Advances in Clinical Medicine 临床医学进展, 2026, 16(6), 89-95
Published Online June 2026 in Hans. https://www.hanspub.org/journal/acm
https://doi.org/10.12677/acm.2026.1662198

灵泽片联合坦索罗辛胶囊治疗良性前列腺增生的早中期疗效分析

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收稿日期：2026年4月29日；录用日期：2026年5月23日；发布日期：2026年6月2日

摘　要

目的：探讨灵泽片联合坦索罗辛缓释胶囊治疗良性前列腺增生(BPH)的临床疗效，为临床优化治疗方案提供依据。方法：选取2022年1月~2025年10月收治的100例良性前列腺增生患者，采用随机数字表法进行随机分组，实施分配隐藏，采用开放标签设计，并基于既往研究数据完成样本量估算，将患者分为A组(中西医联合治疗，50例)与B组(单纯西医治疗，50例)。A组予灵泽片 + 坦索罗辛缓释胶囊，B组仅予坦索罗辛缓释胶囊；治疗3、6个月后，对比两组国际前列腺症状评分(IPSS)、生活质量评分(QOL)、最大尿流率(Qmax)、排尿后残余尿量(PVR)及患者总体改善印象量表(PGI-I)评分。结果：治疗3、6个月后，两组IPSS、QOL、PVR均较基线显著降低，Qmax显著升高($P < 0.001$)；A组各指标改善幅度均显著优于B组($P < 0.05$)。治疗6个月后，A组IPSS改善 ≥5分占86%、Qmax提升 ≥40%占82%、主观改善明显占70%，均显著高于B组($P < 0.05$)。结论：灵泽片联合坦索罗辛缓释胶囊可更有效地缓解良性前列腺增生患者的下尿路症状，改善尿动力学指标，提升生活质量，疗效优于单用坦索罗辛，安全可靠，值得临床推广。

关键词

良性前列腺增生，灵泽片，坦索罗辛缓释胶囊，下尿路症状，尿动力学，中西医结合

Efficacy Analysis of Lingze Tablets Combined with Tamsulosin Hydrochloride Capsules in the Early and Middle Stages of Benign Prostatic Hyperplasia

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文章引用: 金辉, 张丽华, 张彩英. 灵泽片联合坦索罗辛胶囊治疗良性前列腺增生的早中期疗效分析[J]. 临床医学进展, 2026, 16(6): 89-95. DOI: 10.12677/acm.2026.1662198

Received: April 29, 2026; accepted: May 23, 2026; published: June 2, 2026

Abstract

Objective: To investigate the clinical efficacy of Lingze Tablets combined with Tamsulosin Sustained-release Capsules in the treatment of Benign Prostatic Hyperplasia (BPH), and to provide evidence for optimizing clinical treatment strategies. Methods: A total of 100 patients with BPH admitted from January 2022 to October 2025 were enrolled. Random number table method was used for randomization, allocation concealment was implemented, an open-label design was adopted, and sample size estimation was completed based on previous studies before the study started, randomly divided into group A (integrated traditional Chinese and Western medicine, n = 50) and group B (Western medicine alone, n = 50). Group A received Lingze Tablets plus Tamsulosin Sustained-release Capsules, while group B received Tamsulosin alone. After 3 and 6 months of treatment, the International Prostate Symptom Score (IPSS), Quality of Life (QOL) score, maximum urinary flow rate (Qmax), Post-Void Residual urine volume (PVR), and Patient Global Impression of Improvement (PGI-I) score were compared between the two groups. Results: After 3 and 6 months of treatment, IPSS, QOL and PVR in both groups were significantly decreased, and Qmax was significantly increased compared with baseline ($P < 0.001$). The improvement of all indicators in group A was significantly better than that in group B ($P < 0.05$). After 6 months of treatment, 86% of patients in group A had IPSS improvement ≥ 5 points, 82% had Qmax increase ≥ 40%, and 70% had significant subjective improvement, all significantly higher than those in group B ($P < 0.05$). Conclusion: Lingze Tablets combined with Tamsulosin Sustained-release Capsules can more effectively relieve lower urinary tract symptoms, improve urodynamic indexes and quality of life in patients with BPH. The efficacy is superior to Tamsulosin alone, which is safe and reliable and worthy of clinical promotion.

Keywords

Benign Prostatic Hyperplasia, Lingze Tablets, Tamsulosin Sustained-Release Capsules, Lower Urinary Tract Symptoms, Urodynamics, Integrated Traditional Chinese and Western Medicine

1. 引言

良性前列腺增生(BPH)是老年男性中的一种常见疾病，会引起令人困扰的下尿路症状(LUTS) [1]，约50%的 50 岁以上男性患有病理性 BPH，而在 80 岁及以上人群中，这一比例升至 80%以上[2]。BPH 的特征是前列腺尿道周围区域的上皮细胞和间质细胞过度增生[3]，这通常会导致前列腺的大小和结构发生明显变化，从而引发 LUTS，包括排尿症状(尿流细弱、尿流分叉或喷射、间歇性排尿、排尿迟缓及排尿费力)、储尿症状(尿频、尿急、夜尿)以及排尿后症状(排尿不尽和排尿后滴沥) [4] [5]。若不加以治疗，这些症状可能导致膀胱和肾功能恶化，严重影响患者的生活质量[6]。由良性前列腺增生(BPH)引起的下尿路症状(LUTS)患者的治疗方案应根据疾病进展和症状严重程度来确定[7]。轻度病例可能仅需观察等待，而令人困扰的症状则需要调整生活方式并采取针对性治疗。药物治疗方案包括用于快速缓解症状的 α1 受体阻滞剂[8] [9]，以及用于治疗前列腺增生的 5α-还原酶抑制剂[10]，抗胆碱能药物用于治疗膀胱储尿症状[11]，磷酸二酯酶

5 型抑制剂用于治疗下尿路症状和勃起功能障碍[12]，以及去氨加压素用于治疗夜尿症[13]，在临床实践中，α1 受体阻滞剂与 5-α 还原酶抑制剂(5-ARI)或抗胆碱能药物的联合应用是治疗良性前列腺增生(BPH)的一种常见方法[14]。对于存在绝对指征的重症患者或药物难治性患者，建议采用以经尿道前列腺切除术为代表的手术治疗[7]。然而，手术也可能导致并发症和不良反应[15] [16]。除了这些治疗方法外，中国临床医生常选用市售的口服复方中药制剂作为前列腺增生的辅助治疗。复方中药制剂可缓解下尿路症状(LUTS)，并对特定人群的预后产生积极影响[17] [18]。然而，目前针对前列腺增生的此类制剂种类繁多，究竟哪种制剂最为有效仍存在争议。

中医认为，良性前列腺增生(BPH)属于“精淋”和“淋痹”的范畴，多见于老年人。其中大多数是由于脏腑功能逐渐衰退，或长期患病导致肾气受损所致。肾虚、血瘀和湿邪阻滞膀胱，从而引起前列腺增生和排尿困难。中医治疗方法主要包括补肾益气、活血化瘀、散结利尿、疏通膀胱。“灵泽片”的配方简单，由五灵发酵粉、姜黄、贝母和泽泻组成[19]，五灵发酵粉具有补心肾、除湿利尿的功效。莪术具有破血活血之效，贝母可清热散结，泽泻则能利水祛湿。灵泽片通过上述药材的协同作用，适用于肾虚、血瘀、湿阻型良性前列腺增生患者的治疗。灵泽片规格为 0.58 克/丸。灵泽片口服，每次 4 片，每日三次。疗程为 4~12 周。秦[20]等研究了千叶芍和灵泽片治疗良性前列腺增生的效果，结果显示灵泽片有效率更高，且经 6 周治疗后显著改善了患者的排尿症状。孟[19]等研究了灵泽片治疗良性前列腺增生的效果，观察了国际前列腺症状评分(IPSS)和生活质量评分(QOL)，并分析了治疗 30、60 和 90 天后的 IPSS 和 QOL 评分。研究发现，灵泽片能显著降低评分，并显著改善下尿路不适症状。本研究旨在评估坦索罗辛联合灵泽片治疗良性前列腺增生患者的早期至中期疗效，为优化治疗策略提供临床参考。

2. 资料与方法

2.1. 一般资料

选取邵逸夫医院德清分院泌尿外科 2022 年 1 月~2025 年 10 月收治的 100 例良性前列腺增生患者，按随机数字表法分为 A 组(中西医组)与 B 组(西医组)。中西医组 50 例，年龄 47~86 岁，平均年龄(60.11 ± 9.86)岁；病程 3~20 年，平均病程(14.13 ± 3.26)年；前列腺体积 24~46 mL，平均前列腺体积(33.42 ± 1.25) mL。西医组 50 例，年龄 37~85 岁，平均年龄(64.7 ± 5.1)岁；病程 3~21 年，平均病程(12.72 ± 3.18)年；前列腺体积 23~45 mL，平均前列腺体积(32.16 ± 1.13) mL。对比 2 组上述一般资料，差异无统计学意义($P > 0.05$)，具有可比性。

纳入标准：年龄 > 40 岁的男性患者，经诊断为有症状的良性前列腺增生。排除标准：(1) 已服用 α 受体阻滞剂的患者；(2) 血尿；(3) 慢性肾脏病；(4) 双侧输尿管肾积水；(5) 膀胱结石；(6) 膀胱憩室。

2.2. 随机化与分配隐藏

采用随机数字表法实施随机分组：由未参与患者招募与治疗的统计人员生成 1~100 随机数字，奇数入 A 组，偶数入 B 组；分组结果密封于不透光信封，由专人保管，分配隐藏至患者入组给药前，研究者、临床评估人员无法提前获知分组信息。

2.3. 盲法设计

本研究采用开放标签设计，原因：灵泽片为中药片剂，坦索罗辛为西药胶囊，外观、剂型、服用频次差异显著，无法制备匹配安慰剂；且研究为疗效对比观察，干预措施差异明确，实施双盲不具备可行性。开放标签可能导致患者主观评分偏倚，结果分析中已结合客观尿动力学指标校正。

2.4. 样本量估算

研究开始前基于 PASS 15.0 软件完成样本量估算：以 IPSS 评分主要终点为依据，设定 $\alpha = 0.05$，检验效能 $1 - \beta = 0.80$；参考既往中药联合 α 受体阻滞剂治疗 BPH 研究[19]，预计联合治疗组 IPSS 较单药组多改善 3 分，标准差 4.0，计算得每组需样本量 47 例，考虑 10%脱落率，最终确定每组 50 例，总样本量 100 例。

2.5. 治疗方法

共 100 名患者采用计算机随机分组法分为两组。A 组和 B 组各 50 名患者。A 组患者给予灵泽片(浙江佐力药业股份有限公司，国药准字 Z20110050，规格：0.58 g/片)，2.32 g/次，3 次/d 及坦索罗辛胶囊(安斯泰来制药(中国)有限公司，国药准字 H20000681，规格：0.2 mg/粒，0.2 mg/次，1 次/d 治疗，B 组患者接受坦索罗辛胶囊治疗。

2.6. 观察指标

所有患者在入组前均接受了全面评估。每例患者均进行了详细病史采集、包括腹部检查在内的全身体格检查、外生殖器检查及直肠指检。同时进行了神经系统检查以排除任何神经功能缺损。检查项目包括尿液分析、尿培养、基线检查(含肾功能检查、腹部超声、血清前列腺特异性抗原检测)及尿流率测定。向所有患者详细解释了国际前列腺症状评分(IPSS)，并提供 IPSS 评分表以量化下尿路症状(LUTS)的严重程度，同时采用 PGI-I 量表。治疗疗效通过 3 个月和 6 个月时最大排尿量(Qmax)、排尿后残余尿量(PVR)、国际尿路症状评分(IPSS)及 PGI-I 评分的变化进行评估。

2.7. 计学分析

数据采用 SPSS 26.0 版软件进行分析。结果的统计学评估采用 Student’s t 检验和单变量逻辑回归分析，P 值 < 0.05 被视为具有统计学意义。

3. 结果

3.1. 两组患者临床疗效比较

A 组较 B 组疗效更优，差异有统计学意义($P < 0.05$)。见表 1。

Table 1. Comparison of clinical efficacy between two groups of patients
表 1. 两组患者临床疗效比较

观察指标	时间	A 组(n = 50)	P 值	B 组(n = 50)	P 值	两组之间
年龄(岁)		60.11 ± 9.86		64.7 ± 5.1		0.472
前列腺体积(mL)		33.42 ± 1.25		32.16 ± 1.13		0.594
IPSS 评分	基线	18.3 ± 2.7		17.9 ± 3.0		0.310
	3 月后	12.4 ± 2.0	<0.001	14.9 ± 1.8	<0.001	<0.001
	6 月后	8.1 ± 1.7	<0.001	12.5 ± 2.1	<0.001	<0.001
QOL 评分	基线	5.3 ± 0.6		5.2 ± 0.7		0.265
	3 月后	4.2 ± 0.8	<0.001	4.7 ± 0.8	0.003	0.001
	6 月后	3.0 ± 0.8	<0.001	4.2 ± 0.9	<0.001	<0.001

续表

Qmax (mL/s)	基线	7.9 ± 1.1		8.1 ± 1.2		0.212
	3 月后	10.0 ± 1.5	<0.001	9.5 ± 1.3	<0.001	0.042
	6 月后	13.8 ± 1.5	<0.001	11.2 ± 1.3	<0.001	<0.001
PVR (mL)	基线	100.0 ± 30.0		105.0 ± 32.0		0.215
	3 月后	70.0 ± 25.0	<0.001	85.0 ± 28.0	<0.001	0.006
	6 月后	50.0 ± 20.0	<0.001	70.0 ± 25.0	<0.001	<0.001

3.2. 两组患者治疗 6 月后疗效比较

A 组在 IPSS 改善程度及 Qmax 提高程度方面均优于 B 组，主观改善评分 A 组优于 B 组。见表 2。

Table 2. Efficacy comparison of two groups of patients at 6-month follow-up
表 2. 两组患者治疗 6 月后疗效比较

观察指标	A 组 n (%)	B 组 n (%)	P 值
IPSS (改善 ≥ 5 分)	43 (86%)	30 (60%)	0.002
Qmax increase ≥ 40%	41 (82%)	27 (54%)	<0.001
主观改善(PGI-I)			
改善很多	35 (70%)	18 (36%)	0.001
改善一点	12 (24%)	21 (42%)	0.001
无改善或更糟	3 (6%)	11 (22%)	0.001

注：PGI-I：患者总体改善印象量表。

4. 讨论

前列腺增生(BPH)是一种进行性疾病，其特征是症状随时间推移逐渐加重，部分患者甚至需要接受手术治疗。鉴于手术及长期留置导尿管带来的相关风险，本研究探讨了将坦索罗辛环视胶囊与灵泽片联合用于良性前列腺增生患者，在疗效方面优于单纯应用坦索罗辛缓释胶囊患者。灵泽片配方简单，由武陵发酵粉、姜黄、贝母和泽泻组成[21]，武陵发酵粉的化学成分主要包括黄酮类、多糖、腺苷、氨基酸、微量元素和蛋白质[22]-[24]，药理学研究表明，武陵发酵粉具有抗氧化应激、抗炎及改善排尿症状的作用[25]，Chen [26]等的研究显示，黄酮类化合物在预防和治疗良性前列腺增生方面具有巨大的应用潜力。莪术具有活血化瘀、软硬散结及抑制前列腺增生的功效[20]。莪术的化学成分主要包括挥发油、姜黄素、多糖、甾醇、酚酸和生物碱。姜黄油可抑制犬类动物的前列腺增生[27]，贝母具有调节免疫平衡、镇痛、抗炎和抗菌的作用[28]。另一项研究表明，贝母的主要化学成分包括黄酮类、生物碱、多糖、总皂苷及挥发成分[29]，泽泻具有多种生物活性，如利尿、抗肾结石、抗炎、抗氧化应激等[28]，东亚泽泻含有多种化学成分，其中三萜类和倍半萜类是主要化学成分，次要化学成分包括二萜类、挥发油、含氮化合物、苯丙素类及其他[30]。黄酮类和萜类化合物在治疗前列腺疾病中发挥着重要作用。本研究结果显示，中西医组治疗后的残余尿量较少、最大尿流率较大，提示中西医联合治疗可显著改善患者的尿动力学指标，促进膀胱功能尽快恢复。综上所述，灵泽片联合西药治疗良性前列腺增生在早中期可有效缓解患者症状，改善尿动力学指标，效果较为安全可靠，在临床上具有一定的参考价值。

本研究仍存在一定局限性，1) 设计局限：开放标签可能导致患者主观评分偏倚，虽结合客观尿动力

学指标校正，但仍存在偏倚风险；2) 样本与周期：单中心、小样本(100 例)，仅观察 6 个月早中期疗效，缺乏 1 年以上长期有效性与安全性数据；3) 人群局限：未按前列腺体积、症状严重程度分层，未纳入合并糖尿病、心血管病等复杂病例，结果外推受限；4) 机制局限：仅观察临床疗效，未检测炎症因子、前列腺组织学等指标，作用机制未深入阐释；5) 未设安慰剂对照：仅对比联合与单药，无法排除安慰剂效应。

声　明

本研究获得德清县人民医院伦理委员会批准(审批号：LL2022-K14)。

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