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匠人学术

——盐酸曲唑酮缓释剂临床应用

根据世界卫生组织公布的数据,全球已经有超过3亿人是抑郁症患者,中国约有3900万人患有不同程度的抑郁。对中国12个地区精神疾病流行病学调查显示,目前全国有严重精神疾病患者约1600万人。除了精神疾病,睡眠障碍也成为困扰人们健康生活的一大问题,成年人出现睡眠障碍的比例高达30%。精神疾病和睡眠障碍的治疗主要为药物治疗与非药物治疗。

曲唑酮是一种具有镇静催眠作用的抗抑郁药,临床广泛用于抑郁、失眠及抑郁焦虑伴发或合并失眠的患者。虽然美国食品药品监督管理局(FDA)尚未批准曲唑酮作为助眠药上市,但其作为助眠药在美国处方量中名列前茅,在全球范围内是比较常见的精神科“超适应症”用药。为进一步规范盐酸曲唑酮缓释剂的临床应用,本专家编写组整合了国内外临床试验、临床实践指南、处方指南及临床用药经验,撰写了此临床应用专家建议。

应用于抑郁症的治疗时,盐酸曲唑酮缓释剂稳定释放的特性使服药频率降低,服药1次/d,有效药物浓度可维持24h,1周开始起效,2~4周达到最佳疗效。成人服用盐酸曲唑酮缓释剂可以从睡前75~150mg起始,每2~4周增加75mg,最大剂量375mg/d。在住院患者急性期,可耐受时可每3d增加75mg。对于老年或便秘患者,建议给予较低的起始剂量(普通片剂25~50mg、缓释剂50~100mg)。每次增加25mg,直到达到预期的剂量,并避免剂量超过100mg。研究表明,对于治疗2~4周后疗效不佳的患者,可考虑将盐酸曲唑酮缓释剂的剂量增加到450mg/d,但需缓慢加量,以减少不良反应的发生。目前研究表明盐酸曲唑酮缓释剂在治疗抑郁相关失眠方面疗效明显,但大多是小型临床研究,临床中应用盐酸曲唑酮缓释剂治疗失眠的用法用量是基于抑郁症的治疗策略来调整的。

本专家建议已经根据现有的循证医学证据将盐酸曲唑酮缓释剂的临床药理及临床应用较好地展现了出来,但是基于现有的临床试验,仍然缺乏高质量的随机对照试验(RCT)结果,尤其是缺乏不同剂型的盐酸曲唑酮的临床研究证据。希望能够借助本建议给临床医生更好的用药指导,在未来高质量的医学证据产出的道路上做好循证医学铺垫。

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