痛，则在一定的时间内必须禁止使用硝酸甘油。如果使用西地那非（也可能是伐地那非）（半衰期，四小时），则这个时间是24h；使用他达拉非（半衰期17.5小时），则这个时间是48h；如果使用Avanafil（半衰期6-17小时），则这个时间不少于12小时 [162]。

**(iii) 抗高血压药**

 PDE5Is与抗高血压药物的联合给药（血管紧张素转换酶抑制剂，血管紧张素受体阻滞剂，钙阻断剂，β-受体阻滞剂和利尿剂）可能导额外的血压降低，但通常较小[83]。 一般来说，服用抗高血压药的患者（即使是使用多种抗高血压药的患者），联合使用PDE5I不会出现不良反应加重 [163]。

**与α受体-阻断剂相互作用**

 所有PDE5Is均显示与α受体-阻断剂的一些相互作用，在某些条件下可能导致直立性低血压。

•西地那非明确建议，患者服用50或100 mg西地那非时应谨慎使用α受体-阻滞剂（特别是多沙唑嗪）。α受体-阻滞剂服药后4小时内更可能发生低血压。建议西地那非的起始剂量为25 mg [133]。

•只有在患者使用α受体-阻滞剂稳定的情况下才能开始使用伐地那非治疗。伐地那非和坦索罗辛联合用药不造成明显的低血压[139,141,142]。

•服用多沙唑嗪的患者不推荐使用他达拉非（坦索罗辛除外[136，164]。

•Avanafil明确建议，患者在开始Avanafil治疗之前应该对α受体-阻滞剂治疗稳定。在这些患者中，Avanafil的起始剂量为50mg。相反，在那些已经服用优化剂量的Avanafil的患者，应该以最低剂量启动α受体-阻断剂治疗。

**剂量调整**

 抑制CYP34A途径的药物将抑制PDE5Is的代谢分解，从而增加PDE5Is血液浓度（例如酮康唑，利托那韦，阿扎那韦，克拉霉素，茚地那韦，伊曲康唑，奈法唑酮，奈非那韦，沙奎那韦和泰利霉素）。 因此，治疗应该采用较低剂量的PDE5Is。 但是，其他诸如利福平，苯巴比妥，苯妥英和卡马西平等药物可诱导CYP3A4，并增强PDE5Is的分解，因此需要更高剂量的PDE5I。 严重的肾脏或肝功能障碍可能要剂量调整。

**对PDE5Is反应不佳的患者策略**

 患者没有对PDE5I作出反应的两个主要原因是药物使用不当或药效相对不足。数据表明，需要至少六次尝试才能选出最合适的药物[165]。对于不应答者的管理关键是明确潜在的原因。检查患者是否有一直在使用许可的药物。 PDE5Is在市场上有很多仿制品，活性药物的含量变化很大，要检查患者的药物来源。

 检查药物是否是被正确处方并正确使用。患者未能正确使用药物的最常见原因是和医师的咨询不足。最常见的不正确使用药物的原因是：i）没有充分的性刺激; ii）未能使用足够的剂量; iii）在服用药物和尝试性行为之间没有足够的等待时间。

 PDE5I的作用取决于副交感神经末梢的NO释放诱导阴茎勃起。 NO释放的通常刺激是性刺激，没有足够的性刺激（和NO释放），则药物无效。口服不同PDE5Is，需要不同的时间达到最大血浆浓度[132,134,143,150,166-168]。尽管在远低于最大血浆浓度的血浆水平下药理活性已经可以达到，但口服后仍会有一定的起效时间。虽然所有四种药物在某些病人口服15-30min内会起效[134, 143, 150, 166-168]，但大部分病人都需要更长的起效时间[141, 150, 169, 170]。膳食可以延迟西地那非的吸收；高脂肪膳食可以推迟伐地那非的吸收 [171]。 他达拉非受饮食的影响较小，只要服药和性交之间有足够的时间就可以[166]。Avanafil与高脂饮食合用时，吸收速率降低，平均延迟时间为1.25小时，最高血浆浓度平均减少39％（200 mg）。暴露对药效程度（AUC）无影响。Avanafil的最高血浆浓度的微小变化几乎没有临床意义[146,147,150]。

 对某些病人，服用药物后可能要等待很长时间才能发生性交。西地那非和伐地那非半衰期约为4小时，正常的疗效窗口是药物摄入后6至8小时，尽管过了这段时间也有一定的药效。Avanafil的半衰期为六至十七个小时。 他达拉非的半衰期较长，约17.5小时，所以疗效窗口可以长达36小时。 来自一项研究的数据表明受教育程度高的患者，PDE5I的不应答概率会低 [172-176]。 对患者宣教治疗剂量，治疗时机，性刺激，可以提高PDE5I的治疗效果 [172-174]。

 最近的研究数据表明，患者对西地那非治疗的反应也取决于阴茎中编码cGMP降解酶的PDE5A基因的多态性，后者调节cGMP清除率，它是西地那非的主要作用靶点[177]。 一项研究PDE5i有效性的meta-regression的实验数据表明，PDE5Is在白种人中更为有效（相比于亚洲人），对于更严重的ED患者也更有效[178]。

**正确使用PDE5Is患者的临床策略**

 有初步研究数据表明，在睾酮缺陷的患者中，睾酮补充可能改善患者对PDE5I的反应[73,179-181]。 针对ED的其他风险因素的控制也可能是有益的，这将在3.1.4.1.1节讨论。部分数据表明，一些患者可能对特定的一个PDE5I做出更好的反应[182]。 这些差异可能由药物药代动力学的不同来解释，他们提出，尽管作用机制类似，但更换不同的PDE5I可能是有帮助的。此外，对于严重的ED患者，有人建议将他达拉非与短效PDE5I（如西地那非）联合使用，副作用没有明显增加[183]。 如果药物治疗失败，那么患者应该选择其他治疗方法，如海绵体内注射治疗或使用真空装置（VED）。

 联合长效睾酮十一酸酯和他达拉非联合5 mg治疗（每日一次），可显著改善勃起功能[184]。 此外，即使在停止治疗后，EF的改善也可维持一定时间。

##### 3.1.4.2.2 真空装置（VED）

 真空装置（VED）与放置在阴茎底部的收缩环一起提供海绵体的被动充血，而将血液保留在海绵体内。数据表明，无论ED原因是什么，该治疗在性交满意度方面的疗效高达90％；总体满意率在27％至94％之间[185,186]。大多数停止使用VED的患者在三个月内都需要保持治疗。但长期使用VEDs的患者，在两年后，满意度下降到50-64％[187]。与VED相关的最常见的不良事件包括疼痛，无法射精，瘀点，瘀伤和麻木，发生率<30％[186]。如果患者在性交后30分钟内适时解除装置，可以避免严重的不良事件（皮肤坏死）。真空勃起装置禁用于出血倾向患者或抗凝治疗患者。真空勃起装置可用于性交不频繁，不愿使用药物和侵入性治疗的老年患者的治疗 [185,186]。

##### 3.1.4.2.3冲击波治疗

低强度体外冲击波治疗（LI-SWT）被提出是ED治疗的一种新方法 [188-192]。 在此背景下，最近几年针对ED的LI-SWT的研究数量日渐增加。总体而言，大多数的这些研究报告了令人鼓舞的结果，尽管存在LI-SWT的参数设置或治疗方案的不统一。 总体而言，这些研究表明，LI-SWT明显改善ED患者的IIEF分值和勃起硬度得分[193]。RCTs和长期随访，这些方面有力的研究结果的发表将为使用LI-SWT临床使用提供更多依据。 但目前，我们不能给出明确的建议。

#### 3.1.4.3 二线治疗

 对于不能口服药物的患者可以进行海绵体内注射。 成功率较高（85％）[194,195]。这种治疗方法是二十多年前被发明的[176，196]。

##### 3.1.4.3.1海绵体内注射

###### 3.1.4.3.1.1前列地尔

 前列地尔（CaverjectTM，Edex / ViridalTM）是第一个也是唯一批准用于海绵体内治疗的药物[176,196]。单独应用海洛因前列地尔治疗最有效的剂量为5-40μg（注意，欧洲国家没有注册40μg剂量）。勃起在五到十五分钟后出现，并根据注射剂量不同持续不同的时间。患者应该学习正确的注射过程。在自身受限时，可以向他们的性伙伴教授该技术。使用自动专用笔（不会看到针）可以缓解对阴茎穿刺的恐惧，并简化操作技术。对于一般ED患者，海绵体前列地尔注射的有效率> 70％；某些特殊类型ED（例如糖尿病或CVD），注射后有效率达94％，患者满意率为87-93.5％，性伙伴为86-90.3％[176，196]。海绵体注射前列地尔并发症包括阴茎疼痛（50％的患者报告，在所有注射中，约11%的概率会出现疼痛），勃起时间过长（5％），阴茎异常勃起（1％）和纤维化（2％）[176,196,197]。长时间使用后，疼痛通常呈自限性。可以使用碳酸氢钠或局部麻醉患者[176，196，198]。海绵体纤维化（来自小血肿）通常在停止注射后几个月内清除。然而，若穿刺表明早期发作的佩罗尼氏病可能会要求停止海绵体内注射。该治疗的全身副作用罕见。最常见的是轻度低血压，特别是使用较高剂量时。禁忌症包括具有前列地尔超敏反应史的男性，阴茎异常勃起风险的男性和出血倾向的男性。尽管有这些有利的数据，但该治疗的脱落率为41-68％ [176,196,199,200]，大多数脱落发生在头两到三个月。在一项比较研究中，与总体相比药物组合（37.6％），前列地尔单药治疗的终止率最低（27.5％），治疗几个月后，每年的终止率为每年10％。终止原因包括渴望永久性治疗方式（29％），缺乏合适的性伙伴（26％），反应不佳（23％）（特别是早期辍学者），对注射针的恐惧（23％），恐惧并发症（22％），缺乏自发性（21％）。在培训阶段，对患者进行细致的询问，密切的随访对于患者进行海绵体注射计划至关重要[201]。

###### 3.1.4.3.1.2联合疗法

 联合治疗使患者能够受益于药物的不同作用方式，并通过使用较低剂量的每种药物来减轻副作用。

•罂粟碱（20-80 mg）是第一种用于海绵体注射用的口服药物。其作为单一疗法的副作用发生率较高。但罂粟碱是目前尚未获得ED的治疗许可。

•苯妥拉胺已被用于联合治疗以提高疗效。作为单一疗法，治疗效果不佳

•少量文献数据支持使用其他药物，如血管活性肠肽（VIP），NO供体（linsidomine），毛喉素，钾通道开放剂，莫西斯特或降钙素基因相关肽，通常与主要药物联合[202,203]。大多数组合没有标准化，一些药物在世界各地的供应有限

•罂粟碱（7.5-45mg）加酚妥拉明（0.25-1.5mg），罂粟碱（8-16mg）加酚妥拉明（0.2-0.4毫克）加前列地尔（10-20微克），虽然已被广泛使用，单从未获得ED许可[204,205]。罂粟碱的三重组合方案，酚妥拉明和前列地尔有效率最高，达到92％。这种组合有与前列地尔作为单药治疗的类似的副作用，但阴茎疼痛发生率较低。然而，当使用罂粟碱时，纤维化则更常见（5-10％）（取决于剂量）。

•血管活性肠肽（VIP）（25μg）和甲酚酸酚妥拉明（1-2mg）（InvicorpTM，目前

在斯堪的纳维亚获得许可），是两种具有互补模式的药物。临床研究表明，该联合治疗是海绵体注射的有效治疗方法，有效率> 80％，包括那些未能对其他疗法作出反应的人，不同于现有的海绵体内治疗方法，其阴茎疼痛的发生率非常低，阴茎异常勃起风险可忽略[206]。

 尽管有效率很高，但5-10％的患者对海绵体内注射组合没有反应。将西地那非与海绵体注射三联方案的联合应用可以使31％的单独应用三联组合不反应患者获得效果 [207]。但是，联合治疗与33％的患者的不良反应发生率增加有关，其中包括20％的患者出现头晕。在进行阴茎植入术之前，可以对部分患者使用该策略（LE：4）。

###### 3.1.4.3.1.3尿道内/前列地尔

 使用包含前列地尔（125-1000μg）的药物颗粒（MUSE™）的具体配方治疗ED已获得批准[208]。该治疗使得30-65.9％的患者获得满意性交。在临床实践中，仅使用较高剂量（500和1,000μg），具有较低的一致性响应率[208-210]。在阴茎根部应用收缩环（ACTIS™）可以提高该治疗的功效[209,210]。最常见的不良事件是局部疼痛（29-41％），头晕和低血压（1.9-14％）。

 阴茎纤维化和阴茎异常勃起非常罕见（<1％）。尿道出血（5％）和尿路感染（0.2％）均为与治疗管理有关的不良事件。该治疗效率明显低于海绵体内药物治疗[195]。尿道内药物治疗是一种二线疗法，对于喜欢较少侵入性的患者提供了一种替代方案，但效果较差的患者仍应进行海绵体内注射。

 局部前列地尔是施用前列地尔的另一种方式。它是一种包含渗透性的油性增强剂，有利于通过尿道口吸收前列地尔（200和300μg）[211]。有限的临床资料表明，在广泛的轻度至重度ED患者中，对于IIEF，SEP2和SEP3，治疗组显着改善[212]。副作用包括阴茎红斑，阴茎烧灼感和疼痛。全身副作用非常罕见。局部前列地尔只被批准，可用于部分欧洲国家。

#### 3.1.4.4三线治疗（阴茎假体）

对以上治疗没有反应的患者或愿意永久解决ED问题的患者可以考虑阴茎假体的手术植入[213]。两个目前可用的阴茎植入物种类包括充水装置（2-和3片）和韧性装置[48,111,214,215]。由于想获得更“自然”的勃起，患者更喜欢3件充气装置。同样，3件充气装置可以提供适当的刚性和松弛度，因为它们填充在整个海绵体。然而，两件式充水假体可以是被视为患者的可用选择，但水泵安置并发症的风险高。可塑性假体可以手动放置使得阴茎保持直立或松弛状态[48,111,214,215]。

阴茎假体植入有两种主要的手术路径：阴茎阴囊部和耻骨下部[214-217]。阴茎阴囊路径方法提供了极好的视野，避免了背神经损伤，并允许直接观察泵的位置。但是，这种方法，水囊的放置较盲目，这可能是盆腔手术史（主要为根治性膀胱切除术）患者的一个问题。耻骨后方法具有的优势是水囊放置可直视，但泵的植入可能更具挑战性，而且患者阴茎背神经损伤的风险略有增加。无论适应症，假体植入在治疗中有拥有最高的满意率（92-100％的患者和91-95％的性伙伴） [48，111，214，218-224]。在有良性前列腺癌的患者的治疗中，联合植入式阴茎假体手术治疗ED，并联合压力性尿失禁治疗（男性吊带或人造尿道括约肌）是一劳永逸的[48,111,225-227]。心理咨询可以改善阴茎植入物后患者及其伴侣的性心理变化[228]。

##### 3.1.4.4.1并发症

 阴茎假体植入的两个主要并发症是机械故障和感染。一些最常用的3件假体（AMS 700CX / CXRTM和Coloplast）的技术机械故障率<5％[111,229,230]。小心手术操作，并对革兰氏阳性和革兰氏阴性菌进行适当的抗生素预防。在低危患者和手术量较大时，应将感染率降低至2-3％[231-233]。 通过植入物假体（AMS Inhibizone™）抗生素浸渍或亲水涂层假体（Coloplast Titan™），可将感染率进一步降低至1-2％ [111,231,234-237]。感染的高风险人群包括进行修复手术的患者，免疫功能受损的患者（免疫抑制，糖尿病，脊髓损伤）或阴茎纤维化患者[17,111,214,233,238,239]。并发感染时需要去除假体和使用抗生素。 去除受感染设备立即更换新的假体可使80％以上患者成功好转[232,233,238]。 大多数修复手术是由于机械衰竭和组合侵蚀或感染[236,240]。 总的来说93％的病例成功修复 [231-233,241,242]。

##### 3.1.4.4.2三线治疗结论

 阴茎假体植入对于保守治疗不佳的患者来说是一个有吸引力的解决方案。足够的证据表明，对于不适应较少侵入性治疗的患者，这是一种高效，安全和高满意率的方案。

#### 3.1.4.5 ED治疗的建议

|  |  |  |
| --- | --- | --- |
| **建议** | **LE** | **GR** |
| ED之前或治疗中改变生活方式，控制危险因素 | 1a | A |
| 根治性前列腺切除术后，尽早开始勃起勃起治疗。 | 1b | A |
| 首先治疗可以改变的ED病因 | 1b | B |
| 使用磷酸二酯酶5型抑制剂（PDE5Is）作为一线治疗 | 1a | A |
| 有效的患者教育 | 3 | B |
| 性交不频繁或有禁忌症的老年患者使用真空装置，不使用药物治疗 | 4 | C |
| 使用海绵体注射作为二线治疗 | 1b | B |
| 使用阴茎假体植入作为三线治疗 | 4 | C |

#### 3.1.4.6随访

 随访对于评估所提供治疗的疗效和安全性至关重要。这也是评估患者满意度的至关重要的方式，因为ED的成功治疗不仅仅是疗效和安全性。医生必须意识到，没有一项适合所有患者或所有情况的单一治疗方案。

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