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温针联合骨疏康胶囊治疗膝关节骨性关节炎的疗效及对炎症因子的影响

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摘要 目的:分析温针联合骨疏康胶囊治疗膝关节骨性关节炎的疗效及对患者白细胞介素-1(IL-1)、肿瘤坏死因子(TNF- α)、基质金属蛋白(MMP-3)水平的影响。方法:以2013年1月至2016年1月新疆巴音郭楞蒙古自治州人民医院中医科收治的90例膝关节骨性关节炎患者为研究对象,并根据就诊顺序分为观察组、对照组A和对照组B,每组30例。观察组采用温针联合骨疏康胶囊治疗,对照组A仅给予温针治疗,对照组B仅给予骨疏康胶囊治疗。观察和比较三组的临床疗效、视觉模拟评分法(VAS)评分、Lysholm膝关节康复量表(LKSS)评分和症状评分及膝关节液中IL-1、TNF- α 、MMP-3水平。结果:观察组的总有效显著高于对照组A和对照组B($P<0.05$),而对照组A和对照组B之间比较差异无统计学意义($P>0.05$)。治疗后,三组的VAS、症状评分、膝关节液中IL-1、TNF- α 、MMP-3水平均较治疗前显著降低,LKSS评分较治疗前显著升高($P<0.05$)。观察组的VAS、症状评分、膝关节液中IL-1、TNF- α 、MMP-3水平低于对照组A和对照组B,LKSS评分高于对照组A和对照组B($P<0.05$),对照组A和对照组B之间比较差异均无统计学意义($P>0.05$)。结论:温针联合骨疏康胶囊治疗膝关节骨性关节炎的疗效较单用温针或骨疏康胶囊更显著,可有效改善患者的临床症状,可能与降低膝关节液中IL-1、TNF- α 、MMP-3水平有关。

关键词: 膝关节骨性关节炎;温针;骨疏康胶囊;疗效;炎症因子

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Clinical Effects of Needling Warming Therapy Combined Gushukang Capsule on Patients with Knee Osteoarthritis and Its Effect on Inflammatory Factors

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ABSTRACT Objective: To investigate the clinical effects of needling warming therapy combined with Gushukang capsule on patients with knee osteoarthritis and its effect on inflammatory factors. **Methods:** 90 cases of patients with knee osteoarthritis in our hospital from January 2013 from January 2016 were divided into observation group, control group A and control group B, 30 cases in each group. Patients in the observation group were treated with needling warming therapy combined traditional Chinese medicine, patients in the control group A were treated only with needling warming therapy, and patients in the control group B were treated only with traditional Chinese medicine. The clinical effects, VAS (visual analogue scale) scores, LKSS (Lysholm knee rehabilitation scale) scores, symptom scores and the levels of IL-1 (interleukin-1), TNF- α (tumor necrosis factor- α), MMP-3 (matrix metalloproteinase-3) of three group were compared. **Results:** The total effective rate of the observation group were significantly higher than that of the control group A and control group B ($P<0.05$), but there was no significant differences between the control group A and control group B ($P>0.05$); After treatment, the VAS scores, symptom scores and the levels of IL-1, TNF- α , MMP-3 of the observation group were significantly lower than before treatment and that of the control group A and control group B ($P<0.05$), and the LKSS scores were significantly higher than before treatment and that of the control group A and control group B ($P<0.05$). **Conclusion:** Needling warming therapy combined with Gushukang capsule had better clinical effect on patients with knee osteoarthritis than needling warming therapy or Gushukang capsule alone, it could effectively improve the clinical symptoms of patients, and reduce the levels of IL-1, TNF- α , MMP-3 in knee joint fluid.

Key words: Knee osteoarthritis; Needling warming therapy; Gushukang capsule; Clinical effect; Inflammatory factor

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前言

膝关节骨性关节炎是临床常见、多发的慢性进行性骨关节疾病,中老年人多发,且女性的发病率高于男性^[1],其病理基础为膝关节软骨发生退行性病变,并继发骨质疏松。临床表现以关节疼痛、肿胀及功能障碍为主,且病情随着年龄的增长而加重^[2]。祖国医学认为膝关节骨性关节炎属“痹症”范畴,发病之本为肝肾亏虚、正虚邪侵和痰浊淤阻。温针是祖国医学的特色技术,疗效独特^[3]。洪昆达^[4]等研究显示温针治疗各种中医证候分型的膝关节骨性关节炎临床疗效显著,可有效降低患者关节滑液中炎症因子的水平。骨疏康胶囊为具有活血壮骨、补肾益气的功效的中药制剂,主治肾虚兼气血不足所致的原发性骨质疏松症^[5]。白正发^[6]等研究证实骨疏康胶囊可协同增强西药治疗膝关节骨性关节炎的临床疗效,降低炎症因子水平,但目前临床中未见温针结合骨疏康胶囊治疗膝关节骨性关节炎的相关报道。因此,本研究拟分析温针联合中药骨疏康胶囊治疗膝关节骨性关节炎的疗效及对患者膝关节液中炎症因子水平的影响,以期临床膝关节骨性关节炎治疗方案的选择提供参考。

1 资料与方法

1.1 一般资料

以2013年1月至2016年1月新疆巴音郭楞蒙古自治州人民医院中医科收治的90例膝关节骨性关节炎患者为研究对象,所有患者西医诊断均符合美国风湿病学会的膝关节骨性关节炎诊断标准^[7],中医诊断符合《中医病症诊断疗效标准》^[8],均知情同意本研究,入组前一个星期未服用任何药物者。排除合并其他类型关节炎患者,排除妊娠及哺乳期妇女、合并心、肝、肾、消化系统及造血系统等严重疾病者。将90例患者根据就诊顺序分为观察组、对照组A和对照组B,每组30例,观察组中男11例,女19例,年龄40-70岁,平均年龄(56.3±8.5)岁,病程5个月-11年,平均病程(75.6±52.3)月,单侧发病16例,双侧发病14例;对照组A中男12例,女18例,年龄40-69岁,平均年龄(55.8±8.9)岁,病程5个月-11年,平均病程(76.6±53.7)月,单侧发病17例,双侧发病13例;对照组B中男11例,女19例,年龄41-69岁,平均年龄(56.8±8.1)岁,病程5个月-11年,平均病程(75.9±51.7)月,单侧发病15例,双侧发病15例。三组的一般资料比较差异无统计学意义(P>0.05),具有可比性。

1.2 治疗方法

观察组采用温针联合骨疏康胶囊治疗:骨疏康胶囊(辽宁康辰药业有限公司,国药准字Z20060270,每粒装0.32g),4粒

/次,3次/日,连用30d;温针:选择内膝眼、外膝眼、鹤顶、血海、梁丘、阳陵泉、足三里、阿是穴中压痛明显的1-3个穴位为主穴;根据中医分型辩证假甲减配穴,肝肾亏虚型加膝阳关,太溪穴,阳虚寒凝加风市、关元、气海,血瘀阻滞型加三阴交,湿热痹阻型加曲池、合谷。患者取仰卧位,局部皮肤消毒,消毒棉球夹持针身进针,进针深度为2-3cm,针刺采用平补平泻手法,针下得气后,2cm的艾段点燃后插入针柄,为防灼伤皮肤,针与艾段之间可垫一硬纸片,每穴温针2壮。温针每次30min,每天1次,10d为一个疗程,疗程之间间隔2d,共治疗3个疗程。

对照组A仅给予温针治疗,治疗方法同观察组。对照组B仅给予骨疏康胶囊治疗,用法用量同观察组。

1.3 观察指标

(1)治疗前及治疗后采集患者膝关节液2mL,采用酶联免疫吸附法测定白细胞介素-1(IL-1)、肿瘤坏死因子(TNF-α)、基质金属蛋白(MMP-3)含量,试剂盒均购自南京建成生物工程研究所。(2)治疗前后采用视觉模拟评分法(VAS)评价患者的膝关节疼痛情况,分值0-10分,分值越高表示疼痛越严重。(3)采用Lysholm膝关节康复量表(LKSS)对患者治疗前后的膝关节活动度进行评分,满分100分,分值越高表示活动度越高。(4)参照《中药新药临床指导原则》^[9]对治疗前后患者的症状进行评分,最高分33分,分值越高表示症状越严重。

1.4 疗效标准

临床控制:关节疼痛等临床症状消失,活动恢复正常,临床症状积分为0-1分;显效:膝关节疼痛等临床症状消失,膝关节活动不受限,临床症状积分减少2/3以上;有效:膝关节疼痛等临床症状基本消失,膝关节活动轻度受限,临床症状积分减少大于1/3;无效:未达到有效标准者^[9]。总有效率=(临床控制例数+显效例数+有效例数)/总例数×100%。

1.5 统计学方法

采用SPSS17.0进行统计分析,临床疗效等计数资料以%表示,采用卡方检验,各炎症因子水平、VAS评分和LKSS评分等计量资料以均值±标准差表示,采用t检验,以P<0.05表示差异有统计学意义。

2 结果

2.1 三组治疗后临床疗效的比较

治疗后,观察组的总有效率为93.33%,对照组A为76.66%,对照组B为63.33%。观察组的总有效显著高于对照组A和对照组B(P<0.05),但对对照组A和B之间差异无统计学意义(P>0.05)。

表1 三组治疗后临床疗效比较[例(%)]

Table 1 Comparison of the clinical effect between three groups after treatment. [n(%)]

Groups	Cases	Clinical control	Excellent	Effective	Invalid	Total effective rate(%)
Observation group	30	15	7	6	2	93.33
Control group A	30	10	8	5	7	76.66°
Control group B	30	8	6	5	11	63.33°

Note: Compared with observation group, ° P<0.05.

2.2 三组治疗前后VAS、LKSS和症状评分的比较

治疗前,三组的VAS、LKSS和症状评分比较差异均无统

计学意义(P<0.05);治疗后,三组B的VAS和症状评分均较治疗前显著降低,LKSS评分较治疗前显著升高(P>0.05),且观察

组的 VAS 和症状评分低于对照组 A 和对照组 B, LKSS 评分高于对照组 A 和对照组 B ($P < 0.05$), 而对照组 A 和对照组 B 之间比较差异均无统计学意义 ($P > 0.05$)。

表 2 三组治疗前后 VAS、LKSS 和症状评分比较 ($\bar{x} \pm s$)

Table 2 Comparison of the VAS, LKSS and symptom scores between three groups before and after treatment ($\bar{x} \pm s$)

Groups		VAS scores	LKSS scores	Symptom scores
Observation group (n=30)	Before treatment	7.51 $\pm$ 0.98	47.22 $\pm$ 7.15	14.92 $\pm$ 6.22
	After treatment	3.87 $\pm$ 0.99 [°]	79.02 $\pm$ 9.22 [°]	6.58 $\pm$ 2.09 [°]
Control group A (n=30)	Before treatment	7.57 $\pm$ 1.02	46.99 $\pm$ 7.33	15.01 $\pm$ 5.29
	After treatment	4.95 $\pm$ 1.03 [°]	66.03 $\pm$ 8.13 [°]	7.39 $\pm$ 2.95 [°]
Control group B (n=30)	Before treatment	7.60 $\pm$ 1.05	47.07 $\pm$ 7.96	15.05 $\pm$ 5.36
	After treatment	5.06 $\pm$ 1.01 [°]	62.02 $\pm$ 8.03 [°]	7.93 $\pm$ 3.07 [°]

Note: Compared with observation group, [°] $P < 0.05$; Compared with before treatment, [°] $P < 0.05$.

2.3 三组治疗前后 IL-1、TNF- α 、MMP-3 水平比较

治疗前, 三组 B 的膝关节液中 IL-1、TNF- α 、MMP-3 水平比较差异均无统计学意义 ($P > 0.05$); 治疗后, 三组的膝关节液中 IL-1、TNF- α 、MMP-3 水平均较治疗前显著降低 ($P < 0.05$), 且观察组的 IL-1、TNF- α 、MMP-3 水平低于对照组 A 和对照组 B ($P < 0.05$)。

表 3 三组治疗前后 IL-1、TNF- α 、MMP-3 水平比较 ($\bar{x} \pm s$)

Table 3 Comparison of the IL-1, TNF- α , MMP-3 levels between three groups before and after treatment ($\bar{x} \pm s$)

Groups		IL-1 ($\mu\text{g/L}$)	TNF- α (pg/mL)	MMP-3 ($\mu\text{g/L}$)
Observation group (n=30)	Before treatment	192.68 $\pm$ 53.38	402.68 $\pm$ 63.18	129.59 $\pm$ 13.76
	After treatment	118.13 $\pm$ 26.65 [°]	326.26 $\pm$ 46.77 [°]	90.32 $\pm$ 7.69 [°]
Control group A (n=30)	Before treatment	193.23 $\pm$ 55.83	405.56 $\pm$ 60.45	125.58 $\pm$ 12.77
	After treatment	135.65 $\pm$ 25.01 [°]	352.32 $\pm$ 43.71 [°]	108.99 $\pm$ 10.89 [°]
Control group B (n=30)	Before treatment	195.55 $\pm$ 57.25	405.69 $\pm$ 62.75	129.06 $\pm$ 12.98
	After treatment	139.01 $\pm$ 29.33 [°]	360.22 $\pm$ 54.51 [°]	113.55 $\pm$ 11.02 [°]

Note: Compared with observation group, [°] $P < 0.05$; Compared with before treatment, [°] $P < 0.05$.

3 讨论

膝关节骨性关节炎是一种无菌性的慢性炎症疾病, 是膝关节的骨质、滑膜、关节囊及其他结构在膝关节发生继发或原发退行性病变后的结构紊乱, 最终演变为膝关节功能障碍的一种退行性疾病^[10]。在膝关节的疾病类型中, 膝关节骨性关节炎的发病率最高, 是导致膝关节疼痛的主要原因之一, 其发病率随着年龄的增长而升高, 我国目前的发病率达 8.3%^[11]。且该病程长、缠绵难治、致残率高, 严重影响患者的运动功能及生活质量^[12]。祖国医学认为膝关节骨性关节炎属 "痹症" 范畴, 膝关节为筋的府邸, 膝关节疼痛均因肝肾虚导致风、寒、湿三邪肾虚而入, 致使气血闭阻、滞留与膝关节^[13]。

温针始见于东汉时张仲景的《伤寒论》, 是将针灸与艾灸相结合的一种独特疗法, 通过针刺相关穴位, 以及艾条的热疗、光疗及药物刺激作用共同促进局部血液循环及新陈代谢, 改善微循环, 最终发挥活血化瘀、通络止痛的功效^[14]。此法治疗范围广泛, 目前临床较多见其单用或与西药、推拿、热敷、中药等联合应用于治疗各类疾病, 如绝经后骨质疏松、腰椎间盘突出、肩周炎、神经损伤等^[15,16]。骨疏康胶囊属于中药第九类新药, 由淫羊藿、熟地黄、丹参、黄芪、骨碎补、黄瓜子、木耳等中药制成, 是在骨疏康颗粒的基础上二次研发而来, 二者药效基本相同, 具有补肾益气、活血壮骨的功效^[6]。现代药理实验证实其可加速成骨

细胞的周期, 从而促进骨细胞增殖^[17]。黄劲柏^[18]等研究显示温针联合骨疏康颗粒治疗肩关节周围炎疗效显著, 可改善患者肩痛症状, 降低免疫球蛋白水平, 调节免疫功能。本研究将温针联合骨疏康胶囊用于治疗膝关节骨性关节炎, 结果显示观察组的总有效显著高于对照组 A 和对照组 B ($P < 0.05$); 观察组的 VAS、症状评分低于对照组 A 和对照组 B, LKSS 评分高于对照组 A 和对照组 B, 提示温针联合骨疏康颗粒用于治疗膝关节骨性关节炎的临床疗效显著, 可有效改善患者的疼痛症状及膝关节的运动功能, 且疗效优于单用温针和单用中药, 原因可能为温针主要促进血液循环及新陈代谢, 而中药骨疏康胶囊主要促进骨细胞增殖, 两种治疗方法协同作用, 可更有效改善膝关节的退行性病的情况。

IL-1、TNF- α 、MMP-3 等炎症因子在膝关节骨性关节炎的发生与发展中发挥着重要作用, IL-1、TNF- α 等细胞炎症因子刺激滑膜细胞和软骨细胞分泌 MMP 等炎症递质, 使关节软骨、胶原和蛋白多糖降解, 促进膝关节骨性关节炎的发生, 且 IL-1、TNF- α 还可促进滑膜巨噬细胞分化为破骨细胞, 破坏边缘骨质, 抑制基质的修复^[19]。卓廉佳^[20]等研究显示温针联合中药熏洗可有效降低患者膝关节液中 IL-1、TNF- α 、MMP-3 的表达。本研究同样显示治疗后, 观察组的 IL-1、TNF- α 、MMP-3 水平低于对照组 A 和对照组 B ($P < 0.05$), 提示温针联合中药骨疏康胶囊内服治疗膝关节骨性关节炎作用机制可能与抑制细胞炎症

因子的释放有关。本研究中,对照组 A 和对照组 B 之间比较,临床疗效及其他各指标之间差异均无统计学意义,说明单用温针与单用中药,疗效相当。但本研究中样本数较少,且研究时间较短,因此研究结果可能存在偏倚,对于单用温针与单用中药骨疏康胶囊治疗膝关节骨性关节炎的疗效差异还有待进一步研究。

综上所述,温针联合骨疏康胶囊治疗膝关节骨性关节炎的疗效显著,可有效改善患者的临床症状,可能与降低膝关节液中 IL-1、TNF- α 、MMP-3 的水平有关。

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