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·综述·

经皮椎体强化扩张器的临床应用进展

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Clinical application progress of percutaneous vertebral augmentation expander

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[摘 要] 随着人口老龄化的到来,骨质疏松患者不断增加,由此引起骨质疏松压缩性骨折的发病率也呈上升趋势,椎体强化术作为其主要治疗方式而得到广泛应用。但在临床应用中,椎体扩张器的种类繁多、性能各异,故而临床医师在准确把握手术适应证的同时,合理选择扩张器尤为重要。本文主要对 Sky 系统、Osseofix 系统、Vessel-X 骨材料填充系统、Jack 椎体扩张器、Spinejack、Kiva 系统等扩张器的特点进行综述,为临床医师选择扩张器提供参考。

[关键词] 椎体压缩骨折;椎体强化术;扩张器;后凸畸形

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经皮椎体后凸成形术是目前一种成熟的脊柱微创技术,通过特殊扩张器对伤椎进行撑开复位,然后选择性注入骨水泥,从而实现缓解疼痛,恢复伤椎高度,纠正后凸畸形,重建并维持脊柱生物力学性能。由于该技术通常是辅助应用骨水泥治疗椎体压缩性骨折,术中常发生骨水泥渗漏,特别是当骨折累及椎体后壁时,更容易发生骨水泥渗漏[1-2],如果骨水泥渗漏到椎间隙或硬膜外间隙将损伤神经根甚至导致截瘫[3]。此外,骨水泥的不可吸收还可能引起相邻椎体的骨折[4]。在经皮椎体成形术基础上发展起来的经皮椎体强化系

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统,应用球囊扩张撑开复位椎体,具有缓解疼痛快、明显改善后凸畸形等优点,但骨水泥渗漏率较高、椎体复位不满意等缺点也显现出来。为解决上述扩张器的缺陷,新的椎体强化系统新兴发展起来,其应用的扩张器系统主要有:Sky 系统、Osseofix 系统、Vessel-X 骨材料填充系统、Jack 椎体扩张器、Spinejack、Kiva 系统等,其优势各异,现综述如下。

1 各类扩张器的临床应用

1.1 球囊扩张系统

经皮球囊椎体后凸成形术(percutaneous ballnoon kyphoplasty,BKP)是通过球囊扩张复位椎体并形成空腔,恢复椎体高度,有效降低骨水泥注入时的压力,进而降低骨水泥的渗漏率[5]。经皮球囊椎体后凸成形术治疗骨质疏松压缩性骨折,能够有效缓解疼痛并改善后凸畸形[6]。与经皮椎体成形术相比,BKP 能更好地恢复椎体高度及减小 Cobb 角[7-9],降低骨水泥渗漏率[8-9],但是术后长期疼痛缓解和功能改善无差异[7],术后相邻椎体骨折发生率也无差异[8]。虽然众多研究显示,经皮球囊椎体成形术使骨水泥渗漏率有效降低,但骨水泥渗漏率仍高达 7%[10],骨水泥渗漏入椎体静脉丛或椎管仍将导致严重临床并发症[11]。此外,BKP 技术存在球囊收缩撤出后复位椎体高度丢失[12]、手术时间较经皮椎体成形术长的缺点[9]。笔者统计分析所在科室近年来应用该扩张器的手术并发症时发现,骨质疏松严重的高龄患者发生骨水泥渗漏和肺栓塞的风险较高,建议慎重选择此扩张器。

1.2 Sky 膨胀式扩张器

为解决球囊扩张器扩张方向不易控制、常向阻力低的方向扩张、难以撑开陈旧性骨折椎体、撑开压力过高则可出现球囊破裂等问题。Sky 椎体扩张系统的设计采用可聚拢套管的机械扩张原理,术中经椎弓根或椎弓根旁或单侧椎体侧方置入椎体,通过顺时针旋转尾端螺旋螺帽使套管聚拢,可有方向性地扩张复位塌陷椎体,骨折复位满意后逆时针旋转螺帽使套管还原并撤出,然后向空腔内注入骨水泥。该系统具有价格低廉、操作简单、可控性强、机械扩张力量大且分布均匀、撑开后空腔形状相对固定等优点[13-14]。Ee 等[15]对 363 例患者分别采用保守治疗、椎体成形术、球囊椎体后凸成形术及 Sky 膨胀式椎体成形术的临床疗效进行对比,结果显示 3 个外科治疗组恢复椎体前缘高度、改善后凸角效果相似,但 Sky 的并发症少、医疗费用低。Sky 系统虽有偶发退出困难或折断的缺点,其仍是一种安全、有效的椎体扩张器[16]。建议用于陈旧性骨折的复位时,术中要密切观察终板变化情况,谨防强行扩张撑破终板导致骨水泥渗漏。

1.3 Osseofix 系统

美国 Alphatec 公司研发的 Osseofix 椎体扩张复位系统是一体式可永久性植入的网状椎体内置物,其具有可塑性的钛制撑开装置并可选择性地使用骨水泥,能很好固定强化伤椎。因 Osseofix 椎体扩张复位系统撑开后周围骨小梁被压实,故而可以减少注入骨水泥的渗漏[17]。该扩张器一般经双侧椎弓根置入伤椎,可应用于治疗 T_6 ~ L_5 压缩性骨折(AO 分型:A1.1 ~ A1.3,A3.1)。另外,该系统还能治疗年轻患者急性稳定型创伤性椎体骨折。该扩张器的禁忌证为:①伴有游离骨块、硬膜或脊髓受压的骨折;②经治疗后的同节段骨折;③全身性或局部感染;④碘化物过敏;⑤癌症引起的病理性骨折;⑥凝血功能障碍;⑦预先存在的钙离子紊乱;⑧肾衰竭;⑨精神疾病[4,18]。该系统辅助骨水泥治疗骨质疏松或病理性压缩骨折或累及椎体后壁的不完全性爆裂骨折,术后 ODI、VAS 评分较术前明显减低,Cobb 角较术前减小,没有发生骨水泥渗漏[18-19]。Ender 等[19]应用 Osseofix 系统治疗累及椎体后壁的不完全性爆裂骨折,发现术后椎体高度下沉率较低(Osseofix 系统 7%,球囊系统 8% ~30%)[20-22]。Eschler 等[4]采用 Osseofix 系统不联合骨水泥治疗 4 例骨质疏松压缩性骨折患者,平均随访 27.7 个月,术后疼痛、功能、Cobb 角明显改善,无并发症发生。虽然 Osseofix 是一种治疗骨质疏松骨折的安全且有效的椎体扩张系统,但笔者认为应用 Osseofix 系统治疗年轻患者急性稳定型创伤性椎体骨折更具临床意义。

1.4 Vessel-X 骨材料填充系统

台湾 A-Spine 公司研制的 Vessel-X 骨材料填充系统,其设计原理与球囊类似,其将骨水泥注入和椎体复位同时进行且不需取出,有效包裹骨水泥,仅允许少量骨水泥渗漏至外层与骨组织锚定。该系统治疗下胸椎(T_{11}、T_{12})及腰椎压缩性骨折可经椎弓根入路,大多数病例单侧入路治疗即可,从而节约手术时间。大多数患者术后疼痛、活动、止痛药依赖等情况明显改善,肿瘤性患者疼痛症状改善不明显,活动及药物依赖无改善[23]。此外,因术中 Vessel-X 能包裹绝大部分骨水泥,骨水泥的渗漏率降低[24]。Klingler 等[25]应用 Vessel 椎体强化术治疗病理性椎体骨折,指出 Vessel 椎体强化术能克服球囊椎体强化术球囊撤出后肿瘤组织的“回缩”,对伴有椎体后壁破坏(大于 30%)的病理性骨折能有效改善患者症状、恢复椎体高度,未发生有症状的骨水泥渗漏。目前 Vessel 椎体后凸成形术临床应

用较少,其有效性和安全性需要大量研究进一步证实。

1.5 Jack 椎体扩张器

根据胸腰段椎弓根的解剖学特点,结合机械力学原理而设计研发的 Jack 椎体扩张器是由前端的椎体撑开部件和后端的体外操控部件组成[26]。穿刺针在 3 点或 9 点方经椎弓根置入,手钻经工作通道钻入,侧位上钻头尖离椎体前缘 3 ~ 5 mm,退出钻头并放入扩张器,将操作手柄的旋钮顺时针旋转 90°打开折叠状态的(宽部朝上)Jack 扩张器,撑开复位伤椎使上下终板尽量平行,复位完成后逆时针旋转 90°,扩张器恢复到置入前折叠状态并取出,注入骨水泥完成手术。Jack 扩张器系统可有效改善疼痛,矫正后凸畸形,恢复并维持椎体高度[27-28],虽然临床疗效同球囊系统相比无差异,但能更好地改善 Cobb 角[26]。Fan 等[28]报道该技术骨水泥渗漏率仅为 5.1%,低于球囊扩张椎体后凸成形术 7% 的渗漏率[10]。该系统另一特点是可以在通道下取病理活检,以便明确骨折病因和进行进一步治疗。Jack 扩张器系统价格大约为球囊的 1/2[26],这是其临床推广的一大优势。但考虑其直径较大,不适用于椎弓根较小者,术中置入要求高,需要经验丰富的医师完成操作,这些因素又限制其应用。

1.6 Spinejack

Spinejack 是一种钛制永久置入椎体内的椎体扩张器,其设计理念同 Jack 扩张器系统类似,发条式机械扩张可确保有效控制扩张力量和维持椎体复位后骨水泥注入前椎体的高度,其自动锁定安全系统可防止扩张器过度扩张,从而降低扩张器撑破终板的风险[29]。该系统可用于治疗 T_{10} ~ L_5 骨质疏松压缩性骨折、新鲜或陈旧性创伤骨折(AO 分型:A1.1 ~ A1.3,A3.1,B)、原发性骨肿瘤及转移性骨肿瘤引起的病理性骨折[30]。与球囊系统相比,Spinejack 系统能更好地缓解疼痛,改善功能,恢复椎体高度,纠正后凸畸形,恢复脊柱的矢状位平衡,可减少治疗椎体的再骨折及缩短手术时间[31-34]。有学者认为上述治疗效果依赖于骨水泥的注入量[31-32],而 Rotter 等[35]则认为椎体容量 10% 的骨水泥注入量治疗效果最佳。Renaud[36]报道该系统相邻椎体骨折发生率为 2.6%,低于椎体成形术和椎体后凸成形术 10% ~22% 的发生率[37-38],但有骨水泥渗漏损伤神经、扩张器内植物移位及院内皮肤感染等并发症发生。虽然 Spinejack 的临床应用价值仍需要多中心随机对照研究来证实,但其治疗陈旧性或新鲜创伤性骨折的临床应用前景值得肯定[39]。

1.7 Kiva 系统

Kiva 系统是一种经单侧椎弓根入路置入椎体中部,通过线圈式圆柱形扩张复位椎体,最后向不取出的圆柱形扩张器内注入低黏度骨水泥。Kiva 椎体后凸成形术缓解疼痛、改善功能的作用不逊于经典的球囊椎体后凸成形术,骨水泥注入量少,骨水泥渗漏率低[40-42],相邻椎体骨折发生率同球囊系统相似[42]。Korovessis 等[43]发现椎弓根螺钉技术联合椎体后凸成形术治疗新鲜的创伤性 A2、A3 型骨折,Kiva 系统比球囊系统能更好地复位,减少椎管侵占,但对功能改善无明显效果。Korovessis 等[44]认为对于生存期较短的溶骨性椎体转移瘤患者,经 Kiva 系统与球囊扩张系统治疗后比较缓解疼痛、恢复椎体高度、改善 Gardner 角等均无明显差异;但前者骨水泥渗漏率低。Beall 等[45]通过比较 Kiva 系统及球囊系统治疗骨质疏松椎体压缩性骨折患者的 2 年总医疗资源利用和花费,认为 Kiva系统医疗花费更少,能节约医疗资源。综上所述,笔者认为 Kiva 系统经单侧椎弓根入路整体复位椎体对于治疗一侧椎弓根受到破坏的病理性骨折病例是很好的选择。

2 椎体扩张器的选择

经皮椎体强化术主要用于治疗骨质疏松压缩性骨折、病理性骨折、侵袭性血管瘤及 Kümmell 病,达到缓解疼痛并恢复椎体生物力学性能的目的。近年来,随着椎体强化术的推广,各种扩张器的不足不断显现,因此,不断有新扩张器被改良或研发出来。虽然临床应用的扩张器具有各自的设计特点,但都需具备以下条件:①能安全地置入椎体,无副损伤;②能有效复位椎体并能维持其生物力学性能;③符合各类人群的生理解剖特点;④内植物排斥反应小;⑤操作简单,学习曲线短;⑥价格低廉。

临床上,不同的患者甚至是同一患者的不同伤椎具有不同的解剖特点,根据扩张器设计原理并结合患者自身特点选择扩张器显得尤为重要。扩张器的选择应注意:①骨折累及椎体后壁则选择 Osseofix、Vessel-X 扩张器等可降低骨水泥渗漏入椎管的风险[17,25];②Sky、Jack、Spinejack 等扩张器撑开力量大,适用于复位骨小梁较致密的陈旧性骨折椎体[13-14,26,30],而对新鲜的骨折,多种扩张器都可选择;③Jack 扩张器系统可在通道下取病理活检,方便快捷[28];④球囊直径小,可用于椎弓根横径细小的中下胸椎;Sky、Vessel-X、Jack、Spinejack 等因自身尺寸较大,适合于下胸椎或腰椎;⑤各种扩张器价格存在一定的差异,患者自身经济条件也是决定扩张器选择的重要因素。

3 展望

经过多年的临床应用与实践,各类扩张器的设计日益精湛,性能日趋完善,但是仍有扩张力量不可控、扩张器型号过于固定、手术操作要求高等诸多不足。随着脊柱外科微创理念的不断深入,脊柱外科手术的微创化、可视化的不断突破,结合当今计算机程控技术和3D打印技术,撑开力量可数控、形态及大小精确化将是未来扩张器的研发方向,扩张器的应用范围将是全脊柱,适用人群及适用疾病种类也将增多。在未来医学的发展中,微创手术将个体化、精准化、智能化,疾病得到医治的同时,患者将承受更小的精神及经济负担。

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