

老年人缺铁性贫血与生活质量

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【摘要】：目的：本研究旨在评估纠正缺铁性贫血对接受肠外补铁治疗的患者健康相关生活质量的影响，并在一项随机对照试验中比较静脉补铁和安慰剂治疗的效果。**方法：**使用（SF-8 简写形式）对老年缺铁性贫血患者的健康相关生活质量进行问卷调查（共 51 项，2:1 随机、盲法、对照研究）。有严重认知或身体障碍的患者被排除在外。对观察结果进行了显著性水平测试。**结果：**PCS 和 MCS 评分反映了一般健康、身体疼痛、活力、社会功能、情感角色和身心健康的整体改善等领域有显著改善。与 SF-8 的其他五个参数相比，SF-8 的身体功能、身体作用和心理健康改善的领域在 4 周时不那么令人印象深刻。安慰剂治疗前后 SF-8 项目（HRQoL）无统计学差异。**结论：**老年缺铁性贫血患者的 HRQoL 降低，肠外铁剂治疗导致 4 周评估的 HRQoL 快速改善，在大多数领域显著高于安慰剂。

【关键词】：HRQoL；缺铁性贫血；SF-8

Iron Deficiency Anaemia and Quality of Life in Elderly

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Abstract: Objectives: The study is aimed at assessing the effects of correction of iron deficiency anaemia on health-related quality of life on patients treated with parenteral iron, and compares the effects of treatment with intravenous iron and placebo in a randomized controlled trial. Methods: Questionnaire based survey using (SF-8 short form) on health-related quality of life in the elderly patients with iron deficiency anaemia (total 51, 2:1 randomised, blinded, control study) was carried out. Patients with severe cognitive or physical impairment were excluded. Observations were tested for significance level. Results: There was significant improvement in the domains of general health, bodily pain, vitality, social functioning, emotional role and overall improvement in physical and mental health as reflected by PCS and MCS scores. The domains of SF-8 with physical functioning, physical role, and mental health improvement were less impressive at 4 weeks as compared to the other five parameters of SF-8. There was no statistically significant difference in SF-8 items (HRQoL) before and after treatment with placebo. Conclusion: Elderly patients with iron deficiency anaemia have reduced HRQoL and parenteral iron treatment resulted in rapid improvements in HRQoL assessed at 4 weeks, significantly greater than placebo, across most of the domains.

Keywords: HRQoL; Iron deficiency anaemia; SF-8

引言

自 1900 年以来，全球平均预期寿命增加了一倍多，现在接近 70 岁，导致全球老年人口增加。这间接地影响了老年人的各种慢性病负担。在印度，2009 年 60 岁及以上人口的比例为 7%，预计到 2050 年将增加到 20%^[1]。该国现在面

临着如何照顾如此庞大的人口重大挑战。老年人到 2050 年，老年人口的数量将从目前的 1 亿左右增长到 3 亿倍。为应对老年人慢性病的新挑战，国际上多个领域的专家都在努力开发旨在提高老年人生活质量的政策。

众所周知，贫血对健康相关的生活质量（HRQoL）有负

面影响。疲劳是贫血的主要症状，但其他相关症状（如头痛、抑郁、认知障碍）也会对生活质量产生不利影响。与健康相关的生活质量因功能能力低下（运动耐力、工作能力、社交互动和追求休闲活动的的能力低）和主观幸福感下降而降低。在补铁后的第一周，血红蛋白迅速增加，这种改善与HRQoL的良好结果独立相关^[2]。生活质量现在是慢性病患者临床试验中广泛接受的患者报告的健康结果衡量标准。

目前关于IDA患者HRQoL以及治疗是否可以改善其HRQoL的研究数据很少。IDA患者的结果主要集中在疲劳上，但很少报道对其他HRQoL影响的全貌，开放标签研究缺乏安慰剂对照，在某些情况下，还缺乏HRQoL域平均得分或基线数据，限制了对这些结果的解释^[3-9]。

该研究旨在评估纠正缺铁性贫血对接受肠外铁治疗的患者健康相关生活质量的影响，并在一项随机对照试验中比较静脉注射羧基麦芽糖铁或蔗糖铁与安慰剂治疗的效果。

1 材料与方法

这是一项针对老年缺铁性贫血患者的随机双盲对照研究。患者按 2:1 随机分配接受肠外铁剂和安慰剂治疗。在铁剂治疗组中，患者按 1:1 的比例随机接受蔗糖铁或羧基麦芽糖铁进行静脉给药。60 岁及以上患者共 51 例，分为三组，每组/亚组各 17 例。适用的资格标准。MMSE 分数低于 13 的人在筛选时被排除在外。那些患有晚期心肺或肾脏合并症的人被排除在外。完全的身体/功能依赖是额外的排除标准。该研究得到了机构伦理委员会的批准。

符合条件的患者为 60 岁或以上且血清 Hb 水平为 7.0-10.0g/dL 且转铁蛋白饱和度 (TSAT) 水平低于 20% 的男性和女性。符合条件的患者要么没有通过口服铁剂治疗改善贫血，要么不能耐受口服铁剂治疗。如果患者对任何静脉内铁产品过敏或血清铁蛋白水平超过 600ng/ml，则被排除在外。排除铁缺乏、血液系统恶性肿瘤或透析患者或估计肾小球滤过率低于每 1.73 平方米体表面积 30mL/min 的患者以外的已知原因引起的贫血。那些在筛选前 4 周内接受肠外铁剂治疗或其他研究药物，或在筛选前 2 周内接受口服铁剂或输血的患者也被排除在外。

获得所有患者签署的书面知情同意后伦理委员会的批准。在筛选研究资格后，IDA 患者以 2:1 的比例随机接受 30 分钟内用 0.9% 盐水稀释的 1000mg 羧基麦芽糖铁输注或 200mg 蔗糖铁（在 25mg 的测试剂量后）输注 2002 小时内加入 0.9% 生理盐水。在基线访视（第 1 天）时，给予 500ml 0.9% 生理盐水的安慰剂超过 4 小时，然后在第 3 天服用第二剂。生活质量测量在开始治疗前作为基线进行。受试者进行了实验室研究（全血细胞计数、铁化学小组）并完成了医疗结果

调查简表 8 (SF-8)。所有研究数据均由同一研究助理在开始时和 4 周后收集。

2 统计分析

在线可免费访问的统计软件 GraphPad 用于应用显著性检验。使用给定样本量的均值和标准差（非配对 t 检验）对组间基线特征的差异和治疗前后的差异进行 p 值检验分析。显著性水平设定为 0.05。

3 结果

患有缺铁性贫血的老年患者 (>60 岁) 患有中度贫血，女性主要是缺铁性贫血（表 1）。

表 1 铁剂治疗组和安慰剂组的基线特征

	Iron therapy	Placebo	P value
Number of patients	34	17	
Age (mean $\pm$ sd)	64.5(1.82)	63(2.05)	0.0105
Females	84.5%	87%	
Hemoglobin (mean $\pm$ sd)	9.6 (1.59)	9.0 (1.75)	0.2251
MCV (mean $\pm$ sd)	79 (12.00)	75 (10.8)	0.2522
Ferritin (mean $\pm$ sd)	10 (39.7)	27 (52.9)	0.2039

PCS 和 MCS 评分反映了一般健康、身体疼痛、活力、社会功能、情感角色和身心健康的整体改善等领域有显著改善。与其他五个参数相比，SF-8 的身体机能、身体作用和心理健康改善的领域在 4 周时没有那么令人印象深刻（表 2A）。

安慰剂治疗前后 SF-8 项目（HRQoL）无统计学差异（表 2B）。

表 2A 注射铁剂治疗前后的 SF-8 评分

Iron therapy group	Pre treatment	Post treatment	p value
SF-8 item	Mean (SD)	Mean (SD)	
1 General health	39.21(7.47)	46.89(6.32)	<0.0001
2 Physical functioning	41.29(7.62)	47.85(8.11)	0.001
3 Role - physical	41.53 (10.83)	44.39(11.35)	0.2916
4 Bodily pain	40.02(9.13)	48.89(10.87)	<0.001
5 Vitality	41.31 (6.38)	46.92(6.91)	<0.001
6 Social functioning	41.46(9.04)	48.85(8.36)	<0.001
7 Role - emotional	39.18(9.17)	46.93(9.21)	<0.001
8 Mental health	40.13(9.06)	47.85(9.87)	0.0013
Overall PCS score	41.04(8.49)	47.01(9.31)	0.0074
Overall MCS score	40.00(8.69)	47.63(8.44)	0.0005

表 2B 安慰剂治疗前后的 SF-8 评分

MCS: 心理成分汇总; PCS: 物理组件汇总

Placebo group	Pre Rx	Post Rx	p value
SF-8 item	Mean (SD)	Mean (SD)	
1 General health	39.86(8.17)	41.29(7.22)	0.05924
2 Physical functioning	41.29(7.79)	44.85(8.24)	0.2048
3 Role - physical	42.73(10.64)	44.39(10.37)	0.6482
4 Bodily pain	40.52(9.73)	48.33(11.47)	0.04
5 Vitality	41.73(6.28)	44.13(7.41)	0.316
6 Social functioning	42.46(9.64)	46.43(8.43)	0.2104
7 Role - emotional	40.68(9.72)	46.13(8.81)	0.964
8 Mental health	41.73(9.21)	47.38(9.57)	0.89
Overall PCS score	41.57(9.61)	45.43(9.37)	0.2327
Overall MCS score	41.18(9.20)	45.31(8.51)	0.1837

MCS: 心理成分汇总; PCS: 物理组件汇总

4 讨论

随着人类寿命的延长, 老年人口的年龄曲线呈现出 70 岁以上的增长趋势。随着这一变化, 预计医疗保健需求也将上升。在工业化国家, 对老年人的照顾远远好于发展中国家。由于资源有限, 老年患者的 HRQoL 受到影响^[10-13]。贫血是全世界最常见的疾病, 尤其是在老年人中。这确实会降低 HRQoL, 而及时关注可以提高 HRQoL。

不良临床结果与贫血相关, 包括较高的跌倒率和住院率^[14-18]。贫血也与 1 年死亡率高 17% 的风险相关, 但与日常生活活动 (ADL) 表现无关, 60% 后来经历髋部骨折的居民的死亡风险较高, 女性居民的死亡风险是女性居民的两倍^[19-21]。

Balducci 等人假设, 老年人应对疾病的能力通常较低, 这可能会影响与健康相关的生活质量 (HRQoL)^[22]。他们的功能可能会受到健康状况下降和各种合并症中的贫血的影响。在老年人中, 贫血与身体机能缺陷有关, 包括日常生活活动 (ADL) 的功能下降。对老年患者的研究也表明贫血与 HRQoL 之间存在显著关联^[23-31]。Lam 等人发现, 贫血对来自各种问卷 SF-36/SF-12/SF-8 等的 HRQoL 评分有显著影响^[32]。

SF-8 表格有 8 个问题要回答, 每个项目有 5 或 6 分的响应范围, 研究使用了 4 周的回忆期。根据 Ware 等人在美国 2001 年记录的结果^[33], SF-8 分数低于/高于 50 被认为低于/高于人口平均水平。8 具有与 SF-36 相当的效度 (8 个项目中的 7 个的相关系数为 0.67 到 0.79) 并且在重测中具有出色的信度 (0.8 到 0.88)^[34]。大于或小于 50 的值可以被解释为更好或更差高于一般人群的预期, 并且 10 分的得分差异反映了 1 个标准差^[35]。

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PCS和MCS是 8 个量表分数的总和, 占量表中可靠方差的 80% 以上 (方差不是由于测量误差引起的)。在得出结论之前, 应始终将总分与八项量表分数进行比较^[36]。使用八项量表分数的身体和心理成分总分的优势包括更小的置信区间和更小的天花板效应; 所需的分析次数从 8 次减少到 2 次也避免了因多次测试而导致统计功效的一些降低^[37-38]。按照作者 Taft 等人的说法, PCS 和 MCS 的计算过程已遵循^[39]。

我们的研究证实, 如安慰剂组所示, 未经治疗的缺铁性贫血在老年人中将继续存在较差的生活质量 (HRQoL), 这可以通过及时识别和治疗缺铁症得到改善, 如铁治疗组所示。

5 局限

由于我们在印度人口中没有基线分数, 因此在我们的研究中, 这些规范参考了美国人口的数据, 并且分数并未在印度人口中得到验证。样本量很小, 无法得出明确的结论, 但安慰剂组的数量受到限制, 以防止对大样本量的贫血症的纠正被排除在外。另一个限制是没有考虑可能影响 HRQoL 的患者合并症。SF-三个领域的不那么令人印象深刻的改善可能与治疗后 4 周的评估有关, 这可能是一个太早的时期, 无法看到健康质量的变化。目前的研究也没有讨论不同肠外铁剂给药的效果。

6 结论

缺铁性贫血的老年患者 HRQoL 降低, 肠外铁剂治疗导致在 4 周评估的 HRQoL 快速改善, 在大多数领域显著高于安慰剂。及时识别和治疗缺铁性贫血有助于改善老年患者的 HRQoL。

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