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利胆排石汤联合熊去氧胆酸预防经内镜逆行胰胆管造影术后胆总管结石复发的效果及其对胆汁成分和脂质代谢的影响

王凯峰¹, 曹瑞丽², 赵所燕²

(1. 霸州市第三医院药房, 河北 霸州 065700; 2. 霸州市第三医院内科, 河北 霸州 065700)

[摘要] 目的: 探讨利胆排石汤联合熊去氧胆酸预防经内镜逆行胰胆管造影(endoscopic retrograde cholangiopancreatography, ERCP)术后胆总管结石复发的效果及对胆汁成分、脂质代谢的影响。方法: 选取2019年3月至2020年3月于河北省霸州市第三医院行ERCP取石术的胆总管结石患者60例, 随机分为对照组与观察组(各30例)。对照组术后服用熊去氧胆酸片预防结石复发, 观察组术后服用利胆排石汤联合熊去氧胆酸片预防结石复发, 连续用药6个月。评估两组中医症状, 并分析两组胆汁成分[总胆固醇(total cholesterol, TC)、总胆汁酸(total bile acid, TBA)、总胆红素(total bilirubin, TBIL)]和脂质代谢[血清TC、三酰甘油(triglyceride, TG)、低密度脂蛋白(low-density lipoprotein, LDL)、高密度脂蛋白(high-density lipoprotein, HDL)]变化; 同时记录两组不良反应情况及术后6、12个月的结石复发率。结果: 术后7 d和6个月, 观察组中医症状积分、血清TC、TG、LDL水平显著低于对照组($P<0.05$), 血清HDL水平显著高于对照组($P<0.05$)。术后3、7 d观察组胆汁TC、TBIL水平显著低于对照组($P<0.05$), TBA水平显著高于对照组($P<0.05$)。观察组术后6个月结石复发率与对照组相比差异无统计学意义($P>0.05$), 术后12个月结石复发率显著低于对照组($P<0.05$)。两组不良反应发生率比较, 差异无统计学意义($P>0.05$)。结论: 利胆排石汤联合熊去氧胆酸可有效预防ERCP术后胆总管结石复发, 并且可改善患者胆汁成分及脂质代谢。

[关键词] 胆总管结石; 经内镜逆行胰胆管造影; 熊去氧胆酸; 利胆排石汤; 复发; 脂质代谢

Effect of Lidanpaishi Decoction combined with ursodeoxycholic acid on preventing recurrence of choledocholithiasis after endoscopic retrograde cholangiopancreatography and its influence on bile composition and lipid metabolism

WANG Kaifeng¹, CAO Ruili², ZHAO Suoyan²

(1. Department of Pharmacy, Third Hospital of Bazhou City, Bazhou Hebei 065700; 2. Department of Internal Medicine, Third Hospital of Bazhou City, Bazhou Hebei 065700, China)

Abstract Objective: To investigate the effect of Lidanpaishi Decoction combined with ursodeoxycholic acid on preventing

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通信作者 (Corresponding author): 曹瑞丽, Email: 1123699884@qq.com

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the recurrence of choledocholithiasis after endoscopic retrograde cholangiopancreatography (ERCP) and its influence on bile composition and lipid metabolism. **Methods:** Sixty patients with choledocholithiasis who underwent ERCP in the Third Hospital of Bazhou City from March 2019 to March 2020 were randomly divided into a control group and an observation group (30 cases each). To prevent stone recurrence after operation, the control group was treated with ursodeoxycholic acid tablets, while the observation group was treated with Lidanpaishi Decoction combined with ursodeoxycholic acid tablets for a consecutive 6 months. The traditional Chinese medicine (TCM) symptoms of the two groups were evaluated, and the changes of bile components [total cholesterol (TC), total bile acid (TBA), total bilirubin (TBIL)] and lipid metabolism [serum TC, triglyceride (TG), low-density lipoprotein (LDL), high-density lipoprotein (HDL)] were analyzed. The adverse reactions and recurrence rates of stones at the 6th and 12th months after operation were recorded. **Results:** At the 7th day and the 6th month after operation, the TCM symptom score, serum TC, TG and LDL levels in the observation group were significantly lower than those in the control group ($P < 0.05$), and the serum HDL level was significantly higher than that in the control group ($P < 0.05$). The levels of bile TC and TBIL in the observation group were significantly lower than those in the control group at the 3rd and 7th days after operation ($P < 0.05$), while the level of TBA was significantly higher than that in the control group ($P < 0.05$). The recurrence rate of stones at the 12th month after operation was significantly lower than that in the control group ($P < 0.05$). There was no statistically significant difference in adverse reactions rates between the two groups ($P > 0.05$). **Conclusion:** Lidanpaishi Decoction combined with ursodeoxycholic acid can effectively prevent the recurrence of choledocholithiasis after ERCP, and improve the bile composition and lipid metabolism of patients.

Keywords choledocholithiasis; endoscopic retrograde cholangiopancreatography; ursodeoxycholic acid; Lidanpaishi Decoction; recurrence; lipid metabolism

胆总管结石为临床常见的消化系统疾病,近年来因生活方式的变化,其发病率呈逐年增高的趋势。目前,治疗胆总管结石的首选方案为经内镜逆行胰胆管造影(endoscopic retrograde cholangiopancreatography, ERCP)取石,但术后易复发,严重影响其远期疗效^[1]。临床分析胆总管结石复发的危险因素发现:任何影响患者胆汁成分、脂质代谢的因素均可再次诱发结石,并且ERCP术后长期服用熊去氧胆酸能够降低结石复发率^[2]。然而,单纯西药尚未达到令人满意的预防效果。研究^[3]显示:中医药在预防结石复发方面有独特的优势。胆总管结石在中医中属于“胁痛”“胆胀”“黄疸”等范畴,是气滞、血瘀、湿热蕴结于肝胆所致,主要临床表现为胁痛,治疗的关键是疏肝理气、逐瘀排石。利胆排石汤是中医中应用较为广泛的一类汤剂,其基础中药为金钱草、大黄、鸡内金、郁金、茵陈、赤芍、海金沙、虎杖等,具有清热利胆、行气活血、化石等功效^[4]。基于此,本研究将利胆排石汤与熊去氧胆酸联合用于预防ERCP术后结石复发,以期能够解决胆总管结石患者的困扰,让更多患者受益。

1 对象与方法

1.1 对象

选取2019年3月至2020年3月河北省霸州市第三医院收治的60例原发性胆总管结石患者为研究对象,所有患者均接受ERCP取石术治疗,采用随机数字表法将其分为对照组与观察组(各30例)。

1.2 纳入及排除标准

纳入标准:1)年龄18~80岁;2)经临床诊断为原发性胆总管结石;3)采取ERCP取石术治疗,且手术顺利;4)知情同意。排除标准:1)合并有胆内管结石、胆管囊肿、胆管肿瘤;2)患有严重器质性疾病或凝血功能异常;3)既往有ERCP手术史;4)对治疗药物不耐受。

1.3 治疗方法

患者均采用ERCP取石术治疗,并且术后行鼻导管引流,其中对照组术后1 d开始服用熊去氧胆酸片(国药准字H31021875,上海上药信谊药厂有限公司,50 mg/片),剂量为10 mg/kg,1次/d,连续治疗6个月。观察组在对照组的基础上服用利

胆排石汤, 基础方剂: 茵陈、金钱草、郁金、鸡内金、虎杖、乌梅各30 g, 威灵仙、海金沙各20 g, 白芍、赤芍各15 g, 木香、黄芩各12 g, 制大黄9 g; 肝气郁结者加香附、柴胡各10 g; 伴有异常疼痛者加川楝子、延胡索各10 g; 伴有肝胆湿热症状者加蒲公英、白花蛇舌草各30 g; 伴有便秘症状者需用生大黄替代制大黄。1剂/d, 用小火熬成一小碗, 分2次早晚服用, 7 d为1个疗程, 连用6个月。

1.4 观察指标

1) 中医症状积分: 胆总管结石主要临床症状为右肋胀满疼痛, 次要症状为腹痛、少食纳呆、口干、神疲乏力、恶心呕吐、大便不爽, 将主、次要症状按病情严重程度分别赋予0、2、4、6分和0、1、2、3分。于术前、术后7 d对患者临床症状进行评估。2) 胆汁成分: 收集术前(插管成功后从胆囊中抽取)、术后3、7 d(空腹状态下经鼻导管收集)胆汁, 离心后取胆汁上清液, 采用酶联免疫吸附法检测胆汁中总胆固醇(total cholesterol, TC)、总胆汁酸(total bile acid, TBA)和总胆红素(total bilirubin, TBIL)的水平。3) 血脂水平: 采集患者术前、术后7 d和术后6个月的清晨空腹静脉血, 采用全自动生化分析仪检测血清中TC、三酰甘油(triglyceride, TG)、低密度脂蛋白(low-density lipoprotein, LDL)和高密度脂蛋白(high-density lipoprotein, HDL)的含量。4) 结石复发情况: 对所有患者进行为期12个月的随访(其中观察组有1例失访, 对照组有2例失访), 记录两组术后6、12个月的结石复发情况, 根据B超结果判断有无复发。5) 不良反应: 观察两组用药期间发生的不良反应事件。

1.5 统计学处理

采用SPSS 22.0软件进行数据分析。计量资料符合正态分布且方差齐, 以均数±标准差($\bar{x} \pm s$)表示, 组内比较采用配对样本 t 检验, 两组间比较采用独立样本 t 检验; 计数资料用例(%)表示, 采用 χ^2 或Fisher精确概率法进行检验。 $P < 0.05$ 为差异具有统计学意义。

2 结果

2.1 一般资料

两组一般资料如性别、年龄、病程、结石数量等比较差异无统计学意义, 具有可比性(均 $P > 0.05$, 表1)。

2.2 中医症状积分

术前, 两组中医症状积分比较差异均无统计学意义($P > 0.05$); 术后7 d、6个月, 两组中医症状积分逐渐降低($P < 0.05$), 且观察组比对照组降低更显著($P < 0.05$, 表2)。

2.3 胆汁成分

术前, 两组胆汁中的TC、TBIL、TBA含量比较差异均无统计学意义(均 $P > 0.05$); 术后3、7 d, 两组胆汁中的TC、TBIL水平逐渐下降($P < 0.05$), TBA水平逐渐升高($P < 0.05$), 且观察组变化更显著(均 $P < 0.05$, 表3)。

2.4 血脂水平

术前, 两组血清TC、TG、LDL、HDL水平比较差异均无统计学意义(均 $P > 0.05$); 术后7 d、6个月, 两组血清TC、TG、LDL水平逐渐降低($P < 0.05$), HDL水平逐渐升高($P < 0.05$), 且观察组变化更显著(均 $P < 0.05$, 表4)。

2.5 复发情况

术后6个月观察组结石复发率与对照组相比差异无统计学意义($P > 0.05$); 随访至术后12个月, 观察组有1例失访, 对照组有2例失访, 两组结石复发率比较差异有统计学意义($P < 0.05$, 表5)。

2.6 不良反应

两组用药期间均未发生严重不良反应。观察组有2例恶心、1例腹泻, 对照组仅有1例恶心, 两组不良反应发生率比较差异无统计学意义(10.00% vs 3.33%, $P > 0.05$)。

表1 两组一般资料比较($n=30$)

Table 1 Comparison of general data between the 2 groups ($n=30$)

组别	性别(男/女)/例	年龄/岁	病程/年	结石数量
观察组	17/13	52.39 ± 6.27	4.37 ± 1.05	1.35 ± 0.23
对照组	15/15	53.01 ± 6.50	4.32 ± 1.13	1.40 ± 0.25
χ^2/t	0.268	0.376	0.178	0.806
P	0.605	0.708	0.860	0.423

表2 两组术前、术后中医症状积分比较(n=30)

Table 2 Comparison of pre- and post-operative traditional Chinese medicine symptom score between the 2 groups (n=30)

组别	中医症状积分		
	术前	术后7 d	术后6个月
观察组	15.85 ± 3.49	8.22 ± 1.76*	2.43 ± 0.55*
对照组	15.02 ± 3.55	10.59 ± 1.80*	4.67 ± 0.64*
t	0.913	5.156	14.539
P	0.365	<0.001	<0.001

与术前相比, *P<0.05。

Compared with preoperative, *P<0.05.

表3 两组术前、术后胆汁成分水平比较(n=30)

Table 3 Comparison of pre- and post-operative levels of bile composition between the 2 groups (n=30)

组别	时间	TC/(mmol·L ⁻¹)	TBIL/(μmol·L ⁻¹)	TBA/(μmol·L ⁻¹)
观察组	术前	3.56 ± 1.07	593.10 ± 120.26	605.27 ± 87.50
	术后3 d	2.38 ± 0.74* [#]	249.57 ± 60.74* [#]	839.62 ± 97.81* [#]
	术后7 d	1.26 ± 0.38* [#]	145.28 ± 29.15* [#]	1 650.28 ± 110.52* [#]
对照组	术前	3.62 ± 1.05	590.50 ± 116.84	611.03 ± 85.74
	术后3 d	2.79 ± 0.81*	326.13 ± 65.32*	754.35 ± 95.26*
	术后7 d	1.64 ± 0.45*	210.57 ± 31.23*	1 249.69 ± 100.70*

与术前相比, *P<0.05; 与对照组相比, [#]P<0.05。

Compared with preoperative, *P<0.05; Compared with the control group, [#]P<0.05.

表4 两组术前、术后血脂水平比较(n=30)

Table 4 Comparison of pre- and post-operative levels of blood lipid between the 2 groups (n=30)

组别	时间	TC/(mmol·L ⁻¹)	TG/(mmol·L ⁻¹)	LDL/(mmol·L ⁻¹)	HDL/(mmol·L ⁻¹)
观察组	术前	7.78 ± 1.23	2.25 ± 0.67	3.59 ± 0.97	1.09 ± 0.32
	术后7 d	6.01 ± 1.09* [#]	1.56 ± 0.55* [#]	2.75 ± 0.63* [#]	1.52 ± 0.45* [#]
	术后6个月	5.12 ± 0.85* [#]	1.13 ± 0.36* [#]	2.14 ± 0.52* [#]	1.83 ± 0.52* [#]
对照组	术前	7.85 ± 1.17	2.28 ± 0.65*	3.57 ± 0.95	1.06 ± 0.34
	术后7 d	6.64 ± 1.12*	1.97 ± 0.50*	3.10 ± 0.68*	1.28 ± 0.43*
	术后6个月	5.63 ± 0.92*	1.68 ± 0.39 ^a	2.76 ± 0.62*	1.55 ± 0.48*

与术前相比, *P<0.05; 与对照组相比, [#]P<0.05。

Compared with preoperative, *P<0.05; Compared with the control group, [#]P<0.05.

表5 两组术后结石复发率比较(n=30)

Table 5 Comparison of postoperative stone recurrence rates between the 2 groups (n=30)

组别	术后6个月*/[例(%)]		术后12个月/[例(%)]	
	复发	未复发	复发	未复发
观察组	1 (3.33)	29 (96.67)	2 (6.90)	27 (93.10)
对照组	2 (6.67)	28 (93.33)	8 (28.57)	20 (71.43)
χ ²	—		4.626	
P	1.000		0.031	

*Fisher精确概率法。

*Fisher exact probability method.

3 讨论

胆总管结石的主要临床表现为胁痛, 并伴有腹胀、恶心、食欲不振等, 在中医学中应归于“胁痛”“黄疸”“胆胀”等范畴。关于该病的记载最早出现在《内经》中, 如《素问·热论篇》谓“三日少阳受之, 少阳主胆, 其脉循胁络于耳, 故胸胁痛而耳聋”, 又如《灵枢·五邪》书“邪在肝, 则两胁中痛”^[5]。后世医学家关于“胁痛”的论著均是以《内经》为基础, 并且一致认为该病的致病原因为肝郁气滞、血瘀阻络、肝胆湿热, 应以疏肝理气、活血化瘀、清热利湿论治。本研究所用的利胆排石汤是在经典中药方剂“柴胡疏肝散”基础上加减拟定的, 全方具有疏肝利胆、活血化瘀、清热排石的功效。巩阳等^[6]以“柴胡疏肝散”为基础药方自拟化石利胆汤, 发现该汤剂能够抑制ERCP术后患者结石的形成, 可有效预防结石复发。

本研究结果显示: 术后7 d和6个月, 观察组中医症状积分显著低于对照组。这表明利胆排石汤可进一步改善患者临床症状。深入分析发现: 利胆排石汤中的茵陈、金钱草、海金沙、鸡内金等具有清热、通淋的作用, 可有效促进排石^[7]; 威灵仙具有通经止痛、祛风除湿的功效^[8]; 白芍、赤芍、黄芩等具有疏肝解郁、补气的功效^[9], 全方可对症改善患者胁痛、腹胀等症状。

专家认为结石形成的常见原因有3种: 一是胆汁成分改变; 二是胆管狭窄或功能发生障碍, 导致胆汁淤积, 排出量减少; 三是胆道细菌感染^[10]。胆汁成分改变是结石形成的病理基础, 其中胆固醇及胆红素过饱和是形成结石的必要条件, 胆汁酸为胆固醇的代谢产物, 胆汁酸水平减少可导致游离胆红素、钙离子浓度增加, 并促进结石形成^[11]。本研究结果显示: 利胆排石汤与熊去氧胆酸联用可减少患者胆汁中TC、TBIL的含量, 增加TBA的含量, 说明利胆排石汤可通过改变胆汁成分来降低结石形成风险。熊去氧胆酸是胆汁酸成分之一, 具有促进胆汁酸分泌及胆固醇溶解的作用, 是目前临床预防ERCP术后结石复发的常用药^[12]。柴胡自古以来就是保肝的良药, 现代动物研究^[13]表明其具有降低胆固醇的作用。此外, 郁金、茵陈、海金沙等也均具有降脂、保肝的作用^[14-15]。因此, 中西医联合用药可内外兼治, 进一步增强药效。既往研究^[16]显示: 脂质代谢异常可导致胆汁酸“肝肠循环”障碍, 也是诱发结石的重要原因之一。本研究的观察组血清TC、

TG、LDL水平显著低于对照组, HDL水平显著高于对照组, 说明利胆排石汤可改善患者脂质代谢, 这与郁金、茵陈、海金沙等的降脂作用密切相关。

本研究用药的最终目的是预防ERCP术后结石复发, 通过12个月的随访发现: 两组术后6个月结石复发率差异无统计学意义, 术后12个月观察组结石复发率显著低于对照组, 证实利胆排石汤能够有效预防结石复发。这一结果与田金沙等^[17]的研究结果趋势一致: 服用加减化石利胆汤组3年结石复发率为6.30%, 未服用组为11.00%, 差异有统计学意义。用药期间, 两组不良反应发生率比较差异无统计学意义, 说明服用利胆排石汤不会增加药物的不良反应, 具有较高的安全性。

综上所述, 利胆排石汤与熊去氧胆酸联合用药可有效降低患者ERCP术后的结石复发率, 其作用机制可能与改变胆汁成分、降低血脂水平有关。本研究尚存不足之处, 如样本量少、随访时间短、观察指标少等, 需要进一步加以证实。

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