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仙灵骨葆胶囊治疗骨质疏松疼痛患者的疗效及其对骨密度及骨代谢的影响*

李冬萍 李舜君 山永仪 邹冬梅 田立

(西宁市第一人民医院内分泌科 青海 西宁 810000)

摘要 目的:探讨仙灵骨葆胶囊治疗骨质疏松疼痛患者的疗效,并分析其对骨密度及骨代谢的影响,为临床用药提供依据。**方法:**研究对象为我院2015年6月-2017年7月期间收治的60例骨质疏松疼痛患者。根据治疗方案的不同将患者均分为对照组和观察组各30例。对照组患者采用常规西医治疗,观察组在对照组基础上加用仙灵骨葆胶囊治疗,两组均治疗6个月。治疗前及治疗6个月后(治疗后)采用视觉模拟量表(VAS)评分对患者的疼痛程度进行评价。评价并比较两组疗效。分别于治疗前、治疗后对所有患者腰椎、股骨颈骨密度以及血清N端中段骨钙素(N-MID)、骨钙素(BGP)以及I型胶原羧基末端交联肽(β -CTX)进行检测。**结果:**治疗后,观察组患者VAS评分明显低于对照组($P<0.05$),且观察组总有效率为93.33%(28/30),高于对照组的73.33%(22/30)($P<0.05$)。治疗后,两组患者腰椎、股骨颈骨密度均明显增加,且观察组患者腰椎骨密度明显高于对照组($P<0.05$)。治疗后,两组患者 β -CTX水平均明显降低,BGP水平均明显升高,且观察组 β -CTX水平明显低于对照组,而BGP水平明显高于对照组($P<0.05$),两组患者治疗前后N-MID水平均无明显变化($P>0.05$)。**结论:**仙灵骨葆胶囊治疗骨质疏松疼痛患者疗效显著,能够减轻疼痛并改善骨密度及骨代谢。

关键词:仙灵骨葆胶囊;骨质疏松症;疼痛;骨密度;骨代谢

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Effect of Xianling Gubao Capsule on Bone Mineral Density and Bone Metabolism in Treatment of Patients with Osteoporosis Pain*

LI Dong-ping, LI Shun-jun, SHAN Yong-yi, ZOU Dong-mei, TIAN Li

(Department of Endocrinology, Xining First People's Hospital, Xining, Qinghai, 810000, China)

ABSTRACT Objective: To observe the curative effect of Xianling Gubao Capsule in treatment of patients with osteoporosis pain, and analyze its effects on bone mineral density and bone metabolism, and to provide evidence for clinical medication. **Methods:** A total of 60 patients with osteoporosis pain, who were admitted in Xining First People's Hospital from June 2015 to July 2017, were selected and were divided into control group ($n=30$) and observation group ($n=30$) according to different treatment regimen. The control group was treated with conventional western medicine, while the observation group was treated with Xianling Gubao Capsule on the basis of the control group's therapy. The two groups were treated for 6 months. Visual analogue scale (VAS) was used to evaluate the pain degree of the patients before treatment and 6 months after treatment. The curative effects of the two groups were evaluated and compared. The bone mineral density of lumbar vertebrae and femoral neck, N-mid fragment of osteocalcin (N-MID), bone gla protein (BGP) and β -type I collagen cross-linked-telopeptide (β -CTX) were detected before and after treatment. **Results:** After treatment, the VAS score of the observation group was significantly lower than that of the control group ($P<0.05$), and the total effective rate of the observation group was 93.33% (28/30), which was higher than 73.33% (22/30) of the control group ($P<0.05$); the bone mineral density of lumbar vertebrae and femoral neck of the two groups increased significantly, and the bone mineral density of lumbar vertebrae in the observation group was significantly higher than that in the control group ($P<0.05$); the level of β -CTX in the two groups was significantly decreased, and the level of BGP increased significantly, and the level of β -CTX in the observation group was significantly lower than that of the control group, while the level of BGP was significantly higher than that of the control group ($P<0.05$). There was no significant change in the level of N-MID between the two groups before and after treatment ($P>0.05$). **Conclusion:** Xianling Gubao Capsule is effective in the treatment of patients with osteoporosis pain. It can relieve pain and improve bone mineral density and bone metabolism of the patients with osteoporosis pain.

Key words: Xianling Gubao Capsule; Osteoporosis; Pain; Bone mineral density; Bone metabolism

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作者简介:李冬萍(1975-),女,本科,主治医师,从事内分泌代谢疾病方面的研究,E-mail:poyrgh@163.com

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前言

骨质疏松症是临床常见的一种疾病,其临床体征主要为骨微观结构退化、骨量减少。随着近年来我国人口寿命延长、老龄化社会进程的加快,骨质疏松症的发病率也逐年增高^[1-3]。骨质疏松症患者多表现为骨骼疼痛、已发生骨折、驼背、呼吸障碍等,其中疼痛是骨质疏松症患者最常见也是最主要的症状^[4-6]。西医治疗该病多通过补充钙和维生素D,同时辅以运动进行治疗,以增加患者骨密度,取得了一定的效果,但停药后易复发^[7-9]。相关研究表明^[10],中医治疗骨质疏松症对患者症状的改善有着较好的效果,且安全性良好。仙灵骨葆胶囊可强筋骨、补肝肾,具有温阳通络的功效,以往用于骨代谢疾病均取得了良好的疗效^[11-13]。本研究观察仙灵骨葆胶囊对骨质疏松疼痛患者的疗效,并分析其对骨密度及骨代谢的影响,以为临床提供数据支持,报道如下。

1 资料与方法

1.1 临床资料

研究对象为我院2015年6月-2017年7月间收治的60例骨质疏松症患者。根据治疗方案的不同将患者均分为对照组和观察组各30例。对照组男13例,女17例,年龄46~78岁,平均 (58.73 ± 4.21) 岁,病程13个月~17年,平均 (6.39 ± 2.75) 年。观察组男12例,女18例,年龄43~75岁,平均 (59.56 ± 4.87) 岁,病程11个月~18年,平均 (6.74 ± 3.04) 年。两组一般资料比较无统计学差异($P>0.05$),可以比较。本研究已经我院伦理委员会批准通过。

1.2 纳入排除标准

纳入标准:①符合《中药新药临床研究指导原则》中的相关中医诊断标准以及《原发性骨质疏松症诊治指南(2011)》中的相关西医骨质疏松症诊断标准;②所有患者均有明显的腰背痛或髋膝关节疼痛症状。排除标准:①心、肝、肾功能不全者;②继发性骨质疏松症患者;③过敏体质者;④治疗前一个月服用过其它镇痛药物者^[14,15]。

1.3 治疗方法

对照组患者采用常规西医治疗:阿仑膦酸钠(海南全星制药有限公司,国药准字H20060848,规格:70 mg/70 mg/次口服,服药后30 min禁食,1周/次;碳酸钙(河北三九爱德福药业有限公司,国药准字H10970188,规格:0.5 g)500 mg/d。持续治疗6个月。观察组在对照组基础上加用仙灵骨葆胶囊(国药集团同济堂(贵州)制药有限公司,国药准字Z20025337,规格:0.5 g)治疗:仙灵骨葆胶囊成分包括淫羊藿、知母、补骨脂、续

断、丹参、地黄等,3次/d,2粒/次,口服。持续治疗6个月。

1.4 疗效评定

治疗前及治疗6个月后(治疗后)采用视觉模拟量表(Visual analogue scale, VAS)评分对患者的疼痛程度进行评价, VAS评分为患者主观评分,最高为10分,分数越高表示患者的疼痛程度越高^[16]。治疗后参照《中药新药临床研究指导原则》中的骨质疏松症相关标准对两组疗效进行评定,疗效评定分为3个等级:①显效:疼痛及其他临床症状基本消失,骨密度明显增加;②有效:疼痛及其他临床症状得到明显缓解,且骨密度未见下降;③无效:经治疗,患者疼痛及其他临床症状无明显缓解甚至加重,骨密度未见增加甚至下降。总有效率=显效率+有效率。

1.5 观察指标

分别于治疗前、治疗后应用DEXA双能X线骨密度仪对所有患者腰椎、股骨颈骨密度进行测量。分别于治疗前、治疗后采集患者空腹静脉血5 mL,置于抗凝真空采血管中,分离血清,采用电化学发光免疫分析法检测患者骨代谢指标,包括血清N端中段骨钙素(N-mid fragment of osteocalcin, N-MID)、骨钙素(Bone gla protein, BGP)以及 β -I型胶原羧基末端交联肽(β -type I collagen cross-linked-telopeptide, β -CTX),试剂盒购自德国罗氏诊断产品有限公司,严格按说明书进行操作。

1.6 统计学方法

采用SPSS23.0软件进行统计分析。计数资料以n(%)表示,采用 χ^2 检验, N-MID、 β -CTX水平等计量资料以 $(\bar{x} \pm s)$ 的形式表示,采用t检验。 $\alpha=0.05$ 设为检验标准。

2 结果

2.1 两组患者VAS评分变化及疗效比较

治疗前,对照组和观察组患者VAS评分分别为 (6.14 ± 1.53) 分、 (5.95 ± 1.68) 分,组间比较无统计学差异($P>0.05$)。治疗后,对照组和观察组患者VAS评分分别为 (3.55 ± 0.79) 分、 (1.48 ± 0.62) 分,观察组明显低于对照组($t=11.291, P=0.000$)。对照组显效13例,有效9例,无效8例,总有效率为73.33%(22/30)。观察组显效18例,有效10例,无效2例,总有效率为93.33%(28/30),观察组总有效率高于对照组($\chi^2=4.320, P=0.038$)。

2.2 两组患者骨密度变化情况

治疗前,两组患者腰椎、股骨颈骨密度比较无统计学差异($P>0.05$)。治疗后,两组患者腰椎、股骨颈骨密度均明显增加,且观察组患者腰椎骨密度明显高于对照组($P<0.05$)。见表1。

表1 两组患者骨密度变化情况($\bar{x} \pm s$)

Table 1 Comparison of bone mineral density between two groups($\bar{x} \pm s$)

Groups	Time	Lumbar vertebrae(g/cm ³)	Femoral neck(g/cm ³)
Control group(n=30)	Before treatment	0.69 $\pm$ 0.08	0.62 $\pm$ 0.05
	After treatment	0.73 $\pm$ 0.06*	0.65 $\pm$ 0.08*
Observation group(n=30)	Before treatment	0.71 $\pm$ 0.06	0.63 $\pm$ 0.06
	After treatment	0.81 $\pm$ 0.09**	0.67 $\pm$ 0.08*

Note: Compared with before treatment, * $P<0.05$; Compared with control group, ** $P<0.05$.

2.3 两组患者骨代谢指标变化情况

治疗前两组患者骨代谢指标比较差异无统计学意义($P>0.05$)。治疗后,两组患者 β -CTX 水平均明显降低,BGP 水平均明

显升高,且观察组 β -CTX 水平明显低于对照组,而 BGP 水平明显高于对照组($P<0.05$)。两组患者治疗前后 N-MID 水平均无明显变化($P>0.05$)。见表 2。

表 2 两组患者骨代谢指标变化情况($\bar{x} \pm s$)

Table 2 Comparison of bone metabolism index between two groups($\bar{x} \pm s$)

Groups	Time	N-MID($\mu\text{g/L}$)	BGP($\mu\text{g/L}$)	β -CTX($\mu\text{g/L}$)
Control group(n=30)	Before treatment	19.31 $\pm$ 6.62	5.04 $\pm$ 0.49	0.91 $\pm$ 0.28
	After treatment	19.53 $\pm$ 7.37	7.47 $\pm$ 1.26*	0.76 $\pm$ 0.24*
Observation group(n=30)	Before treatment	18.97 $\pm$ 6.71	4.92 $\pm$ 0.51	0.89 $\pm$ 0.25
	After treatment	20.15 $\pm$ 8.19	8.83 $\pm$ 1.39**	0.61 $\pm$ 0.26**

Note: Compared with before treatment,* $P<0.05$; Compared with control group, ** $P<0.05$.

3 讨论

现代医学表明^[17,18],骨质疏松症疼痛是由多种因素造成的,主要包括:(1)骨微细结构破坏:骨质疏松症患者骨微细结构存在显著病变,轻微的外力即可导致骨折;(2)骨骼肌变形:骨质疏松疼痛及骨折与肌肉因素有重要关系,骨骼肌变形时往往产生肌肉疼痛,而这种疼痛与体位密切相关;(3)破骨细胞溶骨:破骨细胞功能亢进,骨量快速丢失,而患者骨量越低,疼痛越为明显;(4)低骨量导致的全身衰竭:主要表现为长期卧床出现的全身疼痛,常见于重症患者。因此,单一因素的改善往往无法从根本上缓解骨质疏松症疼痛^[19,20]。我国传统医学典籍中无骨质疏松症病名的相关记载,但根据其具体的临床表现,应属“骨痹”、“骨痿”等范畴,血瘀络阻、筋骨失调、脾肾两虚为其主要病机^[21,22]。中医认为“肾主骨生髓”,肾中精气充盈则骨质强劲,因此临床治疗应予患者强筋壮骨、滋补肝肾、补骨生髓以治其本,活血通络止痛以治其标^[23-25]。

本研究中对照组采用阿仑膦酸钠抑制破骨细胞活性,降低患者骨转换、加快骨形成,防止骨质丢失,同时以碳酸钙作为钙剂进行补充。而观察组在此基础上加用仙灵骨葆胶囊。仙灵骨葆胶囊源于苗族验方,以往的临床研究表明^[26],其具有毒副作用小、患者接受度高、可长期应用等优点。本研究中观察组患者治疗后的 VAS 评分低于对照组,且观察组总有效率为 93.33%,高于对照组的 73.33%,提示仙灵骨葆胶囊应用于骨质疏松症具有较好的疗效,能明显改善患者疼痛。仙灵骨葆胶囊中淫羊藿可益气、强筋骨,续断行血脉、补肝肾,地黄益精填髓、滋阴补血,补骨脂补益肝脾、强筋强壮,丹参活血养血,知母滋阴润燥、清热泻火^[27]。因此仙灵骨葆胶囊可营养肾精、健脾生骨,同时兼具活血祛瘀、通络止痛的功效,在降低患者骨折风险、增加其骨密度的同时对患者症状有明显的缓解作用。同时本研究中,治疗后两组患者腰椎、股骨颈骨密度均明显增加,且观察组患者腰椎骨密度明显高于对照组,在一定程度上表明加用仙灵骨葆胶囊有助于患者骨密度的提升。骨密度被认为是目前监测骨质疏松可准确量化的唯一指标,而本研究中两组患者治疗后仅腰椎骨密度存在差异,推测其原因为骨密度数值变化相对滞后于骨质疏松症的发展,因此对于本研究中所用药物疗效的监测可能存在不足。有研究认为^[28,29],相比于骨密度,骨代谢标志物可更快速地间接反映机体骨量变化。本研究中,治疗

后,两组患者 β -CTX 水平均明显降低,BGP 水平均明显升高,且观察组 β -CTX 水平明显低于对照组,而 BGP 水平明显高于对照组。 β -CTX 是骨中的胶原成分,为骨吸收代谢的指标,而 BGP 可反映成骨细胞活性,本研究结果表明,仙灵骨葆胶囊可能通过间接改善血清 β -CTX、BGP 水平,促进成骨细胞增殖,以达到治疗骨质疏松症的效果。同时通过监测血清 β -CTX 与 BGP 水平,或能辅助临床对骨质疏松症患者病情诊断。覃裕等人^[30]在研究中对骨质疏松症患者血钙、磷以及碱性磷酸酶等骨代谢标志物进行了监测,发现其缺乏敏感性及特异性。因此并非所有骨代谢指标对骨质疏松症患者的病情进展均有辅助监测价值,临床骨代谢观察指标的选取,仍需更多的研究予以明确。

综上所述,仙灵骨葆胶囊对骨质疏松症患者疗效确切,对患者的疼痛症状有明显的缓解作用,同时可增加患者骨密度,改善患者骨代谢。临床监测患者 β -CTX 及 BGP 水平,可能有助于临床治疗效果的观察。

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