

• 专题研究:神经系统疾病 •

偏头痛药物治疗规范性现状及影响因素分析:一项基于2 028例患者的横断面研究

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[摘要] 目的: 调查偏头痛患者预防性药物治疗的指南遵从性现状, 量化评估治疗不足与潜在过度治疗的规模, 并分析其相关影响因素。方法: 采用横断面研究设计, 纳入2020年1月—2025年8月于南京医科大学第一附属医院头痛专病门诊就诊, 且符合国际头痛疾病分类第3版诊断标准的2 028例偏头痛患者。依据《中国偏头痛诊断与治疗指南(2023版)》及国际头痛学会偏头痛预防药物治疗全球实践建议, 以每月偏头痛天数 ≥ 4 d作为预防性治疗指征, 并结合实际用药情况分为符合指征组(A组)、潜在过度治疗组(B组)、规范急性期治疗组(C组)、用药不当组(D组), 比较各组临床特征及用药模式差异, 并以多因素Logistic回归分析A组治疗不足的影响因素。结果: 2 028例患者中, A组685例(33.8%), 其中21.2%(145/685)存在治疗不足; B组、C组和D组分别为446例(22.0%)、619例(30.5%)和278例(13.7%)。A、B组预防性用药以钙离子拮抗剂和抗癫痫药为主, B组钙离子拮抗剂使用率高于A组(71.3% vs. 40.6%, $P < 0.001$); 急性期药物中, 曲普坦类、对乙酰氨基酚、非甾体抗炎药和降钙素基因相关肽受体拮抗剂在C组使用率最高。多因素Logistic回归分析显示, 急性期特异性药物使用(调整的OR=1.90, 95%CI: 1.27~2.82, $P=0.002$)和每月偏头痛天数增加(调整的OR=1.02, 95%CI: 1.00~1.03, $P=0.036$)与A组治疗不足显著相关。结论: 偏头痛预防性治疗存在明显的“双向不规范”现象, 即符合指征患者治疗不足, 而不符合指征患者存在潜在过度治疗。临床实践中应严格把握预防性治疗指征, 强化对急性期特异性药物使用者的预防治疗评估, 并规范药物选择与头痛分型诊断, 以提高指南遵从性。

[关键词] 偏头痛; 预防性治疗; 指南遵从性; 治疗不足; 过度治疗; 药物分类**[中图分类号]** R747.2**[文献标志码]** A**[文章编号]** 1007-4368(2026)04-482-08**doi:** 10.7655/NYDXBNSN260072

Analysis of the current status and influencing factors of standardized migraine drug treatment: a cross-sectional study based on 2 028 patients

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[Abstract] **Objective:** To investigate guideline adherence to preventive pharmacotherapy in patients with migraine, quantify the extent of undertreatment and potential overtreatment, and analyze the associated influencing factors. **Methods:** In this cross-sectional study, 2 028 patients with migraine who attended the specialized headache clinic of the First Affiliated Hospital of Nanjing Medical University between January 2020 and August 2025 and fulfilled the diagnostic criteria of the International Classification of Headache Disorders, 3rd edition (ICHD-3) were enrolled. According to the Chinese Guidelines for the Diagnosis and Treatment of Migraine (2023 edition) and the International Headache Society's global practice recommendations for preventive pharmacological treatment of migraine, ≥ 4 monthly migraine days was defined as the indication for preventive treatment. Based on treatment indications and actual medication use, patients were categorized into four groups: indication-comforming group (Group A), potential overtreatment group (Group B), appropriate acute treatment group (Group C), and inappropriate medication use group (Group D). Clinical characteristics and medication patterns were compared among the groups. Multivariable logistic regression was performed to identify factors associated with undertreatment in Group A. **Results:** Among the 2 028 patients, 685 (33.8%) were assigned to Group A, of whom 21.2% (145/685) were undertreated. Groups B, C, and D comprised 446 (22.0%), 619 (30.5%), and 278 (13.7%) patients, respectively. Preventive

[基金项目] 国家自然科学基金(81600970)

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medications in Groups A and B were mainly calcium channel blockers and antiepileptic drugs, with a significantly higher use of calcium channel blockers in Group B than in Group A (71.3% vs. 40.6%, $P < 0.001$). For acute medications, triptans, acetaminophen, nonsteroidal anti-inflammatory drugs, and calcitonin gene-related peptide receptor antagonists were used most frequently in Group C. Multivariable logistic regression showed that the use of acute migraine-specific medications (adjusted OR=1.90, 95%CI: 1.27-2.82, $P=0.002$) and a greater number of monthly migraine days (adjusted OR=1.02, 95%CI: 1.00-1.03, $P=0.036$) were significantly associated with undertreatment in Group A. **Conclusion:** Preventive treatment of migraine demonstrated a clear pattern of bidirectional nonadherence, characterized by undertreatment among patients with indications for preventive therapy and potential overtreatment among those without such indications. In clinical practice, stricter adherence to indications for preventive treatment is needed, along with strengthened evaluation of preventive therapy among users of migraine-specific acute medications and more standardized drug selection and headache subtype diagnosis, in order to improve guideline adherence.

[Key words] migraine; preventive treatment; guideline adherence; undertreatment; overtreatment; medication classification

[J Nanjing Med Univ, 2026, 46(04): 482-488, 567]

偏头痛作为全球发病率最高的原发性头痛之一,其终生患病率达14.4%,且因高复发率、高致残性显著降低患者生活质量,造成沉重的社会经济负担^[1]。偏头痛规范化治疗体系包含急性期治疗与预防性治疗两大核心环节:急性期治疗以快速终止头痛发作为目标,曲普坦类、降钙素基因相关肽(calcitonin gene-related peptide, CGRP)受体拮抗剂等特异性药物是临床一线选择;预防性治疗则聚焦于降低发作频率、减轻疾病严重程度,是中重度偏头痛患者长期管理的关键策略^[2]。

既往相关研究多集中于预防性治疗不足这一单一维度,对潜在过度治疗的流行病学特征、成因及临床影响探讨相对欠缺^[3]。临床实践中发现两类突出误区:一是部分医生对未达预防指征的患者,基于血管调节异常等机制推断,或因急性期治疗不充分导致患者频繁就诊,而启动预防性治疗;二是对于已符合预防指征但急性期特异性药物治疗有效的患者,医患双方易因症状控制满意而忽视预防性治疗的必要性^[4]。后者作为隐匿性治疗不足的重要表现,其背后的临床决策逻辑尚未被充分阐明,相关干预策略也缺乏针对性实证依据。

基于此,本研究通过大样本横断面调查,系统评估预防性治疗的规范性全景,首次同时量化治疗不足与潜在过度治疗的规模,并深入分析不同组别的用药结构,重点探索急性期治疗规范性与预防性治疗启动的关联机制,为构建分层、精准的偏头痛管理体系提供数据支撑与实践指导。

1 对象和方法

1.1 对象

回顾性收集2020年1月—2025年8月就诊于

南京医科大学第一附属医院神经内科头痛专病门诊的患者。纳入标准:①符合国际头痛疾病分类第3版原发性偏头痛诊断标准;②头痛发作频率、药物使用史等核心临床资料完整。排除标准:①继发性头痛(如颅内占位性病变、脑血管疾病、感染性疾病等所致);②合并严重肝肾功能不全、精神分裂症等严重并发症;③头痛频率或关键用药记录缺失。初始筛查2 598例,排除继发性头痛160例及资料不全者410例,最终纳入2 028例进行分析。本研究通过南京医科大学第一附属医院医学伦理委员会审批(审批号:2022-SR-211),患者均知情同意。

1.2 方法

1.2.1 预防性治疗指征

参照中华医学会神经病学分会发布的《中国偏头痛诊断与治疗指南(2023版)》和国际头痛学会偏头痛预防药物治疗全球实践建议,将每月偏头痛天数(monthly migraine day, MMD)≥4 d定义为具有预防性治疗指征^[5-6]。对于仅记录月发作次数的病例,结合偏头痛单次发作平均持续1~2 d的临床特征,采用1.5 d/次的系数转换为MMD。为检验此转换假设对主要结论的影响,进行敏感性分析,分别采用1.0 d/次和2.0 d/次进行转换,再重新进行患者分组及统计分析。

1.2.2 药物分类与患者分组

统一药品通用名,并依据指南分为急性期治疗药与预防性治疗药,后者再区分推荐与非推荐。急性期治疗药包括:非甾体抗炎药(nonsteroidal anti-inflammatory drugs, NSAIDs)、对乙酰氨基酚、曲普坦类、CGRP受体拮抗剂。预防性治疗药包括:推荐药物(钙离子拮抗剂:氟桂利嗪;β受体阻滞剂:普萘洛尔、美托洛尔;抗癫痫药:托吡酯、丙戊酸钠;抗抑郁

药:阿米替林、文拉法辛)、非推荐药物(天舒胶囊、乙哌立松、氟伏沙明等循证证据不足的品种)。根据指征与用药,将患者分为4组:A组(符合指征组):MMD \geq 4 d(无论是否使用预防性药物);B组(潜在过度治疗组):MMD $<$ 4 d,且正在使用推荐的预防性药物;C组(规范急性期治疗组):MMD $<$ 4 d,仅使用推荐急性期药物;D组(用药不当组):MMD $<$ 4 d,使用非推荐预防药且未使用推荐急性药。

1.2.3 临床资料收集

收集患者人口学资料(年龄、性别)、临床特征(病程、有无先兆、发作频率)及经颅多普勒超声声学造影发泡试验、磁共振检查结果,脑白质高信号(white matter hyperintensive, WMH)通过1.5T或3.0T磁共振液体衰减反转恢复(fluid-attenuated inversion recovery, FLAIR)序列评估。轻度:侧脑室周围或深部白质散在高信号;中度:融合性高信号;重度:广泛融合高信号。

1.3 统计学方法

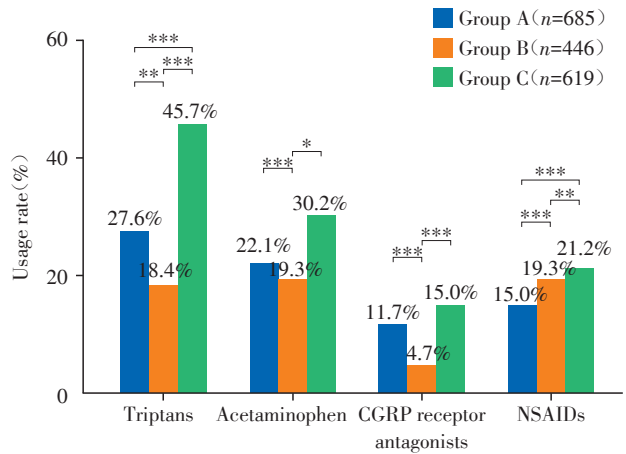
使用R语言4.5.1进行统计分析。计数资料以例数(百分比)[$n(\%)$]表示,组间比较采用 χ^2 检验,当理论频数 $<$ 5时改用Fisher精确检验。符合正态分布的计量资料以均数 \pm 标准差($\bar{x} \pm s$)表示,组间比较采用 t 检验;不符合正态分布者以中位数(四分位数)[$M(P_{25}, P_{75})$]表示,采用Mann-Whitney U 检验。以A组患者是否发生治疗不足为因变量,纳入人口学特征、临床特征、辅助检查结果等为自变量,进行多因素Logistic回归分析,筛选影响因素,计算调整后比值比(adjusted odds ratio, aOR)及其95%置信区间(confidence interval, CI)。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 患者分组与治疗规范性全景

2 028例患者分组情况如下:A组685例(33.8%),B组446例(22.0%),C组619例(30.5%),D组278例(13.7%)。A组患者中,有21.2%(145/685)未接受任何预防性治疗,为治疗不足;B组作为潜在过度治疗群体,规模接近A组。

A、B、C 3组急性期用药结构差异显著(P 均 $<$ 0.001,图1)。曲普坦类药物在C组使用率最高(45.7%),显著高于A组(27.6%)和B组(18.4%)。CGRP受体拮抗剂在C组使用率最高(15.0%)。NSAIDs与对乙酰氨基酚在C组使用率最高(分别为21.2%和30.2%)。

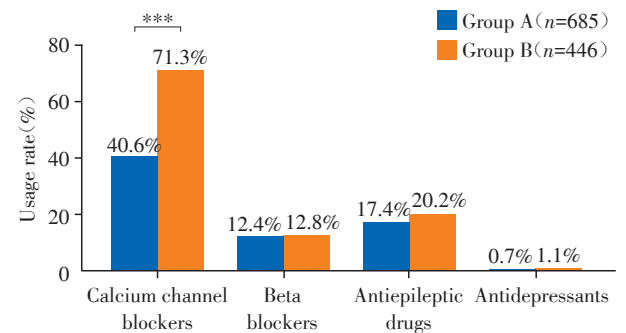


The proportions of patients using triptans, acetaminophen, CGRP receptor antagonists, and NSAIDs were compared among the three groups. * $P < 0.05$, ** $P < 0.01$, and *** $P < 0.001$.

图1 3组患者急性期治疗药物使用率比较

Figure 1 Comparison of acute medication usage rates among the three groups

A、B两组预防用药结构差异明显。B组钙离子拮抗剂使用率(71.3%)显著高于A组(40.6%, $P < 0.001$)。抗癫痫药使用率两组相近(A组17.4%、B组20.2%, $P > 0.05$); β 受体阻滞剂使用率分别为A组12.4%、B组12.8%($P > 0.05$);抗抑郁药在两组中使用率均极低(A组0.7%,B组1.1%,图2)。



The proportions of patients receiving calcium channel blockers, beta blockers, antiepileptic drugs, and antidepressants were compared between the group A and group B. *** $P < 0.001$.

图2 A、B两组预防性治疗药物使用率比较

Figure 2 Comparison of preventive medication usage rates between the group A and group B

2.2 A组与B组临床特征比较

B组患者中无先兆偏头痛比例更高(87.22% vs. 78.39%, $P < 0.001$),急性期曲普坦药物使用率更低(18.39% vs. 27.59%, $P < 0.001$),病程更短[7.00(3.00, 12.00)年 vs. 8.00(4.00, 14.00)年, $P < 0.001$]。两组在年龄、性别、WMH及发泡试验阳性率方面差异无统计学意义(表1)。

表1 A组与B组临床特征比较

Table 1 Comparison of clinical characteristics between the group A and group B

Clinical characteristic	Group A (n = 685)	Group B (n = 446)	P
Age (years, $\bar{x} \pm s$)	39.05 ± 13.28	40.24 ± 13.98	0.074
Sex [n(%)]			0.586
Male	131 (19.12)	92 (20.63)	
Female	554 (80.88)	354 (79.37)	
Presence of aura [n(%)]	148 (21.61)	57 (12.78)	< 0.001
WMH [n(%)]			0.451
Unknown	79 (11.53)	52 (11.66)	
No WMH	478 (69.78)	302 (67.71)	
With WMH	128 (18.69)	92 (20.63)	
Bubble test [n(%)]			0.595
Unknown	298 (43.50)	214 (47.98)	
Positive	194 (28.32)	126 (28.25)	
Negative	193 (28.18)	106 (23.77)	
Migraine-specific medications [n(%)]	189 (27.59)	82 (18.39)	< 0.001
Disease duration [years, $M(P_{25}, P_{75})$]	8.00 (4.00, 14.00)	7.00 (3.00, 12.00)	< 0.001
MMD [d, $M(P_{25}, P_{75})$]	8.00 (4.00, 20.00)	2.00 (1.00, 3.00)	< 0.001

2.3 A组治疗不足的影响因素分析

多因素 Logistic 回归分析显示, 急性期特异性药物(以曲普坦类为代表)使用率(aOR=1.896, 95% CI: 1.271~2.817, $P=0.002$)和MMD增加(aOR=1.017, 95% CI: 1.001~1.032, $P=0.036$)与治疗不足显著相关。年龄、有无先兆、WMH、发泡试验结果及病程与治疗不足无独立关联(表2)。

敏感性分析结果显示, 当采用1.0 d/次或2.0 d/次进行MMD换算时, 各组患者分布比例变化不大。针对A组治疗不足影响因素的多因素分析表明, 急性期特异性药物使用仍与治疗不足显著相关(OR: 1.82~1.93, P 均<0.01), 且置信区间与主要分析高度重叠; MMD的影响方向一致, 但在换算系数为2.0 d/次时, 其统计学显著性减弱($P=0.052$)。其他因素如年龄、WMH等的结论与主要分析一致(表3)。这表明本研究的主要结论对于MMD的换算方法是稳定的。

3 讨论

本研究基于2 028例偏头痛患者的数据, 首次在国内揭示了预防性治疗“治疗不足”与“潜在过度治疗”并存的“双向不规范”现状, 并从用药模式视角剖析了其背后的潜在逻辑。

本研究发现不符合预防指征的B组患者, 其用药模式呈现“急性期治疗不足”与“预防性治疗过度”并存的特征。B组曲普坦类及CGRP受体拮抗剂使用率均为3组最低, 提示其急性发作可能未获充分控制。与此同时, 该组预防性治疗却高度集中于钙离子拮抗剂(71.3%)。这一高预防、低急性特异性治疗的悖论模式可能源于临床上的“机制推断”决策: 一方面, 医生可能将患者因急性期治疗不充分导致的难治性头痛或伴随的眩晕症状, 归因于“血管痉挛”问题, 从而超适应征应用氟桂利嗪等药

表2 偏头痛A组治疗不足影响因素的多因素 Logistic 回归分析

Table 2 Multivariate logistic regression analysis of factors associated with undertreatment in migraine group A

Variable	β	SE	aOR	95%CI	P
Age	-0.010	0.009	0.990	0.973-1.008	0.281
Presence of aura	0.153	0.237	1.165	0.727-1.843	0.519
WMH	0.410	0.254	1.507	0.907-2.465	0.107
Positive bubble test	0.352	0.207	1.422	0.944-2.127	0.089
Migraine-specific medications	0.640	0.203	1.896	1.271-2.817	0.002
Disease duration	-0.014	0.014	0.986	0.960-1.012	0.296
MMD	0.016	0.008	1.017	1.001-1.032	0.036

表3 偏头痛A组治疗不足影响因素的敏感性分析
Table 3 Sensitivity analysis of factors associated with undertreatment in migraine group A OR(95%CI)

Influencing factor	Primary analysis (1.5 d/episode)	Sensitivity analysis (1.0 d/episode)	Sensitivity analysis (2.0 d/episode)
Age	0.99(0.97-1.01)	0.99(0.98-1.01)	0.99(0.97-1.01)
Presence of aura	1.17(0.73-1.84)	1.20(0.75-1.91)	1.15(0.72-1.83)
WMH	1.51(0.91-2.47)	1.48(0.89-2.44)	1.54(0.93-2.53)
Positive bubble test	1.42(0.94-2.13)	1.39(0.92-2.09)	1.45(0.96-2.18)
Migraine-specific medications	1.90(1.27-2.82)**	1.82(1.22-2.73)**	1.93(1.29-2.89)**
Disease duration	0.99(0.96-1.01)	0.99(0.96-1.01)	0.99(0.96-1.01)
MMD	1.02(1.00-1.03)*	1.02(1.00-1.04)*	1.02(1.00-1.04)

* $P < 0.05$, ** $P < 0.01$.

物^[7],这与Sacco等^[8]在欧洲多中心研究中观察到的低频头痛患者钙离子拮抗剂滥用的现象一致。另一方面,大规模流行病学数据表明,无先兆偏头痛是最常见的亚型,在总体偏头痛人群中占70%~80%^[9],Ezzati等^[10]研究指出,近一半的偏头痛患者急性处方药物治疗未达到优化;对于病程较短、无先兆偏头痛比例更高的B组患者,临床医生可能低估了规范急性期治疗的重要性,导致发作控制不佳^[11],患者频繁就诊,加之可能存在的早期干预心态,医生进而倾向于绕过急性期治疗的优化,直接启动预防性治疗。值得注意的是,WMH作为老年人群常见的影像学表现,其与偏头痛的因果关联尚未明确^[12-13],但此类非特异性发现可能强化医生的过度治疗倾向,违背了“预防治疗需严格基于发作频率指征”的指南核心原则^[5-6]。最新指南强调,急性期治疗与预防性治疗各有明确指征,不应相互替代^[14]。因此,B组现象的核心可能并非单纯的过度预防,其根源在于急性期治疗的规范性存在缺口。

多因素分析证实,急性期特异性药物使用与A组治疗不足显著相关(aOR=1.896),且A组曲普坦类使用率显著低于仅需急性治疗的C组。这一关联可能反映了临床上存在的“急性期治疗满意度陷阱”^[15]:对于高频发作患者,若其急性期使用曲普坦类药物并能取得部分症状控制,医患双方可能满足于发作时补救的短期效果,延迟或忽略了从根源上减少发作频率的预防性治疗^[2]。这种将急性期治疗目标替代长期疾病管理目标的认知偏差,与近年来国际学界关注的有效急性期治疗掩盖预防需求的现象高度契合,即尽管存在有效疗法,但治疗升级却因多种临床惰性而延迟^[16]。此外,MMD增加与治疗不足风险正相关,可能提示即使发作频率进一步升高,部分患者仍未及时启动预防治疗,可能与

指南指征向临床实践转化的不足有关。

对D组及极低抗抑郁药使用率的分析,反映了指南与实践间的复杂差距。A、B两组抗抑郁药使用率均极低(A组0.7%,B组1.1%),远低于指南推荐预期。深入分析发现,临床上实际使用的抗抑郁药物如马来酸氟伏沙明、氟哌噻吨美利曲辛、帕罗西汀等多为循证证据不足的品种,而指南明确有效的阿米替林、文拉法辛使用极少^[17]。这一现象源于临床医生对抗抑郁药类效应的错误认知,忽略了不同药物在偏头痛预防中的证据差异。D组中患者使用天舒胶囊、乙哌立松等非指南推荐药物,分析其原因,除中医“辨证论治”的临床习惯外^[18],更核心的原因是头痛分型诊断不精准,将伴有颈肩肌肉紧张的偏头痛误判为颈源性头痛或紧张型头痛,导致治疗靶点偏离疾病本质^[5,19]。此外,Björk等^[20]通过队列研究发现,与β受体阻滞剂相比,某些药物如托吡酯、可乐定的停药风险显著更高(风险比分别为1.34和2.95)。D组患者可能曾尝试过常规药物但因无法耐受而停药,转而尝试其他未被充分验证的替代方案。近年来,靶向CGRP通路的单克隆抗体如艾普奈珠单抗等和小分子拮抗剂如瑞美吉泮等被部分研究证明对预防偏头痛,特别是难治性偏头痛,具有显著疗效和良好耐受性^[21-22]。美国内科医师学会2025年的新指南基于成本效益考量,建议将CGRP靶向药物作为传统一线药物无效或不耐受后的二线选择^[14]。然而,这些新型疗法成本较高,且需长期随访,故本研究使用此类新型预防治疗的患者极少。这种阶梯式治疗策略和现实的可及性障碍,可能导致部分患者在传统治疗失败后,未能及时升级至最有效的新型疗法,而是滞留在使用效果不明确药物的灰色地带。这些选择虽有其实境,但总体上偏离了以高级别证据为基础的规范化治疗路径。

对D组患者的管理,核心在于积极识别并将其治疗策略重新校准至基于循证医学的轨道上。临床医生应警惕急性期治疗不规范与预防治疗非循证的两头落空模式,对于相关患者需重新全面评估其头痛日记、药物使用史、既往治疗失败原因以及生活质量影响。根据2025年欧洲神经病学学会大会上发布的RESOLUTION研究启示,对于复杂患者,在提供标准化患者教育的同时,早期联合使用CGRP靶向预防治疗,能快速、显著地减少偏头痛天数与急性用药,打破恶性循环^[23]。临床实践中应基于最新疗效与耐受性证据选择药物,对传统口服药无效或不耐受者,积极考虑换用证据确凿的新型预防药物,参考2025年更新的NICE指南所倡导的分层治疗框架,平衡疗效与不良反应风险^[24],避免过度延迟CGRP靶向药物的使用。同时,需与患者充分沟通现有治疗方案的局限性,解释指南推荐药物的循证依据,共同制定以改善生活质量和功能为目标的新治疗计划。

本研究的优势在于大样本量、基于指南的清晰分类以及同时关注“治疗不足”与“潜在过度治疗”的“双向不规范”现象。然而,本研究也存在局限性:①作为横断面研究,重点关注治疗行为的规范性本身,未能收集头痛残疾程度、生活质量等纵向临床结局数据^[25],因此无法评估不同治疗策略与患者长期功能预后的关联^[26]。未来的前瞻性研究应纳入这些患者报告结局,更全面地验证规范治疗的价值。②研究中通过发作次数换算MMD可能引入误差,尽管已进行敏感性分析,但未来研究应鼓励患者记录头痛日记以获取更精准的MMD数据^[27]。③本研究为回顾性设计,未系统收集患者焦虑、抑郁等心理共病及受教育程度、经济状况等社会人口学变量,这些因素可能影响患者的治疗选择与依从性,从而对治疗规范性产生混杂影响。未来研究应在前瞻性设计中纳入此类变量,以更全面理解影响治疗决策的因素。

针对上述问题,建议从3个方面推动偏头痛预防性治疗规范化:①强化指南核心原则执行,严格以MMD \geq 4 d作为预防治疗启动指征,避免基于机制推断或非特异性检查结果的过度治疗^[5,13];②识别高风险人群,对符合急性期特异性药物使用指征的患者,主动评估预防治疗需求,打破满意度陷阱^[28-29];③提升诊断与用药精准度,加强原发性头痛分型培训,减少误诊导致的用药偏差,同时规范预防性药物选择,优先使用氟桂利嗪、托吡酯等指南

推荐品种,对传统药物无效或不耐受者,积极考虑CGRP靶向药物等新型疗法^[21,23]。未来可针对急性期特异性药物使用者这一高危人群设计干预性研究,如开发整合指南指征的临床决策支持系统,或开展基于循证的患者教育项目^[30],系统性推动实践转化。

综上所述,当前偏头痛药物治疗领域存在显著的指南与实践之间的差距,表现为治疗不足与潜在过度治疗共存。优化临床实践需要医生在严格遵循循证证据指征的前提下,增强对符合急性特异性药物和预防性药物等使用特征的患者的识别与管理意识,从而真正实现以患者为中心、规范偏头痛的药物治疗。

利益冲突声明:

所有作者声明无利益冲突。

Conflict of Interests:

All authors disclose no relevant conflict of interests.

作者贡献声明:

李跃文负责数据分析、初稿撰写、图表制作;燕兰云参与实验监督和论文修改。

Author's Contributions:

LI Yuewen was responsible for data analysis, initial draft preparation, construction of charts and graphs; YAN Lanyun participated in experiment supervision and manuscript revision.

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- (收稿: 2025-12-10; 修回: 2026-03-04; 录用: 2026-03-05)
(本文编辑: 唐 震)

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- (收稿: 2026-01-15; 修回: 2026-03-17; 录用: 2026-03-20)
(本文编辑: 蒋 莉)