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· 对比研究 ·

不同方案对老年冠心病并轻度肾功能不全患者择期经皮冠状动脉介入治疗后对比剂肾病的预防效果及其影响因素研究

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【摘要】 **背景** 老年冠心病患者是对比剂肾病(CIN)的高危人群,其中合并轻度肾功能不全者术后CIN发生率高达30%以上。有研究显示,静脉水化对老年轻度肾功能不全患者术后CIN的预防效果较佳,但关于口服水化对肾功能不全患者术后CIN预防效果的文献报道较少。**目的** 探讨不同方案对老年冠心病并轻度肾功能不全患者择期经皮冠状动脉介入治疗(PCI)后CIN的预防效果及其影响因素,以期为临床医生及早、准确地诊断和预防CIN提供参考依据。**方法** 本研究为前瞻性研究。选取2018年10月—2020年5月南京大学医学部附属鼓楼医院高淳分院收治的行择期PCI的老年冠心病并轻度肾功能不全患者90例,根据水化方式分为口服水化组和静脉水化组,各45例。口服水化组患者采用口服水化方式,静脉水化组患者采用静脉水化方式。收集患者的临床资料,采用多因素Logistic回归分析探讨老年冠心病并轻度肾功能不全患者择期PCI后并发CIN的影响因素。**结果** 口服水化组患者消化道不适发生率低于静脉水化组($P < 0.05$)。根据患者择期PCI后是否发生CIN将其分为CIN组21例和非CIN组69例。CIN组患者体质指数(BMI)、糖尿病发生率及低密度脂蛋白胆固醇(LDL-C)、胱抑素C水平高于非CIN组,手术时间长于非CIN组,对比剂用量大于非CIN组, β_2 -微球蛋白水平低于非CIN组($P < 0.05$)。多因素Logistic回归分析结果显示,糖尿病[OR=1.632, 95%CI(1.038, 2.564)]、对比剂用量[OR=1.036, 95%CI(1.009, 1.063)]、胱抑素C水平[OR=5.454, 95%CI(1.500, 19.819)]是老年冠心病并轻度肾功能不全患者择期PCI后并发CIN的独立影响因素($P < 0.05$)。**结论** 口服水化与静脉水化对老年冠心病并轻度肾功能不全患者择期PCI后CIN的预防效果相当,但静脉水化可更有效地减少患者消化道不适症状,而糖尿病、对比剂用量、胱抑素C水平是老年冠心病并轻度肾功能不全患者择期PCI后并发CIN的独立影响因素。

【关键词】 冠心病; 肾病; 肾功能不全; 对比剂肾病; 经皮冠状动脉介入治疗; 口服水化; 静脉水化; 影响因素分析

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Prevention Effect of Different Plan on Contrast-induced Nephropathy in Elderly Patients with Coronary Heart Disease Complicated with Mild Renal Insufficiency after Selective Percutaneous Coronary Intervention and Its Influencing Factors CHEN Lu, WANG Yong, XING Yulong, LIU Huaying, ZHAO Xianjing, ZHU Wen

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【Abstract】 **Background** Elderly patients with coronary heart disease are high-risk group of contrast medium nephropathy (CIN), the incidence of CIN of patients with mild renal insufficiency can be as high as 30%. Studies have proved that intravenous hydration have better prevention effect for elderly patients with mild renal insufficiency. However, there are few literature reports on the preventive effect of oral hydration on CIN of patients with renal insufficiency. **Objective** To discuss the prevention plan and influencing factors of CIN in elderly patients with coronary heart disease complicated with mild renal insufficiency after selective percutaneous coronary intervention (PCI), so as to provide reference for clinicians to diagnose and prevent CIN early and accurately. **Methods** This study is a prospective study. A total of 90 elderly patients with coronary heart

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disease complicated with mild renal insufficiency who underwent selective PCI in Gaochun Branch, Nanjing Drum Tower Hospital, the Affiliated Hospital of Nanjing University Medical School from October 2018 to May 2020 were selected and divided into the oral hydration group and the intravenous hydration group, 45 cases in each group. Patients in the oral hydration group were treated with oral hydration, patients in the intravenous hydration group were treated with intravenous hydration. Clinical data of patients were collected, and multivariate Logistic regression analysis was used to explore the influencing factors of CIN in elderly patients with coronary heart disease complicated with mild renal insufficiency after selective PCI. **Results** The incidence of gastrointestinal discomfort in the oral hydration group was lower than that in the intravenous hydration group ($P < 0.05$). Patients were divided into CIN group ($n=21$) and non-CIN group ($n=69$) according to whether they occurred CIN after selective PCI. Body mass index (BMI), incidence of diabetes and levels of low density lipoprotein cholesterol (LDL-C) and cystatin C in the CIN group were higher than those of the non-CIN group, operation time was longer than that of the non-CIN group, amount of contrast agent was greater than that of the non-CIN group, β_2 -microglobulin level was lower than that of non-CIN group ($P < 0.05$). The results of multivariate Logistic regression analysis showed that, diabetes [$OR=1.632, 95\%CI(1.038, 2.564)$], amount of contrast agent [$OR=1.036, 95\%CI(1.009, 1.063)$], cystatin C level [$OR=5.454, 95\%CI(1.500, 19.819)$] were independent influencing factors of CIN in elderly patients with coronary heart disease complicated with mild renal insufficiency after selective PCI ($P < 0.05$). **Conclusion** Oral hydration and intravenous hydration are equivalent in preventing CIN in elderly patients with coronary heart disease complicated with mild renal insufficiency after selective PCI, but intravenous hydration can reduce the symptoms of gastrointestinal discomfort, and diabetes, amount of contrast agent, cystatin C level are independent influencing factors of CIN in elderly patients with coronary heart disease complicated with mild renal insufficiency after selective PCI.

【Key words】 Coronary disease; Nephrosis; Renal insufficiency; Contrast-induced nephropathy; Percutaneous coronary intervention; Oral hydration; Intravenous hydration; Root cause analysis

近年来,随着社会经济水平的提高及人类疾病谱的演变,冠心病发病率逐年增高。经皮冠状动脉介入治疗(percutaneous coronary intervention, PCI)是临床治疗冠心病的主要手段,但术中需应用大剂量对比剂如碘克沙醇、碘海醇、碘海醇等,而对对比剂对肾小管上皮细胞造成的毒性作用如肾髓质缺血、氧自由基的产生、炎症反应是造成对比剂肾病(contrast-induced nephropathy, CIN)的重要原因。目前临床关于CIN的发病机制尚无确切定论。CIN是人体肌酐(serum creatinine, Scr)水平在注射对比剂48~72h内超过 $44 \mu\text{mol/L}$ 或较基础值增加25%^[1-2],患者常表现为尿量减少、心力衰竭症状加重,一般需动态监测Scr水平来确诊。老年患者多合并糖尿病、高血压等基础疾病,且血管病变复杂,因此老年肾功能不全患者PCI后CIN发生率较高^[3-4],而早期发现及干预CIN对减少主要不良心血管事件、降低致残率及死亡率具有重要意义^[5],其中水化治疗是目前临床公认的有效预防CIN的基本措施^[6-7],但是目前尚无统一的方法,常用的有术前、术中或术后静脉滴注0.9%氯化钠溶液。有研究表明,对老年轻度肾功能不全患者应用对比剂之前及之后数小时静脉水化优于使用对比剂之前即刻和之中短时间静脉水化^[8]。但静脉水化增加了护理人员的工作负担和患者静脉留置针的不适感以及患者术前、术后的行动不便,而口服水化则更加简便,可操作性强,然而目前关于口服水化对肾功能不全患者PCI后CIN影响的报道较少。本研究旨在比较口服水化与静脉水化对老年冠心病并轻度肾功能不全患者择期PCI后CIN的预防效果,并分析其影响因素,以期临床医生及早、准确地诊断和预防CIN提供参考依据。

1 对象与方法

1.1 研究对象 本研究是前瞻性研究。连续性选取2018年10月—2020年5月南京大学医学部附属鼓楼医院高淳分院收

治的老年冠心病并轻度肾功能不全患者90例。纳入标准:(1)年龄60~89岁;(2)根据简化经肾脏病膳食改良试验(MDRD)公式计算 $60 \text{ ml/min} < \text{估算肾小球滤过率(estimated glomerular filtration rate, eGFR)} < 89 \text{ ml/min}$;(3)纽约心脏病协会(New York Heart Association, NYHA)分级为I~III级;(4)行择期PCI;(5)配合完成治疗,患者及家属对本研究知情同意并签署知情同意书。排除标准:(1)近1周内使用对比剂者;(2)肾功能异常需透析者;(3)术前使用肾毒性药物者;(4)对比剂用量 $> 300 \text{ ml}$ 者;(5)对本研究使用的对比剂过敏者;(6)有明显胃肠道不适,不能耐受术后饮水者;(7)甲状腺功能异常、恶性肿瘤者。根据水化方式将所有患者分为口服水化组和静脉水化组,各45例。本研究经南京大学医学部附属鼓楼医院高淳分院伦理委员会审核批准,患者对本研究知情并签署知情同意书。

1.2 方法 患者入院后统一发放有刻度的饮水杯及量杯,准备好固定透明的水杯,服用统一发放的温开水。口服水化组患者于PCI前6h至PCI后6h口服温开水1500ml,PCI前6h以 $1 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{h}^{-1}$ 的速率口服,余下温开水在患者PCI后回病房后饮完,告知患者每次饮水以不出现胃部不适为宜。静脉水化组患者于PCI前6h至PCI后6h内静脉滴注0.9%氯化钠溶液,滴速为 $1 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{h}^{-1}$ 。

1.3 观察指标 记录患者的临床资料,包括年龄、性别、体质指数(body mass index, BMI)、收缩压、舒张压、吸烟史(既往累计或连续吸烟超过6个月以上定义为有吸烟史)、合并症(高血压、糖尿病)、CIN发生情况、消化道不适发生情况、实验室检查指标〔总胆固醇(total cholesterol, TC)、低密度脂蛋白胆固醇(low density lipoprotein cholesterol, LDL-C)、高密度脂蛋白胆固醇(high density lipoprotein cholesterol, HDL-C)、三酰甘油(triacylglycerol, TG)、空腹血糖、尿酸、

Scr)、心功能指标〔左心室射血分数(left ventricular ejection fraction, LVEF)、左心室舒张末期容积(Left ventricular end diastolic volume, LVEDV)〕、N末端脑钠肽前体(N-terminal pro-brain natriuretic peptide, NT-proBNP)、手术时间、对比剂用量、 β_2 -微球蛋白、胱抑素C、水化方式。CIN的定义为使用对比剂后Scr水平升高并超过44.2 $\mu\text{mol/L}$ (0.5 mg/dl)或较基础值升高 $> 25\%$,并可排除其他原因所致的急性肾功能损伤^[1-2]。

1.4 统计学方法 应用SPSS 18.0统计学软件进行数据处理。符合正态分布的计量资料以 $(\bar{x} \pm s)$ 表示,组间比较采用两独立样本 t 检验;不符合正态分布的计量资料以 $M(P_{25}, P_{75})$ 表示,组间比较采用非参数检验。计数资料以相对数表示,组间比较采用 χ^2 检验。采用多因素Logistic回归分析探讨老年冠心病并轻度肾功能不全患者择期PCI后并发CIN的影响因素。以 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 口服水化组和静脉水化组患者临床资料比较 静脉水化组患者消化道不适发生率低于口服水化组,差异有统计学意义($P < 0.05$);两组患者年龄、性别、BMI、收缩压、舒张压、有吸烟史者占比、高血压发生率、糖尿病发生率、CIN发生率和TC、LDL-C、HDL-C、TG、空腹血糖、尿酸、Scr、NT-proBNP、 β_2 -微球蛋白、胱抑素C水平及LVEF、LVEDV、手术时间、对比剂用量比较,差异无统计学意义($P > 0.05$),见表1。

2.2 CIN组和非CIN组患者临床资料比较 根据患者择期PCI后是否发生CIN将其分为CIN组21例和非CIN组69例。CIN组患者BMI、糖尿病发生率及LDL-C、胱抑素C水平高于非CIN组,手术时间长于非CIN组,对比剂用量大于非CIN组, β_2 -微球蛋白水平低于非CIN组,差异有统计学意义($P < 0.05$);两组患者年龄、性别、收缩压、舒张压、

表1 口服水化组和静脉水化组患者临床资料比较

Table 1 Comparison of clinical data between the oral hydration group and the intravenous hydration group

指标	口服水化组 (n=45)	静脉水化组 (n=45)	检验统计量值	P 值
年龄 ($\bar{x} \pm s$, 岁)	74.1 \pm 5.7	72.3 \pm 5.4	1.574 ^a	0.119
性别 (男/女)	32/13	35/10	0.526	0.468
BMI ($\bar{x} \pm s$, kg/m ²)	24.3 \pm 3.1	25.6 \pm 4.2	-1.699 ^a	0.093
收缩压 ($\bar{x} \pm s$, mm Hg)	133 \pm 17	131 \pm 17	0.638 ^a	0.525
舒张压 ($\bar{x} \pm s$, mm Hg)	75 \pm 11	78 \pm 13	-0.948 ^a	0.346
吸烟史 [n (%)]	32 (71.1)	33 (73.3)	0.055	0.814
合并症 [n (%)]				
高血压	29 (64.6)	28 (62.2)	0.048	0.827
糖尿病	35 (77.8)	39 (86.7)	1.216	0.270
CIN [n (%)]	12 (26.7)	9 (20.0)	0.559	0.619
消化道不适 [n (%)]	10 (22.2)	2 (4.4)	6.154	0.013
实验室检查指标				
TC ($\bar{x} \pm s$, mmol/L)	4.79 \pm 1.50	4.55 \pm 1.12	0.830 ^a	0.409
LDL-C ($\bar{x} \pm s$, mmol/L)	2.43 \pm 0.83	2.65 \pm 0.79	-1.258 ^a	0.212
HDL-C [$M(P_{25}, P_{75})$, mmol/L]	1.41 (1.08, 1.60)	1.38 (1.02, 1.85)	-0.702 ^b	0.482
TG [$M(P_{25}, P_{75})$, mmol/L]	1.13 (0.91, 1.72)	1.54 (1.03, 2.39)	-1.945 ^b	0.052
空腹血糖 [$M(P_{25}, P_{75})$, mmol/L]	5.4 (4.8, 6.2)	5.6 (4.9, 6.5)	-0.605 ^b	0.545
尿酸 ($\bar{x} \pm s$, $\mu\text{mol/L}$)	368.4 \pm 120.6	362.4 \pm 127.3	0.228 ^a	0.820
Scr [$M(P_{25}, P_{75})$, $\mu\text{mol/L}$]	80.0 (69.0, 91.6)	79.7 (62.0, 91.6)	-0.654 ^b	0.513
心功能指标 ($\bar{x} \pm s$)				
LVEF	0.57 \pm 0.11	0.55 \pm 0.11	0.775 ^a	0.440
LVEDV (ml)	41.1 \pm 9.2	40.5 \pm 7.6	0.336 ^a	0.738
NT-proBNP [$M(P_{25}, P_{75})$, ng/L]	82.5 (165.0, 576.0)	80.0 (162.0, 692.0)	0.442 ^b	0.994
手术时间 ($\bar{x} \pm s$, min)	83.1 \pm 20.5	84.0 \pm 24.9	-0.192 ^a	0.848
对比剂用量 [$M(P_{25}, P_{75})$, ml]	120.0 (95.0, 135.0)	102.5 (120.0, 147.5)	0.738 ^b	0.648
β_2 -微球蛋白 ($\bar{x} \pm s$, mg)	2.4 \pm 1.0	2.0 \pm 0.7	1.881 ^a	0.063
胱抑素C ($\bar{x} \pm s$, mg/L)	1.2 \pm 0.6	1.4 \pm 0.7	-1.384 ^a	0.170

注: ^a为 t 值, ^b为 Z 值, 余检验统计量值为 χ^2 值; 1 mm Hg=0.133 kPa; BMI=体质指数, CIN=对比剂肾病, TC=总胆固醇, LDL-C=低密度脂蛋白胆固醇, HDL-C=高密度脂蛋白胆固醇, TG=总胆固醇, Scr=血肌酐, LVEF=左心室射血分数, LVEDV=左心室舒张末期容积, NT-proBNP=N末端脑钠肽前体

有吸烟史者占比、高血压发生率、消化道不适发生率和 TC、HDL-C、TG、空腹血糖、尿酸、Scr、NT-proBNP 水平及 LVEF、LVEDV、水化方式比较, 差异无统计学意义 ($P > 0.05$), 见表 2。

2.3 老年冠心病并轻度肾功能不全患者择期 PCI 后并发 CIN 影响因素的多因素 Logistic 回归分析 将表 2 中有统计学差异的指标作为自变量, 老年冠心病并轻度肾功能不全患者择期 PCI 后 CIN 发生情况作为因变量 (赋值: 发生 =1, 未发生 =0), 进行多因素 Logistic 回归分析, 结果显示, 糖尿病、对比剂用量、胱抑素 C 水平是老年冠心病并轻度肾功能不全患者择期 PCI 后并发 CIN 的独立影响因素 ($P < 0.05$), 见表 3。

3 讨论

老年冠心病患者发病率较高, 多采用 PCI, 但术中需要使用大剂量的含碘对比剂, 外加老年患者多合并慢性肾脏病等多种基础疾病, 导致肾脏对对比剂的清除能力下降, 因此该类人群术后 CIN 发生率较高^[9-10]。目前临床针对 CIN 尚无特殊、有效的治疗药物和手段, 但临床常采用静脉水化和口服水化预防 CIN, 主要药物包括钾离子通道开放剂 (尼可地尔)、维生

素 C、血管紧张素转换酶抑制剂 (angiotensin converting enzyme inhibitor, ACEI)、抗氧化剂、他汀类药物等^[11-12]。不同方案及途径的水化疗法均可预防 CIN, 其可保证肾脏血流通畅, 降低对比剂对肾小管细胞的毒性作用、肾小管处对比剂浓度, 促进对比剂排泄等^[13-14]。欧洲泌尿生殖放射学会对比剂安全使用委员会指出, 静脉水化对 CIN 的预防效果优于口服水化^[15]。《心血管疾病防治指南和共识 2009》^[16]指出, 如果患者无法进行口服水化, 则应考虑在对比剂给药前 6~12 h、给药后 4~12 h 给予静脉水化, 但速度及剂量尚无统一标准。

本研究结果显示, 口服水化组和静脉水化组患者 CIN 发生率比较差异无统计学意义, 但静脉水化组患者消化道不适发生率低于口服水化组, 与既往研究结果一致^[17-18], 表明口服水化与静脉水化的老年冠心病并轻度肾功能不全患者 CIN 发生率相当, 但静脉水化可更有效地降低患者消化道不适症状发生率。侯晓平等^[19]在不同水化方式防治老年 CIN 的研究中发现, 高龄、心功能降低者更易发生 CIN, 而水化疗法可有效地改善患者肾功能, 尤其是静脉滴注 0.9% 氯化钠溶液

表 2 CIN 组和非 CIN 患者临床资料比较
Table 2 Comparison of clinical data between the CIN group and non-CIN group

指标	CIN 组 (n=21)	非 CIN 组 (n=69)	检验统计量值	P 值
年龄 ($\bar{x} \pm s$, 岁)	74.4 ± 4.9	72.8 ± 5.8	1.218 ^a	0.231
性别 (男/女)	14/7	53/16	0.871	0.351
BMI ($\bar{x} \pm s$, kg/m ²)	27.0 ± 4.9	24.3 ± 3.1	3.090 ^a	0.003
收缩压 ($\bar{x} \pm s$, mm Hg)	133 ± 18	129 ± 15	1.012 ^a	0.314
舒张压 ($\bar{x} \pm s$, mm Hg)	79 ± 13	76 ± 9	1.222 ^a	0.225
吸烟史 [n (%)]	3 (14.3)	22 (31.9)	2.485	0.115
合并症 [n (%)]				
高血压	5 (23.8)	28 (40.6)	1.950	0.163
糖尿病	8 (38.1)	10 (14.5)	5.606	0.018
消化道不适 [n (%)]	1 (4.7)	11 (15.9)	1.742	0.187
实验室检查指标				
TC ($\bar{x} \pm s$, mmol/L)	1.56 ± 0.92	1.85 ± 1.03	-1.197 ^a	0.234
LDL-C ($\bar{x} \pm s$, mmol/L)	3.10 ± 0.96	2.37 ± 0.68	3.849 ^a	< 0.001
HDL-C [M (P ₂₅ , P ₇₅), mmol/L]	1.61 (1.06, 1.71)	1.38 (1.05, 1.60)	-1.045 ^b	0.296
TG [M (P ₂₅ , P ₇₅), mmol/L]	1.56 (1.11, 2.69)	1.23 (0.97, 1.93)	-1.250 ^b	0.211
空腹血糖 [M (P ₂₅ , P ₇₅), mmol/L]	5.6 (5.0, 9.5)	5.5 (4.8, 6.2)	-1.450 ^b	0.147
尿酸 ($\bar{x} \pm s$, μmol/L)	372.9 ± 123.0	340.7 ± 125.7	1.045 ^a	0.299
Scr [M (P ₂₅ , P ₇₅), μmol/L]	73.0 (61.0, 87.1)	80.0 (60.0, 92.6)	-1.236 ^b	0.217
心功能指标 ($\bar{x} \pm s$)				
LVEF	0.57 ± 0.10	0.56 ± 0.11	0.564 ^a	0.574
LVEDV (ml)	39.7 ± 7.6	41.2 ± 8.7	-0.693 ^a	0.490
NT-proBNP [M (P ₂₅ , P ₇₅), ng/L]	162.0 (87.0, 420.0)	169.3 (77.5, 655.0)	-0.234 ^b	0.815
手术时间 ($\bar{x} \pm s$, min)	94.9 ± 23.0	80.1 ± 21.5	2.712 ^a	0.008
对比剂用量 [M (P ₂₅ , P ₇₅), ml]	160.0 (125.0, 190.0)	120.0 (92.5, 135.0)	-4.492 ^b	< 0.001
β ₂ -微球蛋白 ($\bar{x} \pm s$, mg)	1.9 ± 0.7	2.3 ± 0.9	-2.031 ^a	0.045
胱抑素 C ($\bar{x} \pm s$, mg/L)	1.8 ± 0.7	1.1 ± 0.6	4.402 ^a	< 0.001
水化方式 (口服/静脉)	9/12	36/33	0.559	0.455

注: ^a 为 t 值, ^b 为 Z 值, 余检验统计量值为 χ^2 值

表 3 老年冠心病并轻度肾功能不全患者择期 PCI 后并发 CIN 影响因素的多因素 Logistic 回归分析

Table 3 Multivariate Logistic regression analysis of influencing factors of CIN in elderly coronary heart disease patients complicated with mild renal insufficiency after selective PCI

变量	赋值	β	SE	Wald χ^2 值	P 值	OR (95%CI)
BMI	实测值	-0.020	0.115	0.032	0.859	0.980 (0.781, 1.228)
糖尿病	有=1, 无=0	0.490	0.231	4.506	0.034	1.632 (1.038, 2.564)
LDL-C	实测值	1.003	0.542	3.419	0.064	2.727 (0.942, 7.896)
手术时间	实测值	-0.006	0.021	0.087	0.768	0.994 (0.954, 1.035)
对比剂用量	实测值	0.035	0.013	7.031	0.008	1.036 (1.009, 1.063)
β_2 -微球蛋白	实测值	-1.134	0.631	3.227	0.072	0.322 (0.093, 1.109)
胱抑素 C	实测值	1.696	0.659	6.633	0.010	5.454 (1.500, 19.819)

更为有利。本研究结果显示, 糖尿病、对比剂用量、胱抑素 C 水平是老年冠心病并轻度肾功能不全患者择期 PCI 后并发 CIN 的独立影响因素。国外 HELGASON 等^[20] 研究结果显示, 对比剂用量与 CIN 发生呈正相关, 每增加 100 ml 的对比剂用量, CIN 发生率则增加 12.28%; 当合并肾功能不全患者的对比剂用量超过 150 ml 时, 其 CIN 发生率则会增加 5 倍以上。

综上所述, 口服水化与静脉水化对老年冠心病并轻度肾功能不全患者择期 PCI 后 CIN 的预防效果相当, 但静脉水化可更有效地减少患者消化道不适症状, 而糖尿病、对比剂用量、胱抑素 C 水平是老年冠心病并轻度肾功能不全患者择期 PCI 后并发 CIN 的独立影响因素。但本研究为单中心研究, 纳入样本量有限, 随访时间较短, 且未纳入患者用药情况进行对比、分析, 因此结论可能存在一定偏倚, 后续可扩大样本量、完善观察指标、延长随访时间进行多中心研究以进一步证实本研究结论。

作者贡献: 陈璐、王用进行文章的构思与设计, 结果分析与解释; 邢玉龙进行研究的实施与可行性分析; 陈璐、刘华英、赵先静、诸雯进行数据收集、整理、分析; 陈璐、王用撰写论文, 进行论文的修订, 并对文章整体负责、监督管理; 陈璐负责文章的质量控制及审核。

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