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氨甲环酸联合利伐沙班对单侧全膝关节置换术后患者出血量、凝血功能以及膝关节功能的影响*

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摘要 目的:探讨氨甲环酸联合利伐沙班对单侧全膝关节置换术后患者出血量、凝血功能及膝关节功能的影响。**方法:**选取 2015 年 1 月-2016 年 1 月在解放军 425 医院骨科初次行单侧全膝关节置换术的患者 66 例为研究对象,按照随机数字表法分为治疗组与对照组,每组各 33 例。治疗组患者在止血带释放前向关节腔内注射氨甲环酸,对照组患者则给予氯化钠注射液进行静脉滴注,在术后 6-12h 内两组患者均口服利伐沙班。记录并对比两组患者总失血量、隐性出血量、输血率、输血量,对比两组患者手术前后凝血功能指标、膝关节功能评分、膝关节活动度、疼痛视觉模拟评分(VAS),并观察两组患者并发症发生情况。**结果:**与对照组对比,治疗组患者的总失血量、隐性出血量、输血量及输血率均明显降低($P<0.05$);治疗组与对照组患者术前与术后 3 d 的活化部分凝血酶时间(APTT)、凝血酶原时间(PT)、纤维蛋白原(FG)水平比较均无显著差异($P>0.05$);术前两组患者的美国膝关节协会评分(AKSS)及膝关节活动度比较无显著差异($P>0.05$),术后 7 d,治疗组与对照组患者的 AKSS 评分及膝关节活动度均较术前升高($P<0.05$),且治疗组患者的 AKSS 评分及膝关节活动度高于同时期对照组($P<0.05$);术前两组 VAS 评分比较无显著差异($P>0.05$),术后 1 d,两组患者的 VAS 评分比较及与同组术前比较均无显著差异($P>0.05$),术后 7 d,两组患者的 VAS 评分明显较术前及术后 1 d 降低($P<0.05$),但两组之间比较无显著差异($P>0.05$)。两组患者并发症总发生率对比无显著差异($P>0.05$)。**结论:**氨甲环酸联合利伐沙班可有效降低行单侧全膝关节置换术患者的出血量,加快关节功能的恢复,且不影响患者的凝血功能,值得临床推广。

关键词:单侧全膝关节置换术;氨甲环酸;利伐沙班;出血量;膝关节功能

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Effect of Tranexamic Acid Combined Rivaroxaban in Bleeding Volume, Coagulation Function, Knee Function in Patients with Unilateral Total Knee Arthroplasty*

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ABSTRACT Objective: To investigate effect of tranexamic acid combined rivaroxaban in bleeding volume, coagulation function, knee function in patients with unilateral total knee arthroplasty. **Methods:** 66 patients who were underwent unilateral total knee replacement in department of orthopedics, PLA 425 hospital from January 2015 to January 2016 were selected as the subjects, and they were divided into treatment group and control group according to random number table method with 33 cases in each group. Patients in the treatment group were injected tranexamic acid in articular cavity before the tourniquet released, patients in the control group were given intravenous drip of sodium chloride injection, and within 6-12 h after operation, patients in both groups were treated with oral rivaroxaban. The total blood loss, occult bleeding volume, blood transfusion rate and blood transfusion volume were recorded and compared between the two groups, the blood coagulation function index, knee function score, knee mobility and visual analogue scale (VAS) were compared between the two groups before and after operation, and the complications of the two groups were observed. **Results:** Compared with the control group, the total blood loss, occult bleeding volume, blood transfusion and blood transfusion rate of patients in the treatment group were significantly decreased ($P<0.05$). There was no significant difference in activation, partial thromboplastin time (APTT), prothrombin time (PT) and fibrinogen (FG) levels between the treatment group and the control group before and 3d after operation ($P>0.05$). There was no significant difference in the American Knee Society score (AKSS) and knee joint activity between the two groups before operation ($P>0.05$), 7 d after operation, AKSS score and knee joint activity of patients in the treatment group and the control group were significantly higher ($P<0.05$), and AKSS score and knee joint activity of patients in the treatment group were significantly higher than in the control group ($P<0.05$). There was no significant difference in visual analogue scale (VAS) between the two groups before operation ($P>0.05$), 1 d after operation, VAS scores in the two groups were not significantly different, and compared with before operation

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($P>0.05$), 7 d after operation, the VAS score of two groups was decreased compared with before and 1 d after operation ($P<0.05$), but there was no significant difference between the two groups($P>0.05$). There was no significant difference in the total incidence of complications between the two groups($P>0.05$). **Conclusion:** Tranexamic acid combined with rivaroxaban can effectively reduce bleeding in patients underwent unilateral total knee arthroplasty, accelerate the recovery of joint function, and it does not affect the coagulation function of patients, which is worthy of clinical promotion.

Key words: Unilateral total knee arthroplasty; Tranexamic acid; Rivaroxaban; Bleeding volume; Knee function

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前言

近年来,全膝关节置换术的技术越发成熟,已经成为临床上治疗重度膝关节疾病的重要手段,但由于该类手术具有较大的手术创面,且在手术过程中应用了止血带,使患者的围手术期失血量较大,将对患者的预后造成不良影响^[1-3]。同时如何预防全膝关节置换术围手术期的深静脉血栓以及如何处理好抗凝与抗纤溶的平衡也是临床学者需要面对的挑战^[45]。氨甲环酸是临床上常用的止血药物,可竞争性的阻止与抑制纤维蛋白与纤溶酶原和纤溶酶的结合,进而发挥止血作用,但是应用该药物的同时容易使静脉的血液处于高凝状态,易引发深静脉血栓^[67]。利伐沙班是在 2009 年批准上市的新型抗凝药物,可用于预防全膝关节置换术后深静脉血栓的形成^[89]。本研究对氨甲环酸联合利伐沙班治疗单侧膝关节置换术后患者出血量、凝血功能及膝关节功能的影响进行探讨,旨在对临床预防单侧膝关节置换术后出血提供药物依据。

1 资料与方法

1.1 一般资料

选取解放军 425 医院骨科 2015 年 1 月-2016 年 1 月收治的初次行单侧全膝关节置换术的患者 66 例为研究对象。纳入标准:均初次行单侧全膝关节置换术;手术前凝血功能正常;病理资料完整;患者及其家属对本次研究知情,并签署知情同意书。排除标准:近期服用抗凝药物的患者;对本次研究药物存在禁忌症的患者;伴有严重心脑血管疾病的患者;伴有血栓史、凝血功能及肝肾功能异常的患者。66 例患者根据随机数字表法分为治疗组和对照组,每组各 33 例。治疗组患者中男 19 例,女 14 例,年龄 60-84 岁,平均年龄(67.8 ± 7.2)岁,病程 5-14 年,平均病程(9.8 ± 3.4)年,类风湿性关节炎 12 例,骨关节炎 21 例。对照组患者中男 17 例,女 16 例,年龄 62-84 岁,平均年龄(68.5 ± 7.8)岁,病程 5-16 年,平均病程(10.5 ± 3.9)年,类风湿性关节炎 14 例,骨关节炎 19 例。两组患者的一般资料对比无显著差异($P>0.05$)。本研究通过医院伦理委员会批准。

1.2 方法

两组患者均由同一组医师进行手术,进行腰麻或全身麻醉,手术采取屈膝位,手术切口选择在膝关节正中,入路选择在髌旁内侧,人工膝关节假体采用后交叉韧带替代型骨水泥进行固定。止血带压力为 300 mmHg,置于患者患肢大腿根部,在手术切口关闭后,将止血带松开,并在术后放置引流管。治疗组患者在吸血带松开前 15 min 向关节腔内注射 1 g 氨甲环酸(贵州圣济堂制药有限公司生产,规格:5 mL:0.5 g,国药准字:

H20063068),在冲洗后将切口逐层关闭。对照组仅给予 250 mL 0.9%的氯化钠注射液进行静脉滴注。两组患者在术后 6-12 h 内服用利伐沙班片(德国 Bayer Schering Pharma AG 生产;规格:10 mg/片;国药准字:H20140132),10 mg/次,1 次/d,连续服用 15 d。

1.3 观察指标

1.3.1 止血效果 对两组患者总失血量、隐性出血量、输血量、输血量进行记录。其中总失血量 = 输血量 + 患者血容量 $\times$ (术前红细胞压积 - 术后红细胞压积)/平均红细胞压积;隐性失血量 = 总失血量 - 显性失血量;显性失血量 = 术后出血量 + 术中出血量 + 术后引流量。

1.3.2 凝血功能指标 在术前及术后 3 d 抽取患者清晨空腹静脉血 5 mL,以 3000 r/min 的速度离心 10 分钟,待将血清分离后在 2 h 内进行检测,应用日本希森美康 CA1500 全自动凝血仪对患者的活化部分凝血酶时间(Activated partial thromboplastin time,APTT)、凝血酶原时间(Prothrombin time,PT)及纤维蛋白原(Fibrinogen,FG)进行检测。

1.3.3 膝关节功能评分、膝关节活动度 在患者术前及术后 7 d 对膝关节功能进行评分,并记录膝关节活动度。膝关节功能根据膝关节评估系统美国膝关节协会评分(American Knee association score,AKSS)进行评分:疼痛 50 分,关节活动度 25 分,稳定性 25 分,有侧方畸形或屈曲过伸要减分,上下楼梯 50 分,走路 50 分,总分 200 分。得分越高,表示膝关节功能恢复得越好。

1.3.4 疼痛评分 在患者术前、术后 1 d 及术后 7 d 采用视觉模拟评分(Visual analog scale, VAS)对患者的疼痛程度进行评分,0 分表示无痛,1-3 分表示轻度疼痛,4-6 分表示中度疼痛,7-10 分表示重度疼痛,分值越高,疼痛越严重。

1.3.5 并发症 在术后观察两组患者是否有创口渗血、下肢深静脉血栓、皮下瘀斑、鼻衄等并发症的发生,并对比两组并发症发生率。

1.4 统计学分析

采用 SPSS19.0 统计学软件,以($\bar{x}\pm s$)的形式表示计量资料,经 t 检验分析,以%的形式表示计数资料,经 χ^2 检验分析,以 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 两组止血效果对比

与对照组对比,治疗组患者的总失血量、隐性出血量、输血量及输血量均明显降低($P<0.05$),见表 1。

表 1 两组止血效果对比[$\bar{x} \pm s$ 或 $n(\%)$]

Table 1 Comparison of hemostatic effect between the two groups[$\bar{x} \pm s$ or $n(\%)$]

Groups	N	Total blood loss(mL)	Occult bleeding volume(mL)	Blood transfusion volume(mL)	Blood transfusion rate
Treatment group	33	586.15± 127.32	262.18± 73.56	579.32± 39.88	2(6.06)
Control group	33	890.29± 203.78	539.5± 101.32	661.45± 45.19	6(18.18)
t	-	16.872	18.913	10.743	8.996
P	-	0.005	0.002	0.015	0.027

2.2 两组凝血功能指标对比

较均无显著差异($P>0.05$),且两组间同时期比较也无显著差异

治疗组与对照组患者术前与术后 3 d 的 APTT、TT、FG 比 ($P>0.05$),见表 2。

表 2 两组凝血功能指标对比($\bar{x} \pm s$)

Table 2 Comparison of coagulation function indexes in two groups($\bar{x} \pm s$)

Groups	N	APTT(s)		TT(s)		FG(g/L)	
		Before operation	3 d after operation	Before operation	3 d after operation	Before operation	3 d after operation
Treatment group	33	28.29± 4.38	31.82± 3.64	11.01± 1.04	12.04± 1.68	3.92± 0.81	3.70± 0.45
Control group	33	28.09± 3.32	30.80± 3.95	10.87± 1.23	11.82± 1.42	3.98± 0.89	3.75 ± 0.48
t	-	0.891	0.327	0.618	1.017	0.975	0.443
P	-	0.067	0.152	0.135	0.054	0.063	0.115

2.3 两组膝关节功能评分、膝关节活动度对比

膝关节活动度均较术前升高($P<0.05$),且术后 7 d,治疗组患者

术前,两组患者的 AKSS 评分及膝关节活动度对比无显著差异($P>0.05$),术后 7 d,治疗组与对照组患者的 AKSS 评分及

的 AKSS 评分及膝关节活动度高于对照组($P<0.05$),见表 3。

表 3 两组膝关节功能评分、膝关节活动度对比($\bar{x} \pm s$)

Table 3 Comparison of knee function score and knee mobility contrast in two groups($\bar{x} \pm s$)

Groups	N	AKSS scores (points)		Knee mobility($^{\circ}$)	
		Before operation	7 d after operation	Before operation	7 d after operation
Treatment group	33	38.42± 10.13	51.69± 11.39*	69.35° ± 19.16°	81.45° ± 20.23° *
Control group	33	39.31± 10.87	45.32± 11.08*	71.65° ± 20.23°	75.15° ± 18.12° *
t	-	1.152	7.318	0.457	5.394
P	-	0.078	0.026	0.176	0.039

Note: compared with the same group before treatment, * $P<0.05$.

2.4 两组 VAS 评分对比

术前治疗组与对照组的 VAS 评分分别为(6.31± 1.12)分、(6.45± 1.33)分,两组比较无显著差异($P>0.05$),术后 1d,治疗组与对照组的 VAS 评分分别为(7.29± 1.73)分、(7.42± 1.96)分,两组患者的 VAS 评分比较及与同组术前比较均无显著差异 ($P>0.05$), 术后 7 d, 治疗组与对照组的 VAS 评分分别为 (2.18± 0.65)分、(2.45± 0.71)分,两组患者的 VAS 评分明显较

术前及术后 1 d 降低 ($P<0.05$), 但两组之间对比无显著差异 ($P>0.05$)。

2.5 两组并发症对比

治疗组患者发生 2 例创口渗血,7 例皮下瘀斑,2 例鼻衄,并发症总发生率为 33.33%, 对照组患者发生 3 例创口渗血,9 例皮下瘀斑,1 例鼻衄,并发症总发生率为 39.39%,治疗组与对照组患者并发症总发生率对比无显著差异($P>0.05$),见表 4。

表 4 两组并发症对比[n(%)]

Table 4 Comparison of complications of two groups[n(%)]

Groups	N	Wound oozing of blood	Deep venous thrombosis of lower limb	Ecchymosis	Epistaxis	Total incidence
Treatment group	33	2(6.06)	0(0.00)	7(21.21)	2(6.06)	11(33.33)
Control group	33	3(9.09)	0(0.00)	9(27.27)	1(3.03)	13(39.39)
χ^2	-					0.142
P	-					0.196

3 讨论

全膝关节置换术因手术创伤较大而导致手术失血量较多,具有较高的输血率^[10,11]。手术过程中出血量过多将会对患者术后膝关节功能的恢复产生影响,导致术后恢复时间延长,也使术后并发症发生的几率增加^[12,13]。行全膝关节置换术的患者多为中老年人,身体的各种机能相对较差,对于失血具有较差的耐受能力,因此临床上对行全膝关节置换术的患者在围手术期常应用同种异体输血的方法来纠正贫血^[14-16]。但同种异体输血纠正可有效纠正贫血的同时,也给患者带来了输血疾病和潜在危险,例如过敏反应、发热反应、菌血症等^[17]。近年来,随着老年患者骨关节炎、类风湿关节炎等膝关节疾病发生率的升高,全膝关节置换术在临床上的应用率也越来越高^[18-20],因此如何改善该手术围手术期失血量问题是目前关节外科医生需重视的问题。

有研究显示,全膝关节置换术围手术期失血的主要原因是手术过程中的创伤使纤溶反应加剧而引发的^[21,22]。因此较多学者认为可通过应用抗纤溶药物来使全膝关节置换术围手术期失血量降低^[23,24]。氨甲环酸又名凝血酸,可竞争性的阻止与抑制纤维蛋白与纤溶酶原和纤溶酶的结合,进而发挥止血作用,能够抵抗纤维蛋白溶解活性,被广泛应用于预防全膝关节置换术围手术期出血^[25-27]。但是在氨甲环酸的应用过程中,其抗纤溶作用可能会导致下肢深静脉血栓形成的危险性增加,因此较多学者认为在应用氨甲环酸后的6-12 h内应给予抗凝药物治疗^[28],以往抗凝药物主要应用低分子肝素,但是由于低分子肝素在应用时需要剂量进行调整,且患者在出院后的依从性较差,使其应用受到了限制^[29]。利伐沙班作为一种新型的抗凝药物,被广泛应用于全膝关节置换术后预防下肢深静脉血栓的形成,该药物为口服药物,且应用时剂量不需要调整,患者治疗依从性较好。因此本研究中行单侧全膝置换术的患者应用氨甲环酸联合利伐沙班进行止血,结果显示治疗组患者的总失血量、隐性出血量、输血量及输血率均明显较对照组降低,说明氨甲环酸具有较好的止血效果,与文献报道一致^[30]。在两组凝血功能指标分析中显示,两组术前术后凝血功能指标对比均无显著差异($P>0.05$),说明氨甲环酸与利伐沙班联合应用后对患者的凝血系统并不会产生明显的影响。在膝关节功能及膝关节活动度分析中发现,治疗组患者的膝关节功能及膝关节活动度改善程度优于对照组,说明氨甲环酸与利伐沙班联合应用更有助于膝关节功能的改善,分析其原因与氨甲环酸可有效降低患者出血量有关。此外,两组患者在并发症与术后疼痛评分对比中也无显著差异($P>0.05$),两组患者均未发生下肢深静脉血栓,说明氨甲环酸联合利伐沙班可有效降低发生深静脉血栓的危险性,同时不会增加其他并发症的发生。

综上所述,氨甲环酸联合利伐沙班可有效降低行单侧全膝关节置换术患者的出血量,加快关节功能的恢复,且不影响患者的凝血功能,值得临床推广。

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