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· 临床研究 ·

中高血栓风险患者李金斯坦手术围术期不停用抗血栓药物的安全性分析

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摘要

背景与目的:术前长期服用抗血栓药物的患者,围术期如继续服药会增加手术出血风险,而停药则增加血栓栓塞事件发生的风险。对于腹股沟疝手术而言,围术期抗血栓药物的管理尚无共识或高质量临床研究。因此,本研究通过观察长期口服抗血栓药物的腹股沟疝患者围术期不停药行李金斯坦手术的安全性,初步探讨该类患者围术期抗血栓药物的管理策略。

方法:采用前瞻性队列研究方法,连续纳入2018年11月—2022年2月间中南大学湘雅医院疝和腹壁外科中心收治的18例因中高血栓风险而长期口服抗血栓药物的腹股沟疝患者,围术期均不停用抗血栓药物,采取神经阻滞联合喉罩全身麻醉行李金斯坦手术。对患者术中及术后出血情况、术后第1天视觉模拟疼痛评分(VAS)、术后主要心脏不良事件(MACEs)、脑血管并发症、切口不良事件、疝复发和病死率进行观察与随访。

结果:18例腹股沟疝患者均为男性,其中4例曾行心脏瓣膜置换手术、1例合并房颤、9例曾行冠状动脉支架植入术、1例曾行冠状动脉搭桥术、3例既往发作心肌梗死,均为中高血栓风险患者。其中,长期口服华法林患者5例,长期口服抗血小板药物13例,包括服用阿司匹林8例、服用氯吡格雷3例、服用阿司匹林联合氯吡格雷/吲哚布芬2例。18例患者的平均住院时间(9.61 ± 2.59)d,术中平均失血量为(3.77 ± 2.53)mL,手术平均时长为(70.13 ± 13.44)min。术后1例患者出现伤口明显瘀青,1例患者出现伤口少许瘀青,16例患者伤口无明显出血。无1例需输血或发生需外科处理的出血事件。术后第1天中位VAS评分为1.72分。围术期无MACEs和脑血管并发症发生。所有患者均在术后1~5d痊愈出院,出院后中位随访19.34个月,随访率为100%。随访期间无伤口不良事件、疝复发、MACEs、脑血管并发症及死亡发生。

结论:对于具有中高血栓风险的腹股沟疝患者,在全方位的围术期管理前提下,围术期不停用抗血栓药物行李金斯坦手术这一策略是安全可行的,推荐作为选择。

关键词

疝, 腹股沟; 疝修补术; 抗凝药; 围手术期

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Safety analysis of continuation of antithrombotic agents in patients with moderate or high thromboembolic risk undergoing Lichtenstein surgery during perioperative period

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Abstract

Background and Aims: In patients receiving long-term antithrombotic prophylaxis who require surgery, the continuation of therapy during perioperative period will raise the risk of surgical bleeding, while the incidence of thromboembolic events will increase after drug discontinuation. For inguinal hernia procedures, there is, at present, no consensus or high-quality evidence regarding the perioperative management of antithrombotic medication. Therefore, this study was designed to observe the safety of performing Lichtenstein hernioplasty in inguinal hernia patients on long-term anticoagulation without antithrombotic treatment withdrawal during the perioperative period, so as to help investigate the strategies for perioperative management of anticoagulation in these patients.

Methods: Using a prospective cohort design, 18 inguinal hernia patients with moderate or high risk of thromboembolism on long-term anticoagulation admitted to the Department of Hernia and Abdominal Wall Surgery, Xiangya Hospital, Central South University were consecutively enrolled from November 2018 to February 2022. All patients underwent Lichtenstein hernioplasty under nerve block anesthesia combined with laryngeal mask general anesthesia, without interruption of anticoagulation during the perioperative period. The intra- and postoperative bleeding, visual analog pain score (VAS) on postoperative day (POD) 1, postoperative major cardiac adverse events (MACEs), cerebrovascular complications, incision-related adverse events, hernia recurrence and mortality of the patients were observed and followed up.

Results: The 18 inguinal hernia patients included 4 cases who had previously undergone heart valve replacement surgery, one case with concomitant atrial fibrillation, 9 cases who had previously undergone coronary stenting, one case who had previously undergone coronary artery bypass grafting, and 3 cases with previous myocardial infarction. Among them, 5 patients received long-term oral warfarin therapy, and 13 patients treated with long-term oral antiplatelet-agent therapy that included aspirin administration in 8 cases, clopidogrel administration in 3 cases, and aspirin plus clopidogrel or indobufen administration in 2 cases. Of the 18 patients, the mean length of hospital stay was (9.61±2.59) d, the mean intraoperative blood loss was (3.77±2.53) mL, and the mean operative duration was (70.13±13.44) min. After surgery, one patient had obvious wound bruising, one patient had mild wound bruising, and 16 patients had no obvious wound bleeding. Blood transfusion or reoperation was required in none of them. The median VAS was 1.72 on POD 1. There was no MACEs and cerebrovascular complications occurred during perioperative period. All patients were discharged from the hospital 15 d after surgery. The median follow-up time after discharge was 19.34 months, and the follow-up rate was 100%. No wound-related adverse events, hernia recurrence, MACEs, cerebrovascular complications, and death occurred during follow-up.

Conclusion: For inguinal hernia patients with moderate or high thromboembolic risk, the strategy of continuous use of antithrombotic drugs during the perioperative period of Lichtenstein hernia repair is safe and feasible on the premise of a comprehensive perioperative management. So, it is recommended as an appropriate choice for application.

Key words Hernia, Inguinal; Herniorrhaphy; Anticoagulants; Perioperative Period

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外科手术前长期服用抗血栓药物的患者比例达到8.9%^[1]，抗血栓药物的围术期管理已成为外科领域的研究热点^[2]。国内外指南^[3-7]建议，对于出血风险较小的手术，如白内障手术、小的皮肤手术、肠息肉切除术等，围术期可继续抗血栓治疗；而对于心脏手术、脊柱手术、颅脑手术等出血可能导致严重临床后果的手术，建议术前停用口服抗血栓药物，改为肝素桥接抗凝。然而，对于腹股沟疝手术而言，围术期抗血栓药物的管理尚无高质量临床研究，临幊上仍极具争议^[8-17]。尤其对于存在中高血栓风险的患者，术前常规停用抗血栓药物，有可能增加血栓栓塞的风险导致严重后果，而围术期不停用抗血栓药物或停用后改用肝素桥接有可能增加围术期出血风险^[18-19]。围手术期不停药行李金斯坦手术，并对手术并发症进行随访观察，总结围术期抗血栓药物的管理经验，以期为临幊提供一种安全的围术期抗血栓药物管理模式。

1 资料与方法

1.1 一般资料

前瞻性纳入中南大学湘雅医院疝和腹壁外科中心2018年11月—2022年2月间连续收治的18例因中高血栓风险而长期口服抗血栓药物的腹股沟疝患者。患者纳入标准包括：(1)诊断明确的腹股沟疝（单侧/双侧）患者；(2)术前长期（>1个月）口服抗血栓药物（包括抗凝药和抗血小板药物）；(3)合并中高血栓风险^[4]：如心脏二尖瓣或主动脉瓣机械瓣膜置换术后、冠状动脉支架植入术后、房颤合并CHADS2评分3~6分或既往心肌梗死合并Caprini评分≥3分；(4)择期李金斯坦手术。排除标准包括：(1)急诊手术；(2)合并其他凝血系统疾病；(3)未获得知情同意。本研究为前瞻性观察性队列研究，已经获得所在医疗机构伦理委员会审批（伦理审批号：2201806164）。所有患者在院期间均已签署诊疗

知情同意书并同意将病历资料用于后续临床研究。

1.2 围术期管理及手术方式

所有患者均由包括疝外科医生、麻醉医生、心血管内科医生等在内的老年疝病多学科团队进行专业的、个体化的围术期管理。主要包括以下几点：(1)严密的术前评估，包括心脑血管、呼吸系统及凝血系统功能等。术前对抗血栓药物剂量进行一定的调整，确保国际标准化比值（INR）在3.0以下^[20]，最好维持在2.0~2.2之间；(2)术中均采用神经阻滞麻醉联合喉罩全身麻醉，由同一位经验丰富的疝外科医生完成李金斯坦手术；(3)精准手术，彻底止血。术后48 h内，辅以疝带加压包扎；(4)贯彻加速康复外科理念^[21]，术前禁食禁饮6 h，术前排空膀胱，不予常规导尿，术毕伤口局部浸润罗哌卡因镇痛，术后不予常规使用其他止痛药。根据手术时长及出血量，术后补液量控制在500~1 000 mL。术后麻醉苏醒后即鼓励活动和恢复正常饮食。

1.3 观察指标

主要观察指标包括：术中及术后出血情况、围术期输血量和住院时间。术后出血情况分为：(1)无任何出血表现；(2)少许瘀青；(3)明显瘀青；(4)血肿；(5)需要外科处理的出血。次要观察指标包括：术后第1天视觉模拟疼痛评分（VAS）、主要心脏不良事件（MACEs）、脑血管并发症、切口不良事件、疝复发和死亡。MACEs主要包括急性心肌梗死、心脏骤停、严重心律失常、心源性死亡等。脑血管并发症主要包括脑卒中和短暂性脑缺血发作。切口不良事件主要包括切口感染和切口裂开。对患者定期进行随访，随访方式主要包括门诊随访和电话随访。

1.4 统计学处理

数据采用Microsoft Excel软件进行分析。计量资料符合正态分布的用均数±标准差（ $\bar{x} \pm s$ ）表示，不符合正态分布的采用中位数表示，计数资

料采用例数(百分数) [n (%)] 表示。

2 结 果

2.1 患者一般资料

18例患者均为男性;中位年龄71(63~80)岁;单侧腹股沟疝16例(88.89%),双侧腹股沟疝2例(11.11%)。其中,2例(11.11%)患者曾行二尖瓣瓣膜置换术合并房颤、1例(5.56%)曾行主动脉瓣及二尖瓣瓣膜置换术、1例(5.56%)

合并房颤、9例(50.00%)曾行冠状动脉支架植入术、1例(5.56%)曾行冠状动脉搭桥术、3例(16.66%)有心肌梗死病史。18例患者中,长期口服华法林患者5例(27.78%),长期口服抗血小板药物13例,包括服用阿司匹林8例(44.44%)、服用氯吡格雷3例(16.67%)、服用阿司匹林联合氯吡格雷/吲哚布芬2例(11.11%)。服药时长在3个月内者1例(5.56%),3个月~5年者5例(27.78%),5~10年者8例(44.44%),超过10年者4例(22.22%)(表1)。

表1 患者一般资料、服用药物类型、指征及用药时长($n=18$)

Table 1 General information of patients, types of drugs, indications, and duration of medication ($n=18$)

资料	数值[n(%)]	资料	数值[n(%)]
年龄(岁)		适应证	
>65	13(72.22)	二尖瓣瓣膜置换术、房颤	2(11.11)
≤65	5(27.78)	主动脉瓣、二尖瓣膜置换术	1(5.56)
腹股沟疝类型		主动脉瓣膜置换术	1(5.56)
单侧	16(88.89)	房颤	1(5.56)
双侧	2(11.11)	冠状动脉支架植入	9(50.00)
并发症		冠状动脉搭桥术	1(5.56)
高血压	12(66.66)	既往心肌梗死	3(16.66)
糖尿病	2(11.11)	用药时长	
肾功能不全	2(11.11)	≤3月	1(5.56)
卒中	1(5.56)	≤5年	5(27.78)
无其他基础疾病	1(5.56)	≤10年	8(44.44)
服用药物类型		>10年	4(22.22)
阿司匹林	8(44.44)		
氯吡格雷	3(16.67)		
双联抗血小板	2(11.11)		
华法林	5(27.78)		

2.2 患者术中、术后情况

18例患者平均住院时间(9.61 ± 2.59)d,16例(88.89%)患者伤口无明显出血,1例(5.56%)患者伤口少许瘀青,1例(5.56%)患者伤口明显瘀青,未出现血肿或需外科处理的出血及输血事件。平均手术时长为(70.13 ± 13.44)min,术中平均出血量为(3.77 ± 2.53)mL。术后第1天中位VAS疼痛评分为1.72分。所有患者均在术后1~5d痊愈出院。中位随访时长为19.34个月,随访率100%。随访期间无MACEs、伤口不良事件、疝复发、脑血管并发症及死亡发生(表2)。

表2 患者术后临床结局

Table 2 The clinical outcomes of patients after surgery

项目	数值[n(%)]
住院时间(d)	
>7	11(61.11)
≤7	7(38.89)
出血情况	
无任何瘀青	16(88.88)
少许瘀青	1(5.56)
明显瘀青	1(5.56)
血肿	0(0.00)
需要外科处理的出血	0(0.00)
输血	0(0.00)
主要心脏不良事件	0(0.00)
伤口不良事件	0(0.00)
复发	0(0.00)
死亡	0(0.00)

3 讨论

我国人口老龄化程度日益加深^[22]，老年人常合并各种心脑血管疾病，如冠心病、脑梗塞、风湿性心脏瓣膜病、心房颤动等，这些疾病本身及在行介入手术或其他手术后均需长期服用抗血小板聚集药物或抗凝药物^[1, 23]。对于此类需服用抗血栓药物并伴腹股沟疝的老年患者，围术期抗血栓药物的管理是重大挑战。权衡抗血栓药物的潜在保护作用与围术期的出血风险是疝外科医生无法回避的难题，在美国，接受非心脏手术的患者中，定期服用阿司匹林的比例为40%^[24]。而一项来自德国疝登记系统的数据^[23]显示，腹股沟疝手术患者中术前长期口服抗血栓药物的比例为11%。由于这类患者往往基础疾病较为复杂，服用抗血栓药物的种类和剂量不尽相同，加之各医疗机构和医务人员对患者病情的认知存在较大差异，常导致3类情况出现。其一，由于围术期风险较高，基层医务人员常拒绝接诊这类患者，或者接诊后立即将患者转诊至上级医院。其二，有的医务人员按照普通患者的处理方式，在术前停用抗血栓药物，偶尔导致严重的血栓栓塞性并发症发生，甚至造成患者死亡，引发严重的医疗纠纷。其三，有的医务人员按照其他疾病的围术期管理模式，采取停用抗血栓药物加肝素桥接的方式。伴有血栓风险的腹股沟疝手术患者围术期管理颇为复杂，且效果并不理想。国内外各类指南或共识在这一问题上，也莫衷一是，甚至互相矛盾，导致临床无所适从^[9]。

对于低血栓风险的腹股沟疝患者，术前7 d停用抗凝药物或抗血小板药物，不会增加手术风险，这已形成共识^[9]。临床的难点在于中高血栓风险的腹股沟疝患者的围术期处理。根据美国胸科医师学会的定义^[4]，中高血栓风险主要包括心脏瓣膜置换术后、房颤合并CHADS2评分3~6分、既往半年内静脉血栓栓塞史、严重的血栓形成倾向或冠脉支架置入术后等。对于这类腹股沟疝患者，外科医生首先面临的是，选择开放的腹股沟疝修补术还是腹腔镜腹股沟疝修补术。腹腔镜疝修补术具有切口小、术后疼痛轻、切口并发症少、可以同时处理双侧等优点，近年来逐渐得到认可和普及^[25]。而以李金斯坦术为代表的开放腹股沟疝修补术因学习曲线短、可采用局部麻醉等优点仍然

占据主流。虽然已经有多项研究^[26-27]表明，对于长期口服抗血栓药物的患者，腔镜疝修补术是安全可行的，但多数外科医生在术式选择时仍会倾向于选择开放疝修补术。主要原因在于，开放疝修补术可以在局部麻醉或较浅的全身麻醉下完成，对患者的生理干扰较小。而且由于手术部位表浅，有助于术后出血的预防、观察和及时处理。国内多数学者在施行李金斯坦手术时，围术期常规停用抗血栓药物并采用肝素桥接。然而这一策略的缺点是围术期药物调整时间较长，且预防血栓栓塞的效果并不确切^[28]。2015年，新英格兰医学杂志的一项随机对照研究^[29]发现，长期口服华法林的慢性房颤患者，采用肝素桥接策略，动脉栓塞的风险并没有降低，而出血的概率却显著增加。基于此，有学者^[13-17, 30]开始尝试在开放疝手术的围术期不停用抗血栓药物并取得令人满意的结果。正因为如此，笔者所在单位对于所有术前不停用长期口服抗血栓药物的腹股沟疝患者，均常规采用开放李金斯坦手术。笔者的实践体会，李金斯坦术围术期不停用抗血栓药物具有以下3点优势：(1) 不对原有药物治疗方案产生干扰，术前无需等待停药，操作简单；(2) INR控制在3.0以下时，不会增加术中术后出血；(3) 安全有效，从本组结果来看，18例患者均未发生严重的出血或血栓栓塞性并发症。

总之，在全方位的围术期管理的前提下，对中高血栓风险的腹股沟疝患者，采取围术期不停用抗血栓药物行李金斯坦手术是安全可行的。然而，由于本研究纳入病例较少，且为单中心研究，故研究结果尚需进一步扩大样本量来证实。

利益冲突：所有作者均声明不存在利益冲突。

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