·临床研究·

北京社区老年人心血管相关潜在不适当用药情况的前瞻性队列研究

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【摘 要】 目的 分析社区老年人心血管相关潜在不适当用药(PIM)的风险因素及其对死亡的影响,为促进合理用药提供依据。**方法** 2009年9月至2010年6月,依据Beers标准(2019版)对北京市万寿路地区≥65岁老年人PIM的发生情况进行评价。数据经EpiData平行双录入。采用SPSS 25.0统计软件进行数据分析。根据数据类型分别采用t检验、Mann-Whitney U检验、χ^2检验或Fisher精确检验进行组间比较。采用多因素logistic回归模型分析PIM的影响因素。采用Cox比例风险回归模型分析PIM对死亡的影响。**结果** 共纳入1 730名社区老年人,罹患心血管疾病0~7种,常规用药0~11种。多种心血管病共存者占50.4%(872/1 730),多重用药者占8.0%(139/1 730),PIM的发生率为18.6%(321/1 730)。多种心血管病共存(*OR*=2.610,95%*CI* 1.974~3.451)、心血管系统多重用药(*OR*=1.805,95%*CI* 1.215~2.681)及内生肌酐清除率(Ccr)<30 ml/min(*OR*=2.446,95%*CI* 0.991~6.035)是社区老年人群发生PIM的风险因素;大专及以上学历(*OR*=0.474,95%*CI* 0.351~0.640)和已婚(*OR*=0.681,95%*CI* 0.502~0.924)是PIM的保护因素。PIM的发生在总人群中增加了78.3%(*HR*=1.783,95%*CI* 1.155~2.752)的心血管死亡风险,在男性人群中增加了114.8%(*HR*=2.148,95%*CI* 1.154~3.996)的心血管死亡风险。**结论** PIM在社区老人中普遍发生,可作为死亡风险预测的参考指标。

【关键词】 老年人;潜在不适当用药;全因死亡;心血管死亡;队列研究

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Potentially inappropriate medications with risk of cardiovascular events among community-dwelling old adults in Beijing: a prospective cohort study

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【Abstract】 Objective To analyze the risk factors for cardiovascular events related to potentially inappropriate medication (PIM) among community-dwelling elderly people and investigate the impact of PIM on mortality in order to provide a reference for promoting rational use of medicine. **Methods** Between September 2009 and June 2010, a survey was conducted on the elderly people aged≥65 years living in the Wanshou Road area of Beijing based on the Beers standard (2019 version). Parallel double entry was employed to input the data through EpiData. SPSS statistics 25.0 was used for data analysis. Student's t test, Mann-Whitney U test, *Chi*-square test, or Fisher exact test was applied for intergroup comparison depending on data type. Multivariate logistic regression model was conducted to analyze the influencing factors for PIM. Cox proportional hazards regression model was utilized to determine the effect of PIM on mortality. **Results** For the 1 730 included elderly people, they suffered from 0-7 types of cardiovascular diseases and had polypharmacy of 0-11 types of conventional medicines. The patients with comorbidity of multiple cardiovascular diseases accounted for 50.4% (872/1 730), the incidence of polypharmacy was 8.0% (139/1 730), and the incidence of PIM was 18.6% (321/1 730). Comorbidity of multiple cardiovascular diseases (*OR*=2.610, 95%*CI* 1.974-3.451), multiple use of drugs in the cardiovascular system (*OR*=1.805, 95%*CI* 1.215-2.681), and endogenous creatinine clearance rate (Ccr) <30 ml/min (*OR*=2.446, 95%*CI* 0.991-6.035) were risk factors

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for PIM in the elderly population in the community. Education level of college degree or above (*OR*=0.474, 95% *CI* 0.351-0.640) and married (*OR*=0.681, 95%*CI* 0.502-0.924) were protective factors for PIM. The occurrence of PIM increased the risk of cardiovascular death by 78.3% (*HR*=1.783, 95%*CI* 1.155-2.752) in the general population and 114.8% (*HR*=2.148, 95%*CI* 1.154-3.996) in the male. **Conclusion** PIM is quite common among community-dwelling old adults and can be regarded as a reference indicator for predicting mortality risk.

【Key words】 aged; potentially inappropriate medication; all-cause death; cardiovascular death; cohort study

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随着老龄化的不断进展,截至 2022 年末,我国≥60 岁人口占总人口的 19.8%,≥65 岁人口占总人口的 14.9%[1]。老年人常有多种心血管病共存(2 种或 2 种以上心血管系统疾病共存于同一个老年人)[2],需要多重用药(同时常规使用 5 种及以上药物,包括非处方药、处方药、中草药及保健品)[3],容易出现潜在不适当用药(potentially inappropriate medication,PIM)情况。PIM 指药物有效性尚未确立和(或)药物不良事件的潜在风险超过预期的临床获益,同时缺少较安全的可替代药物[4]。PIM 常用《老年患者潜在不适当用药标准》("Beers 标准")[5]进行评估。

本研究基于北京城乡老年人群健康综合研究(Beijing Elderly Comprehensive Health Cohort Study, BECHCS)[6],采用 2019 版 Beers 标准分析北京社区老年人心血管相关 PIM,探究风险因素及其对死亡的影响,为有效防治 PIM 提供人群流行病学证据。

1 对象与方法

1.1 研究对象

本研究数据来自 BECHCS,于 2009 年 9 月至 2010 年 6 月对北京市万寿路地区 36 个社区中 60 岁及以上的 2 万余名社区老年居民进行随机整群抽样,共抽取 5 个社区。纳入标准:(1)年龄≥60 岁;(2)能够理解并配合完成研究课题评估及相关说明;(3)愿意参加本次调查和体检及生物样本采集。排除标准:(1)严重疾病或功能障碍;(2)不能完成体检和评估项目;(3)认知功能异常不能正确回答问题;(4)声明不愿参与该研究。符合条件的常住老年人共计 2 162 名,随访至 2021 年 3 月 31 日得到其生存结局。本研究按照 Beers 标准,纳入≥65 岁老年人群 1 730 例,其中 321 名发生心血管相关潜在不适当用药情况(PIM 组),另有 1 409 名未发生 PIM(非 PIM 组)。本研究获得中国人民解放军总医院医学伦理委员会批准(S2021-327-01),并在中国临床试验注册中心登记注册(ChiCTR2100049866)。所有研究参与者均对研究内容知情并签署知情同意书。

1.2 方法

调查员为经过统一培训的相关科室的临床医师和护士,在社区卫生服务中心对调查者进行问卷调查和体格检查。调查问卷内容包括一般人口学特征、疾病和健康状况、常规用药情况、生活方式等。日常活动能力(activity of daily living, ADL)采用 Barthel 指数量表进行评估,认知功能的筛查采用简易精神状态量表(mini-mental state examination, MMSE)。体格检查包括人体测量学指标、心电图、骨密度、超声检查等。采用标准仪器设备测量身高、体质量、腰围;静坐休息 30 min 后测量 2 次坐位血压,取平均值作为血压值。实验室检查包括空腹血糖、餐后 2 h 血糖、糖化血红蛋白、总胆固醇、甘油三酯、高密度脂蛋白胆固醇、低密度脂蛋白胆固醇、血肌酐、血尿酸、血白蛋白肌酐比值等,于早晨空腹抽取肘静脉血,送至解放军总医院生化室进行测定。社区老人的死亡信息来自于公安部门的户籍死亡系统以及国家疾病预防控制中心的死亡监测系统,并与老人家属或社区委托人通过电话核实。

1.3 统计学处理

数据经 EpiData 平行双录入。采用 SPSS 25.0 统计软件(IBM Corporation, USA)进行数据分析。符合正态分布的计量资料以均数±标准差($\bar{x}\pm s$)表示,组间比较采用 t 检验;不符合正态分布的计量资料使用中位数(四分位数间距)[$M(Q_1, Q_3)$]表示,组间比较采用 Mann-Whitney U 检验。计数资料以例数(百分率)表示,组间比较采用 χ^2 检验或 Fisher 精确检验。采用多因素 logistic 回归模型分析 PIM 的影响因素。采用 Cox 比例风险回归模型分析 PIM 对死亡的影响。$P<0.05$ 为差异有统计学意义。

2 结 果

2.1 北京社区老年人一般资料

1 730 名社区老年人年龄 65~95(73.7±5.2)岁,男性和女性社区老年人年龄、文化程度、婚姻状况和生活方式[吸烟、饮酒及有规律的体力活动(至少 150 min/周的中度活动或 75 min/周的剧烈活动或同等的组合[7])]比较,差异有统计学意义(表 1)。

表1 北京社区老年人一般资料

Table 1 General data of elderly population in Beijing communities

Item	Male(n=720)	Female(n=1 010)	P value
Age(years, $\bar{x}\pm s$)	74.7±5.6	73.0±4.8	<0.01
Han Chinese[n(%)]	703(97.6)	988(97.8)	0.801
College degree or above[n(%)]	337(46.8)	214(21.2)	<0.01
Married[n(%)]	656(91.1)	767(75.9)	<0.01
BMI(kg/m^2, $\bar{x}\pm s$)	24.9±3.1	25.0±3.5	0.534
Smoking[n(%)]	134(18.6)	49(4.9)	<0.01
Alcohol drinking[n(%)]	263(36.5)	75(7.4)	<0.01
Regular physical activity[n(%)]	676(93.9)	900(89.1)	0.01
Number of cardiovascular diseases[$M(Q_1, Q_3)$]	2(1,3)	2(1,3)	0.345
Number of cardiovascular system medications used[$M(Q_1, Q_3)$]	1(0,3)	1(0,3)	0.464

BMI: body mass index.

2.2 北京社区老年人心血管疾病患病和用药情况

北京社区老年人患心血管疾病0~7种,存在多种心血管病共存者占50.4%(872/1 730);常规使用心血管系统药物0~11种,存在心血管系统多重用药者占8.0%(139/1 730)。北京社区老年人心血管疾病患病率和用药率分布情况见图1。

2.3 北京社区老年人群涉及的心血管用药PIM

依据Beers标准,北京社区老年人中有321名发生心血管相关潜在不适当用药情况,总例次达358次,发生率为18.6%,具体药物种类/名称及不适当使用情况见表2。

2.4 PIM组与非PIM组临床资料比较

PIM组与非PIM组年龄≥75岁、大专及以上学历、已婚、体质量指数(body mass index,BMI)、多种心血管病共存、心血管系统多重用药及内生肌酐清除率(endogenous creatinine clearance rate,Ccr)<30 ml/min情况比较,差异有统计学意义(P<0.05;表3)。

2.5 社区老年人心血管PIM相关风险因素的多因素logistic回归分析

将单因素分析中有统计学意义的单变量纳入多因素logistic回归分析,结果显示,多种心血管病共存、心血管系统多重用药及Ccr<30 ml/min是PIM的风险因素;大专及以上学历和已婚是PIM的保护因素(表4)。

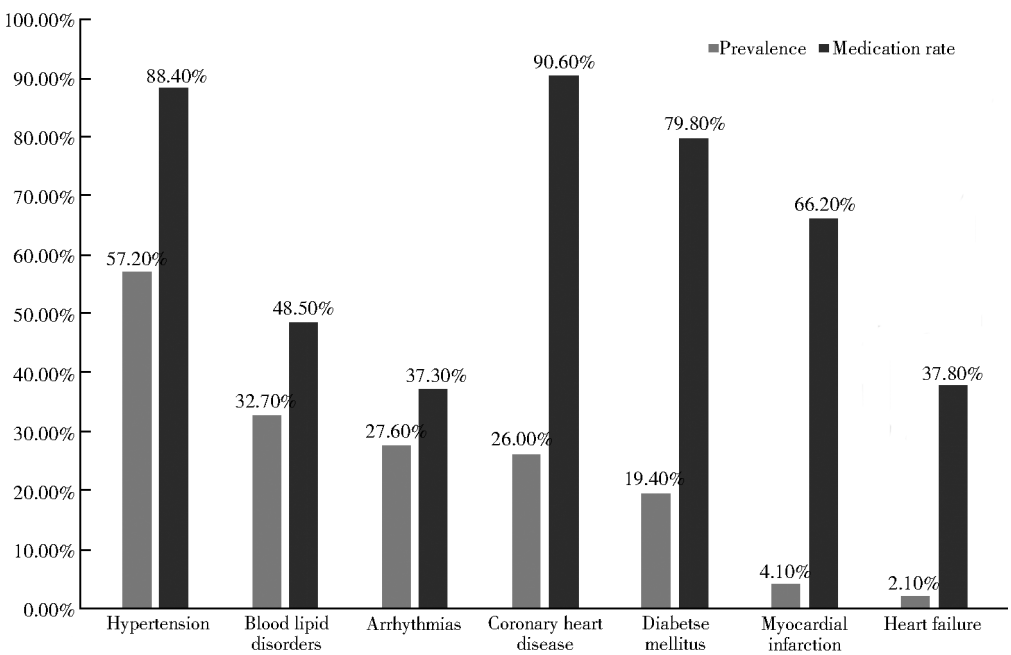

图1 北京社区老年人心血管疾病患病率和用药率分布情况

Figure 1 Distribution of cardiovascular disease prevalence and medication use among elderly people in Beijing communities

表 2 北京社区老年人群涉及的心血管 PIM 情况分布

Table 2 Distribution of cardiovascular PIM among the elderly population in Beijing communities

Drug type/name	Inappropriate use	Reason	Proposal	Evidence strength	Suggested strength	[n(%)]
Peripheral α1 Blocking drug	Used for hypertension	Elevated risk of orthostatic hypotension	Avoid	Secondary	Strong	6(1.7)
Other CNS α receptor agonists	Used for hypertension	High risk of adverse reactions in the central nervous system; may cause bradycardia, orthostatic hypotension	Avoid	Low	Strong	108(30.2)
Digoxin	As a first-line treatment for atrial fibrillation or heart failure	Increase risk of toxic effects	Avoid	Low	Strong	8(2.2)
Rapid release nifedipine	Under any circumstances	Induce hypotension and myocardial ischemia	Avoid	High	Strong	126(35.2)
Amiodarone	As a first-line treatment for atrial fibrillation	More toxic than other antiarrhythmic drugs	Avoid	High	Strong	9(2.5)
Verapamil/diltiazem	Heart failure	May promote fluid retention or exacerbate heart failure	Avoid or use with caution	Secondary	Strong	13(3.6)
NSAIDs and COX-2 inhibitors	Heart failure	May promote fluid retention or exacerbate heart failure	Avoid or use with caution	Low	Strong	26(7.3)
NSAIDs	Chronic kidney disease grade Ⅳ or above (Ccr<30 ml/min)	Increase risk of acute kidney injury and further decline in renal function	Avoid	Secondary	Strong	6(1.7)
Aspirin	For primary prevention of cardiovascular diseases	Significantly increase the risk of bleeding in the elderly population	Patients aged≥ 70 years use with caution	Secondary	Strong	46(12.8)
RAS inhibitors	Combined use with another RAS inhibitor	Increase risk of hyperkalemia	Patients with chronic kidney disease grade 3A and above should avoid routine use	Secondary	Strong	10(2.8)

PIM: potentially inappropriate medication; CNS: central nervous system; NSAIDs: non-steroidal anti-inflammatory drug; COX-2 inhibitors: cyclooxygenase-2 inhibitors; Ccr: endogenous creatinine clearance rate; RAS: renin-angiotensin system.

表 3 PIM 组与非 PIM 组临床资料比较

Table 3 Comparison of clinical data between PIM group and non-PIM group [n(%)]

Item	PIM group(n=321)	Non-PIM group(n=1 409)	P value
Age≥75 years	156(48.6)	581(41.2)	0.016
Male	122(38.0)	598(42.4)	0.146
Han Chinese	311(96.9)	1 380(97.9)	0.250
College degree or above	66(20.6)	485(34.4)	<0.01
Married	246(76.6)	1 177(83.5)	0.004
BMI(kg/m^2)			0.019
<18.5	8(2.5)	25(1.8)	
18.5-<24.0	97(30.2)	542(38.5)	
≥24.0	216(67.3)	842(59.8)	
Coexistence of multiple cardiovascular diseases	226(70.4)	646(45.8)	<0.01
Multidrug use in the cardiovascular system	47(14.6)	91(6.5)	<0.01
Smoking	28(8.7)	155(11.0)	0.231
Alcohol drinking	61(19.0)	277(19.7)	0.789
Regular physical activity	288(89.7)	1 288(91.4)	0.336
Ccr<30 ml/min	8(2.5)	15(1.1)	0.044
Mild cognitive impairment	33(10.3)	108(7.7)	0.122
ADL damage	33(10.3)	189(13.4)	0.130

PIM: potentially inappropriate medication; BMI: body mass index; Ccr: endogenous creatinine clearance rate; ADL: activity of daily living.

表 4 北京社区老年人心血管 PIM 相关风险因素的多因素 logistic 回归分析

Table 4 Multivariate logistic regression analysis of cardiovascular PIM related risk factors in the elderly population of Beijing communities

Factor	*OR*	*B*	*SE*	*Wald* χ^2	95%*CI*	*P* value
College degree or above	0.474	-0.759	0.153	24.484	0.351-0.640	<0.01
Married	0.681	-0.386	0.156	6.099	0.502-0.924	0.014
Coexistence of multiple cardiovascular diseases	2.610	0.996	0.140	50.456	1.974-3.451	<0.01
Multidrug use in the cardiovascular system	1.805	0.550	0.203	7.380	1.215-2.681	0.003
Ccr<30 ml/min	2.446	1.000	0.462	4.676	0.991-6.035	0.052

PIM: potentially inappropriate medication; Ccr: endogenous creatinine clearance rate.

2.6 PIM对全因死亡和心血管死亡的影响

截至2021年3月31日末次随访,北京社区老年人随访时间为11.27(10.84,11.35)年,死亡率为21.1%(365/1 730),死亡密度为203.88/10 000人年。在总人群中,PIM每增加1例次,心血管死亡风险增加65.0%(*HR*=1.650,95%*CI* 1.196~2.277)。在男性人群中,PIM每增加1例次,心血管死亡风险增加100.5%(*HR*=2.005,95%*CI* 1.302~3.087),全因死亡风险增加39.4%(*HR*=1.394,95%*CI* 1.038~1.871)。PIM的发生在总人群中增加了78.3%的心血管死亡风险(*HR*=1.783,95%*CI* 1.155~2.752),在男性人群中增加了114.8%的心血管死亡风险(*HR*=2.148,95%*CI* 1.154~3.996)。PIM对全因死亡和心血管死亡的影响详见表5和表6。

表5 北京社区老年人PIM对全因死亡的影响

Table 5 Impact of PIM on all-cause mortality among elderly residents in Beijing communities

Factor	Coarse model		Model 1		Model 2	
	P value	*HR*(95%*CI*)	*P* value	*HR*(95%*CI*)	*P* value	*HR*(95%*CI*)
Total population						
Continuous variable						
PIM increases by 1 instance	0.013	1.282(1.053-1.561)	0.153	1.155(0.948-1.409)	0.189	1.150(0.933-1.418)
Binary variable						
No PIM occurs	1.000	1.000	1.000	1.000	1.000	1.000
PIM occurred	0.058	1.271(0.992-1.629)	0.292	1.144(0.891-1.470)	0.398	1.118(0.863-1.448)
Male						
Continuous variable						
PIM increases by 1 instance	0.014	1.392(1.069-1.811)	0.022	1.373(1.047-1.800)	0.027	1.394(1.038-1.871)
Binary variable						
No PIM occurs	1.000	1.000	1.000	1.000	1.000	1.000
PIM occurred	0.041	1.440(1.015-2.043)	0.083	1.367(0.960-1.947)	0.133	1.327(0.917-1.919)
Female						
Continuous variable						
PIM increases by 1 instance	0.179	1.216(0.914-1.616)	0.954	0.992(0.745-1.320)	0.929	0.987(0.733-1.327)
Binary variable						
No PIM occurs	1.000	1.000	1.000	1.000	1.000	1.000
PIM occurred	0.348	1.184(0.833-1.682)	0.890	0.975(0.682-1.394)	0.862	0.968(0.671-1.397)

PIM: potentially inappropriate medication. Coarse model: PIM is included as an independent variable in the model; Model 1: adjusting for gender, age, ethnicity, smoking status, alcohol consumption, physical activity, education level, and marital status; Model 2: further adjust the coexistence of multiple cardiovascular diseases, multiple drug use in the cardiovascular system, BMI, cognitive function, and daily activity ability based on Model 1.

表6 北京社区老年人PIM对心血管死亡的影响

Table 6 Impact of PIM on cardiovascular mortality in elderly residents in Beijing communities

Factor	Coarse model		Model 1		Model 2	
	P value	*HR*(95%*CI*)	*P* value	*HR*(95%*CI*)	*P* value	*HR*(95%*CI*)
Total population						
Continuous variable						
PIM increases by 1 instance	<0.001	1.848(1.385-2.464)	0.001	1.641(1.227-2.195)	0.002	1.650(1.196-2.277)
Binary variable						
No PIM occurs	1.000	1.000	1.000	1.000	1.000	1.000
PIM occurred	<0.001	2.109(1.395-3.187)	0.002	1.913(1.258-2.907)	0.009	1.783(1.155-2.752)
Male						
Continuous variable						
PIM increases by 1 instance	0.001	1.903(1.315-2.755)	0.001	1.912(1.321-2.767)	0.002	2.005(1.302-3.087)
Binary variable						
No PIM occurs	1.000	1.000	1.000	1.000	1.000	1.000
PIM occurred	0.006	2.279(1.268-4.096)	0.006	2.321(1.279-4.213)	0.016	2.148(1.154-3.996)
Female						
Continuous variable						
PIM increases by 1 instance	0.007	1.807(1.172-2.785)	0.072	1.484(0.965-2.282)	0.096	1.479(0.932-2.347)
Binary variable						
No PIM occurs	1.000	1.000	1.000	1.000	1.000	1.000
PIM occurred	0.015	2.058(1.150-3.684)	0.056	1.789(0.985-3.250)	0.088	1.707(0.923-3.159)

PIM: potentially inappropriate medication. Coarse model: PIM is included as an independent variable in the model; Model 1: adjusting for gender, age, ethnicity, smoking status, alcohol consumption, physical activity, education level, and marital status; Model 2: further adjust the coexistence of multiple cardiovascular diseases, multiple drug use in the cardiovascular system, BMI, cognitive function, and daily activity ability based on Model 1.

3 讨 论

罗娅婵等[8]开展的 meta 分析结果显示,基于 Beers 标准在北京社区老年人中开展的研究中,PIM 的发生率为 17.5%~42.5%,而本研究中 PIM 的发生率为 18.6%,可能由于本研究仅分析了心血管相关的潜在不适当用药情况。

老年患者多种心血管病共存引发的心血管系统多重用药现象易导致药物的过度或重复使用,毒性蓄积,发生 PIM,这一风险已在国内外多项研究中确证[9,10]。慢性肾病患者由于肾脏清除功能下降,药物代谢减慢,导致血药浓度升高,药物毒性蓄积,增加 PIM 和急性肾损伤或肾功能进一步衰退的风险。大专及以上学历是 PIM 的保护因素,这和沈国栋等[11]研究结果一致,可能是由于文化程度偏高的老年人对用药风险的认知程度较高。而在已婚老年人中,可能由于有亲属照顾陪伴及用药管理使 PIM 的发生风险降低。

多项研究证实,PIM 的发生与出院后发生药物不良事件(adverse drug events, ADEs)、急诊、再入院和死亡等不良结局相关[12-14]。Muhlack 等[15]研究显示,PIM 与死亡相关(RR=1.59,95%CI 1.45~1.75),但只有一项研究关注心血管事件,没有发现具有统计学意义的相关性。可见老年人群心血管相关 PIM 对全因死亡和心血管死亡的影响研究较为缺乏,有必要进一步深化研究。

本研究存在局限性。首先,研究对象来自于北京市万寿路社区,地区特异性使得结论的外推需谨慎。其次,社区老年人群的患病和用药情况由患者自报,可能存在偏倚。

综上,本研究分析了老年人群心血管相关 PIM 及风险因素,PIM 的发生还可增加心血管死亡风险,在男性人群中该影响更为显著。提示应关注老年人群 PIM 对健康结局的影响,并制定相应的管理措施。

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