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骨康胶囊联合玻璃酸钠注射液治疗骨性关节炎的疗效及对炎症反应的影响*

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摘要 目的:探讨骨康胶囊联合玻璃酸钠注射液治疗骨性关节炎的疗效,及其对机体炎性应激反应的影响。**方法:**将 110 例骨性关节炎患者依据随机数据表法分为对照组和观察组,每组患者 55 例,给予对照组患者玻璃酸钠注射液治疗,给予观察组患者骨康胶囊联合玻璃酸钠注射液治疗,比较治疗后的总有效率,临床症状评分、炎症因子及不良反应发生率。**结果:**观察组治疗总有效率为 90.91%,显著高于对照组 70.91%,差异有统计学意义(x^2=7.308,P<0.05);治疗前两组间 Lysholm 评分、VAS 评分、TNF-α 及 CRP 水平对比差异无显著性(P>0.05);观察组治疗后 Lysholm 评分显著高于对照组,VAS 评分、TNF-α 及 CRP 水平显著低于对照组,差异有统计学意义(P<0.05);药物不良反应发生率比较,差异无统计学意义(x^2=0.121,P=0.728)。**结论:**骨康胶囊与玻璃酸钠注射液联合治疗方案,可有效提高骨性关节炎的临床治疗效果,改善患者临床症状,降低炎性应激反应,安全性较高,具有一定的临床价值。

关键词:骨性关节炎;骨康胶囊;玻璃酸钠注射液;临床疗效;炎症反应

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Effect of Gukang Capsule combined with Sodium Hyaluronate Injection in the Treatment of Osteoarthritis and Its Effect on Inflammatory Reaction*

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ABSTRACT Objective: To investigate the effect of Gukang capsule combined with Sodium Hyaluronate Injection treatment of osteoarthritis, and its influence on inflammatory reaction stress. **Methods:** A total of 110 cases of osteoarthritis patients were selected as the research object, based on the random data table they were divided into control group and observation group, 55 cases in each group, patients in the control group were treated with Sodium Hyaluronate Injection treatment, observation group of patients were treated with Gukang capsule combined with Sodium Hyaluronate Injection treatment, the total effective rate, the clinical symptom score, the inflammatory factor and the incidence of adverse reaction after treatment were compared. **Results:** The total effective rate of treatment in the observation group was 90.91%, which was significantly higher than that of the control group (70.91%), and the difference was statistically significant (x^2=7.308, P<0.05). There was no significant difference in Lysholm score, VAS score, TNF-α and CRP level between the two groups before treatment (P>0.05). The Lysholm score of the observation group was significantly higher than that of the control group. The VAS score, TNF-α and CRP were significantly lower than those in the control group, and the difference was statistically significant (P<0.05). There was no significant difference in the incidence of adverse drug reactions between the two groups (x^2=0.121, P=0.728). **Conclusion:** Gukang capsule combined with Sodium Hyaluronate Injection, can effectively improve the osteoarthritis of clinical therapeutic effect, improve the patients clinical symptoms, reducing the inflammatory response to stress, high safety, which has a certain clinical value.

Key words: Osteoarthritis; Gukang capsule; Sodium Hyaluronate Injection; Clinical efficacy; Inflammatory reaction

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前言

骨性关节炎是临床上骨科较为常见的一种慢性、渐进性及退行性关节病变疾病,该病以中老年人群患者为主,研究指出在 60 岁以上老年患者中近 35%患者在影像学检查中呈现骨关节炎改变[1,2]。该病临床表现以慢性关节疼痛、僵硬、肿胀伴活动受限为主,严重时导致行动障碍,甚至出现畸形[3,4]。西医治疗以非甾体类消炎镇痛药、阿片类、氨基葡萄糖抗炎药、双醋瑞因、透明质酸及肾上腺皮质激素为主[5]。玻璃酸钠补充治疗可有效改善患者临床体征,提高患者生活质量,在适应症的临床治疗中应用广泛[6,7]。近年来研究发现,中药内服在骨性关节炎的治疗上效果显著,骨康胶囊是一种复方制剂,已逐渐应用于骨折

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和骨性关节炎临床治疗[8]。本研究旨在探讨骨康胶囊联合玻璃酸钠注射液在骨性关节炎治疗中的疗效,现将研究内容报告如下。

1 资料与方法

1.1 一般资料

选取 2016 年 5 月至 2017 年 5 月青海省人民医院收治的骨性关节炎患者 110 例作为研究对象,本研究内容及流程均严格符合医院伦理委员会标准,并通过伦理委员会许可后展开。所有患者均符合《中华医学会风湿病学分会·骨关节炎诊断及治疗指南》[9]中相关标准,患者对研究内容均知情同意,签署知情同意书且临床资料齐全;同时排除:① 伴有严重肝肾功能异常者、精神疾病、急慢性感染性疾病及自身免疫性疾病者;② 类风湿性关节炎、类强制性脊柱炎及感染性关节炎等;③ 治疗 2 周前有接受激素及其他镇痛类药物治疗者;④ 依从性差不能按照疗程完成治疗者;⑤ 孕妇及妊娠妇女;⑥ 关节严重畸形,腿部静脉和淋巴回流障碍者,膝关节感染者;⑦ 对研究所选药物过敏者。依据随机数据表法将 110 例患者平均分为对照组和观察组,均 55 例,对照组中男 30 例,女 25 例,患者年龄为 52 岁~78 岁,平均年龄为(68.42± 6.51)岁,病程为 1~8 年,平均病程为(4.73± 2.18)年;观察组患者中男性 28 例,女性 27 例,患者年龄为 51 岁 ~79 岁,平均年龄为(68.69± 6.74)岁,病程为 1~8 年,平均病程为(4.88± 2.25)年。两组患者男女比例,平均年龄及病程等资料比较,均无明显差异(P>0.05)。

1.2 治疗方法

参照《骨关节炎诊治指南》[10],对照组患者给予玻璃酸钠注射液(上海景峰制药有限公司生产,国药准字 H20000643,产品规格 2.5 mL:25 mg/ 支)膝关节腔内注射治疗,每次 25 mg,每周 1 次,注射 5 次。观察组患者给予骨康胶囊联合玻璃酸钠注射液治疗,玻璃酸钠使用方法同对照组,骨康胶囊(生产厂家贵州维康子帆药业股份有限公司,产品批号 20160714,产品规格 0.4 g× 48 粒)口服治疗,每次 3~4 片,每日 3 次,治疗 2 个月。

1.3 疗效评估

1.3.1 临床效果评价 临床效果评价分为显效、有效和无效三个等级[11],显效定义为:治疗后患者关节疼痛、压痛感、肿胀等临床症状基本消失,实验室检查结果恢复正常;有效:治疗后患者临床症状明显缓解,实验室检查结果明显改善;无效:治疗后患者临床症状无变化甚至加重。总有效例数为显效和有效例数之和。

1.3.2 临床症状评分 采用 Lysholm 膝关节功能评分量表对膝关节功能进行评价,包括跛行、肿胀、支持、上楼、下蹲、绞锁、疼痛及不稳定等内容,评分范围为 0 分 ~100 分,分数越高表示膝关节功能越好;采用视觉模拟评分法(visual analogue scales,VAS)评估关节疼痛程度,0 分代表无痛、10 分代表剧痛[12]。

1.3.3 指标检测 分别于治疗前及治疗 2 个月后抽取两组患者清晨空腹外周静脉血 3 ml,离心 10 min(3000 r/min),取血清,检测炎症因子、肿瘤坏死因子 -α(tumor necrosis factor-α,TNF-α)和超敏 C 反应蛋白(hypersensitive3 C-reactive protein,hs-CRP)水平,方法为 ELISA,检测试剂盒购自上海酶联生物有限公司,操作流程均严格按照检测说明书进行。

1.3.4 不良反应 观察并比较治疗过程中药物不良反应。

1.4 统计学处理

采用 SPSS17.0 统计学软件对研究数据进行处理分析,计数资料表示方法为例数(%),比较方法为卡方检验,临床症状评分、炎症因子等指标经正态性验证后均符合正态分布,表示方法为,组内治疗前后比较采用配对 t 检验,两组间样本均数比较采用独立样本 t 检验,P<0.05 代表差异有统计学意义。

2 结果

2.1 两组疗效对比

对照组治疗后 55 例患者中显效 24 例,无效 16 例,所占比例分别为 43.64%和 29.09%,治疗总有效率为 70.91%,观察组中显效患者 33 例(60.00%),无效患者 5 例(9.09%),总有效率为 90.91%,观察组总有效率明显优于对照组(x^2=7.308,P<0.05)(表 1)。

表 1 疗效比较[n(%)]

Table 1 Comparison of curative effect[n(%)]

Group	Cases	Excellence	Effective	Invalid	Total effective rate
Control group	55	24(43.64)	15(27.27)	16(29.09)	39(70.91)
Observation group	55	33(60.00)	17(30.91)	5(9.09)	50(90.91)
x^2 value/P value					7.308/0.026

2.2 临床症状评分比较

治疗前两组间 Lysholm 评分及 VAS 评分对比无较大差异(P>0.05);组内水平比较,治疗后两组 Lysholm 评分均较治疗前水平显著升高,VAS 评分显著降低,对比差异均有显著性(P<0.05);组间比较,观察组治疗后 Lysholm 评分(78.19± 13.48)分,显著高于对照组(65.16± 13.55)分,VAS 评分(2.23± 0.46)分显著低于对照组(3.82± 0.79)分,差异有统计学意义(P<0.05)(表 2)。

2.3 炎症因子水平比较

两组治疗前后炎症因子水平检测结果如表 3 所示。治疗前两组间 TNF-α 及 CRP 水平比较差异不显著(P>0.05);治疗后两组 TNF-α 及 CRP 水平较治疗前均明显降低(P<0.05),治疗后观察组 TNF-α 及 CRP 水平为(17.49± 4.18)ng/L,(4.93± 1.25)mg/L,显著低于治疗后对照组水平 [(26.52± 3.83)ng/L,(6.86± 1.55)mg/L],差异有统计学意义(P<0.05)(表 3)。

2.4 不良反应比较

治疗过程中,对照组患者中出现眩晕及腹部不适患者各 2 例,潮热患者 1 例,总不良反应率为 9.09%,观察组中腹部不适患者 2 例,眩晕及潮热各 1 例,不良反应率为 7.27%,两组不良反应率比较,差异无统计学意义(x^2=0.121,P=0.728)。

表 2 临床症状评分比较($\bar{x}\pm s$,分)

Table 2 Comparison of clinical symptom scores($\bar{x}\pm s$, scores)

Group	Cases	Detection time	Lysholm score	VAS score
Control group	55	Before treatment	53.54± 10.93	7.74± 1.61
		After treatment	65.16± 13.55	3.82± 0.79
t1 value/P value			4.950/0.000	16.210/0.000
Observation group	55	Before treatment	54.16± 10.99	7.68± 1.56
		After treatment	78.19± 13.48	2.23± 0.46
t2 value/P value			10.247/0.000	24.851/0.000
t3 value/P value			5.056/0.000	12.899/0.000

注:t1 值和 t2 值分别表示对照组与观察组同组内治疗前后水平比较;t3 值表示治疗后对照组与观察组组间水平比较。

Note: t1 value and t2 value respectively represent the level of comparison between the control group and the observation group before and after treatment; t3 value indicates the comparison between the control group and the observation group.

表 3 炎症因子水平比较($\bar{x}\pm s$)

Table 3 Comparison of inflammatory factor levels

Group	Cases	Detection time	TNF-α(ng/L)	CRP(mg/L)
Control group	55	Before treatment	36.45± 6.87	10.07± 1.94
		After treatment	26.52± 3.83	6.86± 1.55
t1 value/P value			9.363/0.000	9.587/0.000
Observation group	55	Before treatment	36.26± 6.95	10.05± 1.98
		After treatment	17.49± 4.18	4.93± 1.25
t2 value/P value			17.164/0.000	16.216/0.000
t3 value/P value			11.812/0.000	7.188/0.000

注:t1 值和 t2 值分别表示对照组与观察组同组内治疗前后水平比较;t3 值表示治疗后对照组与观察组组间水平比较。

Note: t1 value and t2 value respectively represent the level of comparison between the control group and the observation group before and after treatment; t3 value indicates the comparison between the control group and the observation group.

3 讨论

骨性关节炎疾病作为一种衰老性疾病,是中老年患者致残的主要原因之一,严重威胁中老年人心理及身体健康[13]。该病具有明显的性别、年龄及地域分布特点,在发展中国家较为高发,而且发病原因较为复杂,目前普遍认为其发生与关节炎症、软骨退变、遗传及环境因素等有关[14,15]。多项研究证实炎症在骨性关节炎发病过程中起着重要作用,因此抑制炎症反应是临床治疗骨性关节炎的有效措施[16,17]。非甾体类消炎镇痛药是当前治疗骨性关节炎的首选,但由于服用剂量较大,服用时间较长,往往会导致患者肾功能、中枢神经系统及胃肠道黏膜损伤,药物不良反应较多[18,19]。近年来,局部注射治疗及口服氨基葡萄糖治疗的出现增加了骨性关节炎治疗的选择性,但其整体治疗效果仍不尽满意[20]。

玻璃酸钠注射液是临床治疗骨性关节炎的重要药物,是从鸡冠中提取或乳酸菌发酵而来,玻璃酸钠局部注射目的在于润滑关节腔,覆盖于软骨表面以减轻关节面摩擦,还可渗入变性软骨内,抑制软骨变性及变性软骨代谢,此外,相关研究指出,该药剂还可抑制滑膜中炎性介质的释放及渗透,促进渗出液吸收,进而缓解疼痛[21-23]。祖国医学认为,骨性关节炎的根本内因是肾精亏虚,肾虚血瘀贯穿整个病理过程,其治疗应以补肾活血、祛风除湿及温经散寒为主[24]。骨康胶囊是一种中药复方制剂,主要由补骨脂、续断、芭蕉根、三七和酢浆草等组成,其中补骨脂、续断具有补肝肾、强筋骨等温肾助阳之功;三七可活血化瘀,消肿止痛;芭蕉根和酢浆草具清热解毒散瘀之功,全方具有滋补肝肾、强筋壮骨、通络止痛之功,可促进骨折部位消肿散瘀、减轻疼痛,促进伤口愈合,在骨伤治疗上效果显著,不良反应少[25,26]。相关研究指出,骨康胶囊辅助治疗可有效改善桡骨远端骨折患者临床症状,降低术后疼痛及肿胀,更有利于腕关节功能恢复以及骨折愈合,缩短病程[27]。尽管骨康胶囊在骨科治疗应用较广,但关于其与玻璃酸钠注射液对骨性关节炎的报道相对较少,本研究旨在探讨两药联合治疗骨性关节炎的疗效。

本研究结果中,治疗后对照组与观察组总有效率分别为 70.91%和 90.91%,与单纯玻璃酸钠注射液相比,联合骨康胶囊治疗后治疗的总有效率显著提高,研究结果揭示,骨康胶囊辅助治疗可有效提高治疗效果,其原因可能为:玻璃酸钠可有效润滑关节软骨,对关节软骨起到一定的保护作用,在此基础上,联合骨康胶囊治疗,可进一步的改善软骨代谢,进而提高治疗效果。而且本研究结果还发现,两组治疗后 Lysholm 评分及 VAS 评分较治疗前均显著改善,但联合骨康胶囊治疗组患者的症状评分改善效果更佳,说明在玻璃酸钠治疗基础上,联合骨康胶囊可进一步改善关节功能,再加骨康胶囊的活血化瘀、清热解毒的功效使得治疗后疼痛明显降低。

骨性关节炎作为一种慢性炎症性疾病,炎症反应是疾病发

生机制之一,骨性关节炎患者普遍存在滑膜炎症状,而且滑膜炎与关节退变的关系已被研究证实[28,29]。研究指出,骨性关节炎发病进程中一直存在单核细胞及炎性介质的释放,而且随着病情严重程度的增加,TNF-α 及 CRP 等炎症因子水平升高愈显著,炎症因子水平与骨性关节炎病情程度呈显著正相关性[30,31]。本研究结果指出,对照组与观察组治疗后 TNF-α 及CRP 水平均显著降低,揭示两种方案均可有效抑制炎性因子的释放,减轻机体炎性应激水平,然而观察组两指标水平下降更为显著,研究结果表明,在玻璃酸钠注射液治疗的基础上联合骨康胶囊可进一步抑制炎症介质的释放,其原因可能为骨康胶囊的药物组成成分中如续断、芭蕉根等均具有明显的抗炎症痛作用,研究结果揭示了玻璃酸钠与骨康胶囊的协同抗炎作用,两药联合方案更有助于病情的控制。此外本研究对两种方案的药物不良反应结果进行了比较,结果表明,与单纯的玻璃酸钠注射液治疗相比,联合骨康胶囊治疗不会产生严重不良反应,安全性较高。

综上所述,玻璃酸钠注射液及其联合骨康胶囊均是治疗骨性关节炎的有效方案,与单纯的玻璃酸钠注射液治疗相比,联合骨康胶囊可有效提高临床总有效率,安全性较高,其疗效改善可能与骨康胶囊可有效改善膝关节功能,降低疼痛,并能够进一步抑制炎症因子的释放,减轻机体炎性应激反应等有关。

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