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述评 EDITORIAL

利福昔明在消化疾病中的临床应用进展

崔东来, 陈 卫, 姚希贤

崔东来, 姚希贤, 河北医科大学第二医院消化内科 河北省石家庄市 050000
陈卫, 河北体育学院医院内科 河北省石家庄市 050041
崔东来, 1985年毕业于南通医学院, 现任河北医科大学第二医院主任医师, 博士研究生, 主要从事慢性胃病、慢性肝病的研究工作, 发表研究论文40篇, 主编、参编著作6部.
通讯作者: 崔东来, 050000, 河北省石家庄市, 河北医科大学第二医院消化内科. liver369@126.com
电话: 0311-87222301
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Clinical application progress of Rifaximin in the treatment of digestive diseases

Dong-Lai Cui, Wei Chen, Xi-Xian Yao

Dong-Lai Cui, Xi-Xian Yao, Department of Gastroenterology, the Second Hospital of Hebei Medical University, Shijiazhuang 050000, Hebei Province, China
Wei Chen, Department of Internal Medicine, Hospital of Hebei institute of Physical Education, Shijiazhuang 050041, Hebei Province, China
Correspondence to: Dong-Lai Cui, Department of Gastroenterology, the Second Hospital of Hebei Medical University, Shijiazhuang 050000, Hebei Province, China. liver369@126.com
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Abstract
Rifaximin, a derivative of rifamycin, has high antibacterial activity on various kinds of Gram-positive and -negative aerobes and anaerobes, and it is a new drug in the treatment of giardiasis. Rifaximin is not easy to be absorbed after oral administration, and mild systemic adverse reaction is the main characteristic. Recently, Rifaximin has been widely and effectively used in the therapy of many diseases related to intestinal bacterial infection such as hepatic encephalopathy, diverticular disease, overgrowth of intestinal bacteria, inflammatory bowel disease (IBD) and *H pylori* infection. The above advances were reviewed in the present article.

Key Words: Rifaximin; Diverticular disease; Overgrowth of intestinal bacteria; Inflammatory bowel disease; *Helicobacter pylori*

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摘要
利福昔明(Rifaximin)是利福霉素衍生物, 对多种革兰阳性、革兰阴性需氧菌和厌氧菌均有高度抗菌活性, 是治疗大肠埃希菌所致旅游者腹泻的一种新药. 口服不易被肠道吸收, 在肠道内有较高浓度, 全身不良反应轻微是其特点. 近年来利福昔明在肝性脑病、肠内胀气及肠道气体相关性疾病、憩室病、肠内细菌过度生长、炎症性肠病(IBD)以及幽门螺杆菌感染(*H pylori*)的根除等疾病治疗中应用日趋广泛并取得了较好疗效.

关键词: 利福昔明; 憩室病; 肠内细菌过度生长; 炎症性肠病; 幽门螺杆菌

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■背景资料
利福昔明在国内已有多家药厂生产, 但治疗适应证主要是肠道感染的治疗. 近年来, 利福昔明在肝性脑病、肠内胀气及气体相关性疾病、憩室病、肠内细菌过度生长、炎症性肠病(IBD)以及幽门螺杆菌感染(*H pylori*)的根除等疾病治疗中应用日趋广泛并取得了较好疗效, 本文对其在消化系统疾病中治疗进展进行了综述.

0 引言
利福昔明是利福霉素衍生物, 为半合成的抗生素, 抗菌谱广、抗菌作用强, 与其他胃肠道抗生素相比, 口服不易被肠道吸收, 在肠道内有较高浓度, 对多种革兰阳性、革兰阴性需氧菌和厌氧菌均有高度抗菌活性, 其作用机制为抑制细菌多聚酶, 阻止合成, 进而抑制细菌蛋白质合成, 在临床上适用于革兰阳性及革兰阴性需氧及厌氧菌所致急、慢性肠道感染、腹泻综合征, 肠道菌群改变所致腹泻, 术前及术后肠道用药. 近年来, 本药在其他消化系疾病中的应用日趋增加. 肝性脑病、肠内胀气及气体相关性疾病、憩室病、肠内细菌过度生长、炎症性肠病(IBD)以及幽门螺杆菌感染(*H pylori*)均与胃肠道细菌感染有关. 本文对其在上述消化系统疾病中的应用进展进行了综述.

1 肝性脑病(hepatic encephalopathy, HE)
血氨升高是HE发生的因素之一, 因此, 减少血氨

■同行评价
本文题目简洁明确, 文中针对利福昔明在消化道常见疾病中的作用进行了综述, 参考文献均为近年较新的国际性期刊发表的文章, 代表性较好, 内容基本反映了主题, 有参考价值.

产生, 降低血氨是治疗HE的关键, 常用药物有不吸收的双糖(如乳山梨醇或乳果糖)[1]和肠道难吸收的抗生素(如新霉素、巴龙霉素、甲硝哒唑、万古霉素), 前者易引起腹泻, 后者可能产生耳、肾毒性而限制了他的使用. 随机、双盲、对照研究表明利福昔明可改善HE的症状、体征, 降低血氨, 且副作用少, 可长期用于HE的治疗[2-10]. Mas *et al*[7]通过前瞻性的随机、双盲、对照对利福昔明与乳山梨醇治疗肝硬化患者Ⅰ-Ⅲ期HE的有效性和安全性进行了评价. 103例急性HE患者均除外了精神病患者、慢性肾功能衰竭、慢性呼吸功能衰竭、感染、入选前7 d曾用过抗生素或镇静剂, 孕妇或哺乳期妇女, 对利福昔明或对双糖类药物过敏者, 随机接受利福昔明(50例, 1200 mg/d)或乳山梨醇(53例, 60 g/d), 疗程为5-10 d, 治疗初始饮食中蛋白质限制在20 g/d以内, 随后在精神状态允许范围内可逐渐增加到0.5 g/(kg·d), 结果利福昔明组总有效率为81.6%, 乳山梨醇组为80.4%, 利福昔明组在降低血氨水平及改善脑电图方面的疗效显著优于乳山梨醇. Williams *et al*[4]随机、双盲、多中心研究也得出了同样结论. Pedretti *et al*[11]比较了利福昔明和巴龙霉素对HE的治疗效果, 利福昔明剂量为1200 mg/d, 巴龙霉素的剂量为1500 mg/d, 疗程为5-10 d, 结果两组均有改善临床症状, 降低血氨作用, 两组间无统计学差异. Miglio *et al*[12]采用随机、双盲方法比较了利福昔明、新霉素长期和短期治疗对HE的疗效和耐受性. 49例肝性脑病患者入组, 治疗方法为利福昔明400 mg, 每日3次, 巴龙霉素为1 g, 每日3次, 每月连用14 d, 共6 mo, 结果表明, 两组治疗后语言、记忆、行为、情绪、数字连接试验、震颤等症状和体征较治疗前均明显好转, 血氨水平也显著下降. 利福昔明巴龙霉素、新霉素相比, 治疗HE具有相同或更好的疗效, 但由于其口服不易吸收, 副作用较少, 故可作为治疗HE的首选抗生素, 特别是有肾功能损伤时.

2 炎症性肠病(IBD)

肠道细菌及其代谢产物可导致或加重溃疡性结肠炎[4-17], 应用抗生素治疗IBD取得了一定疗效, 但长期应用可产生严重的全身副作用. 近年来利福昔明治疗IBD的研究日趋增多[18-24]. Shafran *et al*[25]进行的开放性研究表明利福昔明对活动性克罗恩病治疗有效. Prantera *et al*[16,24]对利福昔明治疗克罗恩病进行了随机、双盲、多中心安慰剂对照研究, 83例轻、中度克罗恩病患者随机纳入3个治疗组: A组利福昔明800 mg, 每日1次, 加安慰剂, B组利福昔明800 mg, 每日2次, 加安慰剂, C组安慰剂组, 结果B组临床缓解率为52%, A组为32%, C组为33%, B组对伴有C反应蛋白升高患者的缓解率和有效率显著高于A组和C组. Pimentel *et al*[26]采用开放、前瞻性研究方法, 观察了利福昔明对不能耐受激素治疗的溃疡性结肠炎患者的治疗效果, 10例患者服用利福昔明(400 mg, 每日2次, 共4 wk), 另加美沙拉嗪, 全部患者肠道炎症活动指数都有所改善, 4 wk后临床症状消除率达70%. 28例中度至严重溃疡性结肠炎患者因病情顽固而静脉内给予皮质类固醇(甲泼尼龙), 采用随机、安慰剂对照方法, 患者随机接受利福昔明400 mg或安慰剂, 一日2次, 共10 d, 作为标准皮质类固醇治疗方案的辅助治疗, 临床终点为大便改善并无严重结肠炎的全身症状, 26例患者完成此项研究, 因严重不良反应2例患者在安慰剂组撤出, 利福昔明组阳性反应率为64.3%, 安慰剂组为41.7%. 在降低排便次数、直肠出血及乙状结肠镜检查评分方面都优于对照组. 虽然初步的研究结果令人鼓舞, 但需要进行大规模的临床对照研究以便进一步确定利福昔明对溃疡性结肠炎疗效.

3 小肠细菌过度生长

小肠细菌过度生长可引起肠道产气过多, 导致腹胀、腹部不适、矢气过多等症状[27-29]. 有研究报道, 短期使用利福昔明可减少肠道产氢气量, 可改善与气体过多相关的症状. 随机、双盲对照研究表明利福昔明在改善症状方面, 特别是对腹泻、肠鸣和疲乏等症状的作用尤为明显[30-34]. Biancone *et al*[35]研究表明, 短疗程利福昔明治疗对克罗恩病患者伴有的小肠细菌过度生长治疗有效, 21例小肠细菌过度生长患者随机接受利福昔明1200 mg/d和氯四环素1 g/d治疗, 对治疗前后的禁食呼氢量以及给予50 g葡萄糖后的峰值呼氢量和总呼氢量进行评价, 结果表明, 利福昔明组的禁食呼氢量、峰值呼氢量和总呼氢量均显著下降, 而氯四环素没有变化, 利福昔明组70%的患者经治疗后呼氢试验正常, 而氯四环素组只有27%. 另一项研究也表明利福昔明是治疗小肠过度生长有效、安全的药物. 对21例健康对照者和34例患者的肠道产气情况采用服用乳果糖后呼氢试验和呼甲烷试验进行评价, 34例患者参加双盲对照检查试验, 随机接受

利福昔明(400 mg, 每日2次, 共7 d)或活性碳(400 mg, 每日2次, 共7 d)治疗, 在治疗前及治疗后第1, 10天对下列指标进行评价: 腹胀、腹痛、矢气次数、腹围以及累积呼氢量, 结果表明患者的呼氢量高于健康对照者, 利福昔明显著降低呼氢量和症状总评分, 并使患者矢气次数和腹围显著减少, 而活性碳没有上述作用. Fanigliulo *et al*[32]观察了不同剂量的利福昔明对小肠细菌过度生长的临床疗效, 90例连续就诊的小肠细菌过度生长(50 g葡萄糖后呼氢试验阳性)患者随机纳入3个不同剂量治疗组(600, 800, 1200 mg/d), 治疗时间均为7 d, 结果1200 mg治疗组呼氢试验恢复正常率为60%, 显著高于其他两组, 说明利福昔明对小肠细菌过度生长治疗有效.

4 肠易激综合征(IBS)

是一种以腹痛或腹部不适伴排便习惯改变为特征的功能性肠病, 其发病机制尚不清楚. 结肠动力异常和小肠细菌过度生长可能与之有关, 抑制细菌过度生长可能能改善IBS症状[26,36]. Cuoco *et al*[33]采用回顾性方法观察了利福昔明对伴有小肠细菌过度生长的IBS的疗效, 对96例先前诊断为IBS的患者, 进行呼氢试验诊断有无小肠细菌过度生长, 96例患者中44例有小肠细菌过度生长, 对这44例患者给予利福昔明1200 mg/d治疗, 疗程为14 d, 结果82.6%的患者呼氢试验恢复正常, IBS症状得到明显改善. Sharara *et al*[36]采用双盲、随机、安慰剂对照研究方法也表明利福昔明对IBS患者的腹胀及胃肠胀气治疗有效.

5 结肠憩室病

治疗憩室病的目的是减轻症状和防止并发症的发生, 高纤维饮食、解痉药和美沙拉嗪常用于治疗本病, 有一定的疗效[37-40]. 最近研究表明, 周期性使用利福昔明对缓解单纯症状性憩室病的效果较单用高纤维素饮食组要好[39,41-47]. Papi *et al*[44]研究大样本的单纯症状性憩室病患者, 长期、周期性应用利福昔明对获得性症状的缓解作用, 并比较利福昔明与甘露聚糖联合治疗组与单用甘露聚糖组的憩室炎发生率, 研究结果表明, 周期性使用利福昔明与甘露聚糖联合治疗比单用甘露聚糖能更有效地减轻单纯憩室病患者的获得性症状. Tursi *et al*[37]研究表明, 美沙拉嗪联合利福昔明较后者单独应用更能有效减轻憩室病和的症状, 减少其复发次数. 至于利福昔明治疗单纯性憩室病的作用机制目前尚不清楚, 一种假设是他能降低肠道菌群的代谢活动, 使纤维素的分解和产气减少; 另一种可能是由于粪便滞留在憩室中导致细菌过度生长, 加剧了纤维素的分解及产气活动, 故利福昔明可能通过抑制细菌过度生长产生治疗作用.

6 幽门螺杆菌感染

*H pylori*感染是慢性胃炎、消化性溃疡、胃黏膜相关性淋巴瘤及胃癌重要病因之一[48-54]. 世界卫生组织已经把*H pylori*列为第一类致癌因子. 根除*H pylori*已成为治疗慢性胃病最重要的方法之一[55]. 研究表明单一药物治疗*H pylori*根除率平均为18.6%, 二联治疗为48.2%, 三联为82.3%, 以铋剂和质子泵抑制剂为主加两种敏感抗生素组成的三联疗法具有较高的*H pylori*根除率, 但副作用大且耐药性问题日益严重[56-60]. 体外研究表明, *H pylori*对利福昔明具有较高的敏感性, 50%抑菌浓度(MIC_{50})为4 mg/L, 90%抑菌浓度8 mg/L[61-62], 在临床上治疗*H pylori*感染也取得了较好疗效[61,63-67]. 利福昔明悬浮液对*H pylori*根除治疗研究表明, 71例有上消化道症状的*H pylori*阳性患者纳入研究, 前30例患者接受单一利福昔明治疗, 剂量为600 mg, 每日3次, 疗程为14 d, 后41例患者随机、开放纳入以下4组: (1)利福昔明600 mg , 每日3次+胶体铋240 mg, 每日2次; (2)利福昔明600 mg, 每日3次+奥美拉唑20 mg, 每日2次; (3)利福昔明600 mg, 每日3次+阿莫西林1 g, 每日2次; (4)利福昔明1800 mg, 每日3次+灭滴灵500 mg, 每日3次, 疗程为14 d, 结果以利福昔明单一治疗*H pylori*根除率为37%, 高于以往报道的单一药物治疗疗效(克拉霉素除外), 二联治疗*H pylori*总根除率为43%(各治疗组之间无统计学差异). Dell'Aana *et al*[68]采用随机开放方法比较了利福昔明悬液和胶囊对*H pylori*的根除疗效. 20例有上消化道症状*H pylori*阳性随机纳入: A组: 利福昔明悬液1800 mg, 每日3次+奥美拉唑20 mg, 每日2次; B组: 利福昔明胶囊1800 mg, 每日3次+奥美拉唑20 mg, 每日2次, 疗程为2 wk. 结果两组治疗后上消化道症状如灼心、腹胀、上腹部疼痛明显好转, *H pylori*根除率分别为A组40%和B组60%. Gasbarrini *et al*[64]研究了以利福昔明为主的三联疗法对*H pylori*的根除率, 48例的*H pylori*阳性的患者随机分为两组: 利福昔明片剂400 mg, 每日3次, 埃索美拉唑40 mg, 每日1次, 克拉霉素500 mg, 每日2次或左氧氟沙星500 mg, 每日1次, 疗程为7 d. 结果两组间*H pylori*的

根除率无统计学差异, 前者为58%, 后者为42%, 但两组均有良好的耐受性. 与当前标准*H pylori* 根除治疗方法相比, 虽然利福昔明对的根除率不高, 但由于其安全性、依从性好, 大样本、长疗程如四周、高剂量的治疗方案仍有可能取得较高的根除率, 值得深入研究.

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电编 张敏 编辑 张焕兰

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• 消息 •

关于2006年度山西省期刊质量评估结果的通报

本刊讯 为推动期刊出版事业的繁荣和发展, 中共山西省委宣传部、山西省新闻出版局、山西省科学技术厅共同组织了2006年度期刊质量评估工作. 此次参评的为2005年度山西省出版的196种期刊, 其中, 社科期刊110种、科技期刊86种. 评估结果如下: 一级(优秀)期刊共88种, 其中社科期刊42种, 科技期刊46种, 包括世界胃肠病学杂志和世界华人消化杂志; 二级期刊共103种, 其中社科期刊64种, 科技期刊39种; 三级期刊共5种, 其中社科期刊4种, 科技期刊1种. (中共山西省委宣传部、**山西省新闻出版局、山西省科学技术厅 2007-01-30)**