

乌菝莓膏治疗高位复杂性肛瘘术后创面的临床观察^Δ

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摘要 目的:观察乌菝莓膏治疗高位复杂性肛瘘术后创面的临床疗效及安全性。方法:选取拟行高位复杂性肛瘘患者72例,按随机数字表法分为对照组和观察组,各36例。两组患者均行高位复杂性肛瘘术。对照组患者术后清洗创面,给予凡士林油纱条外敷创面,每天1次;观察组患者术后清洗创面,给予乌菝莓膏外敷创面,再敷凡士林油纱条,每天1次。两组患者均用药至创面愈合为止。观察两组患者治疗后临床疗效、创面愈合时间、创面分泌物pH值、创面分泌物量(以浸透纱布总数计)和疼痛程度[采用视觉模拟(VAS)评分法]、创面二次感染发生率及不良反应发生情况。结果:观察组患者治疗后治愈率和创面分泌物pH值均显著高于对照组,创面愈合时间、创面分泌物浸透纱布总数、VAS评分和创面二次感染发生率均显著低于或短于对照组,差异均有统计学意义($P<0.05$)。两者患者均未见明显不良反应发生。结论:乌菝莓膏治疗高位复杂性肛瘘术后创面疗效较好,并能改善创面微环境,降低复发率,且安全性较好。

关键词 高位复杂性肛瘘;乌菝莓膏;复发率;视觉模拟评分

Clinical Observation of *Cayratia japonica* Cream in the Treatment of Wound after High Complex Anal Fistula Surgery

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ABSTRACT OBJECTIVE: To observe clinical efficacy and safety of *Cayratia japonica* cream in the treatment of wound after high complex anal fistula surgery. METHODS: 72 patients with high complex anal fistula were selected and divided into control group and observation group according to random number table, with 36 cases in each group. Both groups received high complex anal fistula surgery. Control group was given vaseline gauze for wound dressing, once a day, after cleaning surgery wound; observation group applied *C. japonica* cream and then was given vaseline gauze for wound dressing, once a day, after cleaning surgery wound. Both groups was given medicine until wound healing. Clinical efficacy, healing time, pH value of wound secretion, the rate of pterygium, the amount of wound secretion (by total amount of soaked gauze), pain degree (by VAS score) the incidence of wound secondary infection and the occurrence of ADR were observed in 2 groups after treatment. RESULTS: The cure rate pH value of wound secretion (by total amount of soaked gauze), VAS score and in observation group after treatment were significantly lower or shorter than in control group, with statistical significance ($P<0.05$). There were no obvious adverse reactions in 2 groups. CONCLUSIONS: *C. japonica* cream can effectively reduce recurrence rate after high complex anal fistula surgery and improve wound microenvironment with good safety.

KEYWORDS High complex anal fistula; *Cayratia japonica* cream; Recurrence rate; VAS

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高位复杂性肛瘘为反复发作的肛周感染、破溃流脓,且经久不愈,在其他国家被称为“良性的癌症”,术后复发率较高^[1]。乌莓膏具有清热解毒、消肿散结的功效,药少力专,制作简便,专治肛周感染性疾病,可用于肛周脓肿未成熟期至肛瘘术后创面恢复的各个阶段^[2]。本研究观察了乌莓膏治疗高位复杂性肛瘘术后创面的临床疗效及安全性,现报道如下。

1 资料与方法

1.1 纳入与排除标准

纳入标准:(1)符合国家中医药管理局发布的《中医病证诊断疗效标准》^[3]中高位复杂性肛瘘的诊断标准者;(2)年龄18~75岁。排除标准:(1)肠镜检查肿瘤、炎性肠病等器质性病变者;(2)合并糖尿病、营养不良、结核等基础疾病者;(3)既往有肛瘘手术史者。

1.2 研究对象

选取2015年1月—2015年12月我院收治的拟行高位复杂性肛瘘术患者72例,按随机数字表法分为观察组和对照组,各36例。两组患者一般资料比较,差异无统计学意义($P>0.05$),具有可比性,详见表1。本研究方案经医院医学伦理委员会批准,患者知情同意并签署知情同意书。

表1 两组患者一般资料比较($\bar{x}\pm s$)

Tab 1 Comparison of general information of patients between 2 groups($\bar{x}\pm s$)

组别	n	性别,例		年龄,岁	病程,年
		男	女		
观察组	36	20	16	40.8±10.1	3.6±2.1
对照组	36	28	8	38.2±13.5	3.2±2.4
$t\chi^2$		5.156		1.225	1.548
P		0.151		0.585	0.292

1.3 治疗方法

对照组患者术后对创面进行常规消毒,擦尽脓性分泌物及坏死组织,外敷凡士林油纱条,再以敷料固定,每天1次。观察组患者术后对创面进行常规消毒,擦尽脓性分泌物及坏死组织,给予乌莓膏(南京市中医院,批准文号:苏药制字Z04000790)外敷创面,再敷凡士林油纱条,每天1次。两组患者均用药至创面愈合为止。

1.4 观察指标

(1)术后复查彩色三维腔内B超以确定治愈情况。(2)观察两组患者创面愈合时间、分泌物pH值、分泌物量(以浸透纱布总数计)及疼痛程度[采用视觉模拟(VAS)评分法]。(3)观察两组患者二次感染和不良反应发生情况。

1.5 统计学方法

采用SPSS 17.0软件对数据进行统计分析。计量资料以 $\bar{x}\pm s$ 表示,采用t检验;计数资料以率表示,采用 χ^2 检验。 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 两组患者临床疗效比较

观察组患者治愈率明显高于对照组,差异有统计学意义($P<0.05$)。两组患者临床疗效比较见表2。

表2 两组患者临床疗效比较

Tab 2 Comparison of clinical efficacies between 2 groups

组别	n	未愈,例	治愈,例	治愈率,%
观察组	36	3	33	91.67*
对照组	36	12	24	66.67

注:与对照组比较,* $P<0.05$

Note: vs. control group, * $P<0.05$

2.2 两组患者创面愈合指标和疼痛程度比较

观察组患者创面愈合时间、分泌物浸透纱布总数、VAS评分均显著少于或短于对照组,分泌物pH值显著高于对照组,差异均有统计学意义($P<0.05$)。两组患者创面愈合指标和疼痛程度比较见表3。

表3 两组患者创面愈合指标和疼痛程度比较($\bar{x}\pm s$)

Tab 3 Comparison of wound healing index and pain degree between 2 groups

组别	n	愈合时间,d	分泌物pH值	分泌物浸透纱布总数,个	VAS评分,分
观察组	36	36.3±10.1*	8.4±0.6*	16.8±2.7*	2.8±2.0*
对照组	36	52.9±15.4	6.0±0.9	29.4±2.9	7.4±2.9

注:与对照组比较,* $P<0.05$

Note: vs. control group, * $P<0.05$

2.3 两组患者创面二次感染发生率比较

观察组3例患者出现创面二次感染,对照组12例患者出现创面二次感染,观察组患者二次感染发生率(8.33%)显著低于对照组(33.33%),差异有统计学意义($P<0.05$)。

2.4 不良反应

两组患者均未见明显不良反应发生。

3 讨论

高位复杂性肛瘘术后残留的管壁组织有两种转归^[4]:一是逐渐机化,不再产生临床症状;二是病菌感染,产生炎症反应。改善高位复杂性肛瘘术后创面微环境无疑对其转归有益处^[5]。首先,创面肉本身是伤口愈合过程中不良状况的表现,会造成创面引流不畅,进而形成慢性伤口或窦道,导致术后复发。乌莓膏具有明显杀菌抑菌效应,能显著消除肛门炎症性组织^[6-7]。乌莓膏是中华中医药学会肛肠分会创始人丁泽民老中医研制的纯中药外用制剂,具有清热解毒、消肿散结的功效^[8]。均对本临床研究提供理论支持。

本研究显示,乌莓膏能显著降低创面肉的发生率,从而降低高位复杂性肛瘘术后创面复发率。其次,创面分泌物pH值是反映创面微环境的另一项指标。有研究表明,细菌感染、炎症反应能导致肛瘘术后创面分泌物pH值降低^[9]。本研究显示乌莓膏能显著提高创面分泌物pH值,提示乌莓膏可能通过控制创面细菌感和炎症反应来提高高位复杂性肛瘘术后创面疗效。再次,长期临床观察显示,创面分泌物量的多少与术后复发率的相关性较大^[10]:一方面,分泌物多可能存在未切除干净的支道;另一方面,创面分泌物增多可能和创面细菌感染、炎症反应增强有关。本研究显示,观察组的分泌物浸透纱布总数显著少于对照组,表明乌莓膏能显著减少创面分泌物量,其可能通过清热解毒(抑制创面细菌感和炎症反应)、消肿散结(作用于未切除干净的支道)功效从而降低高位复杂性肛瘘术后复发率,提高临床疗效。

本研究结果还显示,观察组患者VAS评分以及治愈率均明显优于对照组,差异有统计学意义($P<0.05$)。说明乌莓膏对于高位复杂性肛瘘术后感染的治疗有效,并且可以有效降低术后疼痛指数。观察组患者的创面二次感染明显少于对照组,差异有统计学意义($P<0.05$)。两组患者均未见明显不良反应发生,说明乌莓膏是一种安全有效的药物。

综上所述,乌莓膏能有效提高高位复杂性肛瘘术后治愈率,降低复发率,并能改善创面微环境,缓解疼痛,且安全性较好。但本研究样本量较小,仍有待扩大样本继续探讨。

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益肺清化颗粒联合化疗用于中晚期非小细胞肺癌的临床观察

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摘要 目的:观察益肺清化颗粒联合化疗用于中晚期非小细胞肺癌的临床疗效及安全性。方法:选取中晚期非小细胞肺癌患者100例,按随机数字表法分为对照组和观察组,各50例。对照组患者给予长春瑞滨+顺铂或吉西他滨+顺铂化疗;观察组患者在对照组基础上加用益肺清化颗粒20g溶于温水200ml冲服,tid。观察两组患者治疗前后中医证候评分、卡氏(KPS)评分、生存质量量表(SF-36)评分评估患者生存质量,比较两组患者肿瘤坏死因子 α (TNF- α)和可溶性白细胞介素-2受体(sIL-2R)水平,并比较两组患者临床疗效及不良反应发生情况。结果:观察组患者临床总有效率为94.0%,显著高于对照组的78.0%,差异有统计学意义($P<0.05$)。治疗前,两组患者中医证候评分、KPS评分、SF-36量表评分及TNF- α 和sIL-2R水平比较,差异均无统计学意义($P>0.05$)。治疗后,两组患者中医证候积分、KPS评分、SF-36量表评分及TNF- α 水平均显著升高,且观察组显著高于对照组;而sIL-2R水平显著降低,且观察组显著低于对照组,差异均有统计学意义($P<0.05$)。观察组患者恶心呕吐、骨髓抑制、脱发、腹泻的发生率显著低于对照组,差异有统计学意义($P<0.05$)。结论:益肺清化颗粒联合化疗治疗中晚期非小细胞肺癌效果显著,能有效改善患者生存质量,且安全性较好。

关键词 益肺清化颗粒;化疗;非小细胞肺癌;中医证候;生存质量;临床疗效

Clinical Observation of Yifei Qinghua Granules Combined with Chemotherapy in the Treatment of Middle-advanced Non-small Cell Lung Cancer

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ABSTRACT OBJECTIVE: To observe the clinical efficacy and safety of Yifei qinghua granules combined with chemotherapy in the treatment of middle-advanced non-small cell lung cancer (NSCLC). METHODS: 100 patients with middle-advanced NSCLC were selected and divided into control group and observation group according to random number table, with 50 cases in each group. Control group received vinorelbine+cisplatin or gemcitabine+cisplatin chemotherapy; observation group was additionally given Yifei qinghua granules 20 g dissolved in 200 ml warm water orally, tid, on the basis of control group. TCM syndrome integral were observed in 2 group before and after treatment, KPS score and SF-36 scale were used to evaluate the quality of life. The levels of TNF- α and sIL-2R clinical efficacies and the occurrence of ADR were compared between 2 groups. RESULTS: Total effective rate of observation group was 94.0%, which was significantly higher than 78.0% of control group, with statistical significance ($P<0.05$). There was no statistical significance in TCM syndrome score, KPS score, SF-36 scale, the levels of TNF- α and sIL-2R of observation group before and after treatment ($P>0.05$). After treatment, TCM syndrome score, KPS score and SF-36 scale, the levels of TNF- α in 2 groups were increased significantly, and the observation group was significantly higher than the control group; the level of sIL-2R in 2 groups were decreased significantly, and the observation group was significantly lower than the control group, with statistical significance ($P<0.05$). The incidence of nausea and vomiting, myelosuppression, alopecia in observation group were significantly lower than in control group, with statistical significance ($P<0.05$). CONCLUSIONS: Yifei qinghua granules combined with chemotherapy is effective in the treatment of middle-advanced NSCLC, can promote the quality of life with good safety.

KEYWORDS Yifei qinghua granule; Chemotherapy; Non-small cell lung cancer; TCM syndrome; Quality of life; Clinical efficacy

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