益骨汤口服联合太极拳锻炼治疗老年性骨质疏松症肾阳虚证

刘魏[1],童培建[2],肖鲁伟[2],何帮剑[2]

（1.浙江省德清县中医院,浙江　德清　313200;
2.浙江中医药大学附属第一医院,浙江　杭州　310006）

摘　要　目的:观察益骨汤口服联合太极拳锻炼治疗老年性骨质疏松症肾阳虚证的临床疗效,并分析其作用机制。**方法:**将80例老年性骨质疏松症肾阳虚证患者随机分为2组,每组40例,分别采用益骨汤口服联合太极拳锻炼治疗和钙剂联合阿仑膦酸钠口服治疗。益骨汤水煎服,每日1剂,分2次服用,连续服用6个月;太极拳每日早晚锻炼1次,每次15~20 min,连续6个月;碳酸钙D3咀嚼片(Ⅱ)每日口服1次,每次1片,连续服用6个月;阿仑膦酸钠每周口服1片,连续服用6个月。分别于治疗前和治疗开始后1个月、3个月、6个月,比较2组患者腰背部疼痛视觉模拟量表(visual analogue scale,VAS)评分、临床症状评分以及生长激素(growth hormone,GH)、胰岛素样生长因子-Ⅰ(insulin-like growth factors-Ⅰ,IGF-Ⅰ)血清含量;并于治疗前和治疗开始后6个月,比较2组患者腰椎骨密度。**结果:**①腰背部疼痛VAS评分。时间因素和分组因素存在交互效应($F=36.390$,$P=0.000$);2组患者腰背部疼痛VAS评分总体比较,差异有统计学意义,即存在分组效应($F=7.257$,$P=0.000$);治疗前后不同时间点腰背部疼痛VAS评分的差异有统计学意义,即存在时间效应($F=2\,717.259$,$P=0.000$);2组患者腰背疼痛VAS评分均呈下降趋势,但2组的下降趋势不完全一致[(6.87±0.34)分,(4.68±0.43)分,(3.45±0.39)分,(1.59±0.36)分,$F=1\,282.371$,$P=0.000$;(6.79±0.36)分,(5.47±0.27)分,(4.24±0.31)分,(2.54±0.34)分,$F=1\,547.065$,$P=0.000$];治疗前,2组患者腰背部疼痛VAS评分比较,差异无统计学意义($t=-0.946$,$P=0.347$);治疗开始后1个月、3个月和6个月,益骨汤联合太极拳组VAS评分均低于钙剂联合阿仑膦酸钠组($t=10.029$,$P=0.000$;$t=9.925$,$P=0.000$;$t=12.148$,$P=0.000$)。②临床症状评分。时间因素和分组因素存在交互效应($F=44.886$,$P=0.000$);2组患者临床症状评分总体比较,差异有统计学意义,即存在分组效应($F=10.506$,$P=0.000$);治疗前后不同时间点临床症状评分的差异有统计学意义,即存在时间效应($F=1\,281.241$,$P=0.000$);2组患者临床症状评分均呈下降趋势,但2组的下降趋势不完全一致[(19.86±1.83)分,(15.66±0.52)分,(12.19±0.68)分,(9.61±0.87)分,$F=673.543$,$P=0.000$;(19.89±1.11)分,(17.45±0.68)分,(15.49±0.52)分,(12.68±0.69)分,$F=687.054$,$P=0.000$];治疗前,2组患者临床症状评分比较,差异无统计学意义($t=0.081$,$P=0.936$);治疗开始后1个月、3个月和6个月,益骨汤联合太极拳组临床症状评分均低于钙剂联合阿仑膦酸钠组($t=13.036$,$P=0.000$;$t=24.324$,$P=0.000$;$t=17.380$,$P=0.000$)。③腰椎骨密度。治疗前,2组患者腰椎骨密度比较,差异无统计学意义($t=-0.777$,$P=0.439$);治疗开始后6个月,2组患者腰椎骨密度均高于治疗前[(0.63±0.12)g·cm^{-2},(0.86±0.25)g·cm^{-2},$t=-5.246$,$P=0.000$;(0.61±0.11)g·cm^{-2},(0.74±0.18)g·cm^{-2},$t=-3.897$,$P=0.000$],益骨汤联合太极拳组腰椎骨密度高于钙剂联合阿仑膦酸钠组($t=-2.464$,$P=0.016$)。④GH血清含量。时间因素和分组因素存在交互效应($F=69.456$,$P=0.000$);2组患者GH血清含量总体比较,差异有统计学意义,即存在分组效应($F=-5.959$,$P=0.000$);治疗前后不同时间点GH血清含量的差异有统计学意义,即存在时间效应($F=790.502$,$P=0.000$);2组患者GH血清含量均呈升高趋势,但2组的升高趋势不完全一致[(0.79±0.44)ug·L^{-1},(2.51±0.77)ug·L^{-1},(4.10±0.88)ug·L^{-1},(5.59±1.08)ug·L^{-1},$F=494.694$,$P=0.000$;(0.78±0.47)ug·L^{-1},(1.44±0.64)ug·L^{-1},(2.69±0.81)ug·L^{-1},(3.99±1.03)ug·L^{-1},$F=332.258$,$P=0.000$];治疗前,2组患者GH血清含量比较,差异无统计学意义($t=-0.068$,$P=0.946$);治疗开始后1个月、3个月和6个月,益骨汤联合太极拳组GH血清含量均高于钙剂联合阿仑膦酸钠组($t=-6.742$,$P=0.000$;$t=-7.433$,$P=0.000$;$t=-6.751$,$P=0.000$)。⑤IGF-Ⅰ血清含量。时间因素和分组因素存在交互效应($F=10.313$,$P=0.000$);2组患者IGF-Ⅰ血清含量总体比较,差异有统计学意义,即存在分组效应($F=-4.466$,$P=0.000$);治疗前后不同时间点IGF-Ⅰ血清含量的差异有统计学意义,即存在时间效应($F=380.659$,$P=0.000$);2组患者IGF-Ⅰ血清含量均呈上升趋势,但2组的上升趋势不完全一致[(178.95±7.59)ug·L^{-1},(233.96±20.58)ug·L^{-1},(255.18±22.49)ug·L^{-1},(296.82±28.29)ug·L^{-1},$F=231.799$,$P=0.000$;(177.12±10.19)ug·L^{-1},(210.39±17.67)ug·L^{-1},(232.54±

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通讯作者:何帮剑　E-mail:69554628@qq.com

21.01)ug·L^{-12},(264.98±32.57)ug·L^{-1},$F=163.707$,$P=0.000$];治疗前,2组患者IGF-Ⅰ血清含量比较,差异无统计学意义($t=-0.907$,$P=0.367$);治疗开始后1个月、3个月和6个月,益骨汤联合太极拳组IGF-Ⅰ血清含量均高于钙剂联合阿仑膦酸钠组($t=-5.495$,$P=0.000$;$t=-4.652$,$P=0.000$;$t=-4.668$,$P=0.000$)。**结论**:益骨汤口服联合太极拳锻炼与钙剂联合阿仑膦酸钠口服治疗老年性骨质疏松症肾阳虚证,均能在一定程度上缓解腰背部疼痛、改善患者的临床症状和提高患者骨密度,但前者的临床疗效优于后者,其作用机制可能与其能提高患者血清GH、IGF-Ⅰ含量有关。

关键词 骨质疏松;肾阳虚;益骨汤;太极拳;生长激素;胰岛素样生长因子1;骨密度;阿仑膦酸钠;临床试验

Oral application of Yigu Tang(益骨汤) combined with shadow boxing exercises for treatment of osteoporosis with kidney-yang deficiency syndrome in the aged

LIU Wei[1],TONG Peijian[2],XIAO Luwei[2],HE Bangjian[2]

1. Traditional Chinese Medical Hospital of Deqing county,Deqing 310053,Zhejiang,China

2. The First Affiliated Hospital of Zhejiang Chinese Medical University,Hangzhou 310006,Zhejiang,China

ABSTRACT **Objective**:To observe the clinical curative effects of oral application of Yigu Tang(益骨汤,YGT) combined with shadow boxing exercises for treatment of osteoporosis with kidney-yang deficiency syndrome in the aged,and to analyze its mechanism of action. **Methods**:Eighty aged patients with kidney-yang deficiency type osteoporosis were randomly divided into 2 groups,40 cases in each group,and were treated with combination therapy of oral application of YGT and shadow boxing exercises(group A) and combination therapy of oral application of calcium agents and alendronate sodium(group B) respectively. The YGT were taken one dose a day in the morning and evening respectively for consecutive 6 months. The shadow boxing exercises were performed in the morning and evening respectively,15-20 minutes at a time for consecutive 6 months. The Caltrate D tablets were taken once a day,1 tablet at a time for consecutive 6 months. The alendronate sodium tablets were taken once a week,1 tablet at a time for consecutive 6 months. The low back pain visual analogue scale(VAS) scores,the clinical symptom scores and the serum contents of growth hormone(GH) and insulin-like growth factors-Ⅰ(IGF-Ⅰ) were measured and compared between the 2 groups before treatment and at 1,3 and 6 months after the beginning of the treatment respectively,and the lumbar bone mineral density(BMD) was measured and compared between the 2 groups before treatment and at 6 months after the beginning of the treatment. **Results**:There was interaction between time factor and group factor in low back pain VAS scores($F=36.390$,$P=0.000$). There was statistical difference in low back pain VAS scores between the 2 groups,in other words,there was group effect($F=7.257$,$P=0.000$). There was statistical difference in low back pain VAS scores between different timepoints before and after the treatment,in other words,there was time effect($F=2\,717.259$,$P=0.000$). The low back pain VAS scores presented a time-dependent decreasing trend in the 2 groups,while the 2 groups were inconsistent with each other in the decreasing trend of low back pain VAS scores(6.87+/-0.34,4.68+/-0.43,3.45+/-0.39,1.59+/-0.36 points,$F=1\,282.371$,$P=0.000$;6.79+/-0.36,5.47+/-0.27,4.24+/-0.31,2.54+/-0.34 points,$F=1\,547.065$,$P=0.000$). There was no statistical difference in low back pain VAS scores between the 2 groups before treatment($t=-0.946$,$P=0.347$). The low back pain VAS scores were lower in group A compared to group B at 1,3 and 6 months after the beginning of the treatment($t=10.029$,$P=0.000$;$t=9.925$,$P=0.000$;$t=12.148$,$P=0.000$). There was interaction between time factor and group factor in clinical symptom scores($F=44.886$,$P=0.000$). There was statistical difference in clinical symptom scores between the 2 groups in general,in other words,there was group effect($F=10.506$,$P=0.000$). There was statistical difference in clinical symptom scores between different timepoints before and after the treatment,in other words,there was time effect($F=1\,281.241$,$P=0.000$). The clinical symptom scores presented a time-dependent decreasing trend in the 2 groups,while the 2 groups were inconsistent with each other in the decreasing trend of clinical symptom scores(19.86+/-1.83,15.66+/-0.52,12.19+/-0.68,9.61+/-0.87 points,$F=673.543$,$P=0.000$;19.89+/-1.11,17.45+/-0.68,15.49+/-0.52,12.68+/-0.69 points,$F=687.054$,$P=0.000$). There was no statistical difference in clinical symptom scores between the 2 groups before treatment($t=0.081$,$P=0.936$). The clinical symptom scores were lower in group A compared to group B at 1,3 and 6 months after the beginning of the treatment($t=13.036$,$P=0.000$;$t=24.324$,$P=0.000$;$t=17.380$,$P=0.000$). There was no statistical difference in lumbar BMD between the 2 groups before treatment($t=-0.777$,$P=0.439$). The lumbar BMD was higher at 6 months after the beginning of the treatment compared to pretreatment in the 2 groups(0.63+/-0.12 vs 0.86+/-0.25 g/cm(-2),$t=-5.246$,$P=0.000$;0.61+/-0.11 vs 0.74+/-0.18 g/cm(-2),$t=-3.897$,$P=0.000$),and was higher in group A compared to group B($t=-2.464$,$P=0.016$). There was interaction between time

factor and group factor in serum contents of GH($F=69.456$,$P=0.000$). There was statistical difference in serum contents of GH between the 2 groups in general, in other words, there was group effect($F=-5.959$,$P=0.000$). There was statistical difference in serum contents of GH between different timepoints before and after the treatment, in other words, there was time effect($F=790.502$,$P=0.000$). The serum contents of GH presented a time-dependent increasing trend in the 2 groups, while the 2 groups were inconsistent with each other in the increasing trend of serum contents of GH(0.79 +/- 0.44, 2.51 +/- 0.77, 4.10 +/- 0.88, 5.59 +/- 1.08 ug/L, $F=494.694$, $P=0.000$; 0.78 +/- 0.47, 1.44 +/- 0.64, 2.69 +/- 0.81, 3.99 +/- 1.03 ug/L, $F=332.258$, $P=0.000$). There was no statistical difference in serum contents of GH between the 2 groups before treatment($t=-0.068$,$P=0.946$). The serum contents of GH were higher in group A compared to group B at 1, 3 and 6 months after the beginning of the treatment($t=-6.742$,$P=0.000$; $t=-7.433$,$P=0.000$; $t=-6.751$,$P=0.000$). There was interaction between time factor and group factor in serum contents of IGF-Ⅰ($F=10.313$,$P=0.000$). There was statistical difference in serum contents of IGF-Ⅰ between the 2 groups in general, in other words, there was group effect($F=-4.466$,$P=0.000$). There was statistical difference in serum contents of IGF-Ⅰ between different timepoints before and after the treatment, in other words, there was time effect($F=380.659$,$P=0.0000$). The serum contents of IGF-Ⅰ presented a time-dependent increasing trend in the 2 groups, while the 2 groups were inconsistent with each other in the increasing trend of serum contents of IGF-Ⅰ(178.95 +/- 7.59, 233.96 +/- 20.58, 255.18 +/- 22.49, 296.82 +/- 28.29 ug/L, $F=231.799$, $P=0.000$; 177.12 +/- 10.19, 210.39 +/- 17.67, 232.54 +/- 21.01, 264.98 +/- 32.57 ug/L, $F=163.707$, $P=0.000$). There was no statistical difference in serum contents of IGF-Ⅰ between the 2 groups before treatment($t=-0.907$,$P=0.367$). The serum contents of IGF-Ⅰ were higher in group A compared to group B at 1, 3 and 6 months after the beginning of the treatment($t=-5.495$,$P=0.000$; $t=-4.652$,$P=0.000$; $t=-4.668$,$P=0.000$). **Conclusion**: Both combination therapy of oral application of YGT and shadow boxing exercises and combination therapy of oral application of calcium agents and alendronate sodium can relieve low back pain, improve patients' clinical symptoms and increase patients' BMD to some extent, however, the former surpasses the latter in clinical curative effects, and its mechanisms of action may be that it can increase the serum contents of GH and IGF-Ⅰ.

Keywords osteoporosis; kidney-yang deficiency; Yigu Tang; shadow boxing; growth hormone; insulin-like growth factor I; bone density; alendronate sodium; clinical trial

目前,骨质疏松症已成为全球发病率最高、花费最大的疾病之一,严重威胁老年人的健康。据统计全球有30%的女性和12%的男性一生中会发生骨质疏松性骨折,该病已成为影响人们健康和生活质量的社会问题[1-2]。目前我国骨质疏松症患者的数量居世界首位,且患病人数仍在逐年增加。如何有效防治老年性骨质疏松症,减少骨质疏松性疼痛,降低骨质疏松性骨折的发生率,以及改善老年患者的生存质量,已成为国际学术界关注的焦点[3]。近年来中医药治疗老年性骨质疏松症取得了一定的进展。益骨汤能促进成骨细胞增殖,抑制骨吸收,加快骨形成,具有抗骨质疏松的作用[4]。太极拳为国家级非物质文化遗产,老年人练习太极拳能够增强体魄。目前临床上将益骨汤口服联合太极拳锻炼治疗老年性骨质疏松症肾阳虚证尚未见报道。为了探讨益骨汤口服联合太极拳锻炼治疗老年性骨质疏松症肾阳虚证的临床疗效并分析其作用机制,2016年11月至2017年8月,我们采用此方法治疗老年性骨质疏松症肾阳虚证患者40例,并与采用钙剂联合阿仑膦酸钠口服治疗的40例患者做对比,现报告如下。

1　临床资料

1.1　一般资料　纳入研究的患者共80例,男41例、女39例。年龄68~78岁,中位数74岁。均为浙江中医药大学附属第一医院的门诊患者(所有病例均为第一作者在浙江中医药大学附属第一医院学习期间所收集)。病程1~5年,中位数3年。试验方案经浙江中医药大学附属第一医院医学伦理委员会审查通过。

1.2　诊断标准

1.2.1　骨质疏松症诊断标准　采用《中国人骨质疏松症建议诊断标准(第二稿)》中的骨质疏松症的诊断标准[5]。

1.2.2　肾阳虚证诊断标准　采用《中医药防治原发性骨质疏松症专家共识(2015)》中肾阳虚证的诊断标准[6]:腰背冷痛,酸软无力,驼背弯腰,活动受限,畏寒喜暖,遇冷加重,尤以下肢为甚,伴小便频多、舌淡苔白、脉弱等。

1.3 纳入标准 ①符合上述诊断标准;②65岁≤年龄≤80岁;③未出现骨质疏松性骨折;④近6个月内未接受过系统抗骨质疏松药物及运动治疗;⑤自愿参与本研究,并签署知情同意书。

1.4 排除标准 ①合并严重心、肝、肾及消化道疾病者;②过敏体质及对中药过敏者;③老年痴呆及精神障碍者。

2 方 法

2.1 分组方法 采用随机数字表将符合要求的80例老年性骨质疏松症肾阳虚证患者随机分为益骨汤联合太极拳组和钙剂联合阿仑膦酸钠组,每组40例。2组患者基线资料比较,差异无统计学意义,有可比性(表1)。

2.2 治疗方法

2.2.1 益骨汤联合太极拳组 采用益骨汤口服联合太极拳锻炼治疗。①益骨汤口服。益骨汤的主要药物组成:山药20 g、生地黄20 g、骨碎补15 g、补骨脂15 g、丹参15 g 仙茅10 g、仙灵脾10 g。水煎服,每日1剂,分2次服用,连续服用6个月。②太极拳锻炼。采用二十四式简化太极拳[7],由课题组专职人员进行指导,每日早晚锻炼1次,每次15~20 min,连续6个月。注意动作以腰为轴,以意念引导气血运行周身,重点放在腰部。

2.2.2 钙剂联合阿仑膦酸钠组 采用钙剂联合阿仑膦酸钠口服治疗。钙剂选择碳酸钙D3咀嚼片(Ⅱ)(美国惠氏-百宫制药有限公司),每日口服1次,每次1片,连续服用6个月;阿仑膦酸钠(杭州默沙东制药有限公司),每周口服1片(70 mg),连续服用6个月。

2.3 疗效评价方法 分别于治疗前和治疗开始后1个月、3个月、6个月,比较2组患者腰背部疼痛视觉模拟量表[8](visual analogue scale,VAS)评分、临床症状评分以及生长激素(growth hormone,GH)、胰岛素样生长因子-Ⅰ(insulin-like growth factors-Ⅰ,IGF-Ⅰ)血清含量;并于治疗前和治疗开始后6个月,比较2组患者腰椎骨密度。临床症状评分采用《中药新药临床研究指导原则(试行)》中原发性骨质疏松症的中医证候量表[9]进行评定,总评分区间为0~27分,分值越高表明患者临床症状越重;采用双能X线吸收法骨密度仪测定患者正位腰椎骨密度值;采用化学比色法检测患者GH血清含量;采用酶联免疫法检测患者IGF-Ⅰ血清含量。

2.4 数据统计方法 采用SPSS17.0统计软件对所得数据进行统计分析,2组患者性别的比较采用χ^2检验,年龄、体质量指数、病程及腰椎骨密度的组间比较和腰椎骨密度治疗前后的组内比较均采用t检验,腰背部疼痛VAS评分、临床症状评分及GH、IGF-Ⅰ血清含量的比较采用重复测量资料的方差分析,检验水准$\alpha=0.05$。

3 结 果

3.1 腰背部疼痛VAS评分 时间因素和分组因素存在交互效应;2组患者腰背部疼痛VAS评分总体比较,差异有统计学意义,即存在分组效应;治疗前后不同时间点腰背部疼痛VAS评分的差异有统计学意义,即存在时间效应;2组患者腰背部疼痛VAS评分均呈下降趋势,但2组的下降趋势不完全一致;治疗前2组患者腰背部疼痛VAS评分比较,差异无统计学意义;治疗开始后1个月、3个月和6个月,益骨汤联合太极拳组VAS评分均低于钙剂联合阿仑膦酸钠组(表2)。

3.2 临床症状评分 时间因素和分组因素存在交互效应;2组患者临床症状评分总体比较,差异有统计学意义,即存在分组效应;治疗前后不同时间点临床症状评分的差异有统计学意义,即存在时间效应;2组患者临床症状评分均呈下降趋势,但2组的下降趋势不完全一致;治疗前2组患者临床症状评分比较,差异无统计学意义;治疗开始后1个月、3个月和6个月,益骨汤联合太极拳组临床症状评分均低于钙剂联合阿仑膦酸钠组(表3)。

3.3 腰椎骨密度 治疗前,2组患者腰椎骨密度比较,差异无统计学意义;治疗开始后6个月,2组患者腰椎骨密度均高于治疗前,益骨汤联合太极拳组腰椎骨密度高于钙剂联合阿仑膦酸钠组(表4)。

3.4 GH血清含量 时间因素和分组因素存在交互效应;2组患者GH血清含量总体比较,差异有统计学意义,即存在分组效应;治疗前后不同时间点GH血清含量的差异有统计学意义,即存在时间效应;2组患者GH血清含量均呈升高趋势,但2组的升高趋势不完全一致;治疗前,2组患者GH血清含量比较,差异无统计学意义;治疗开始后1个月、3个月和6个月,益骨汤联合太极拳组GH血清含量均高于钙剂联合阿仑膦酸钠组(表5)。

表 1　2 组老年性骨质疏松症肾阳虚证患者基线资料比较

组别	样本量(例)	性别(例)		年龄($\bar{x}\pm s$,岁)	体质量指数($\bar{x}\pm s$,kg·m^{-2})	病程($\bar{x}\pm s$,年)
		男	女			
益骨汤联合太极拳组	40	22	18	72.80±5.90	23.64±2.78	2.80±1.20
钙剂联合阿仑膦酸钠组	40	19	21	75.60±3.80	24.15±2.93	2.90±1.40
检验统计量		$\chi^2=0.450$		$t=0.347$	$t=0.798$	$t=0.343$
P 值		0.502		0.729	0.427	0.733

表 2　2 组老年性骨质疏松症肾阳虚证患者腰背部疼痛视觉模拟量表评分

组别	样本量(例)	腰背部疼痛视觉模拟量表评分($\bar{x}\pm s$,分)					F 值	P 值
		治疗前	治疗开始后 1 个月	治疗开始后 3 个月	治疗开始后 6 个月	合计		
益骨汤联合太极拳组	40	6.87±0.34	4.68±0.43	3.45±0.39	1.59±0.36	4.15±0.38	1 282.371	0.000
钙剂联合阿仑膦酸钠组	40	6.79±0.36	5.47±0.27	4.24±0.31	2.54±0.34	4.76±0.32	1 547.065	0.000
合计	80	6.84±0.35	5.08±0.54	3.84±0.53	2.07±0.59	4.46±0.50	2 717.259[1)]	0.000[1)]
t 值		−0.946	10.029	9.925	12.148	7.257[1)]	$F=36.390$[2)],	
P 值		0.347	0.000	0.000	0.000	0.000[1)]	$P=0.000$[2)]	

1)主效应的 F 值和 P 值;2)交互效应的 F 值和 P 值

表 3　2 组老年性骨质疏松症肾阳虚证患者临床症状评分

组别	样本量(例)	临床症状评分($\bar{x}\pm s$,分)					F 值	P 值
		治疗前	治疗开始后 1 个月	治疗开始后 3 个月	治疗开始后 6 个月	合计		
益骨汤联合太极拳组	40	19.86±1.83	15.66±0.52	12.19±0.68	9.61±0.87	14.33±0.98	673.543	0.000
钙剂联合阿仑膦酸钠组	40	19.89±1.11	17.45±0.68	15.49±0.52	12.68±0.69	16.38±0.75	687.054	0.000
合计	80	19.88±1.51	16.56±1.08	13.84±1.76	11.15±1.73	15.36±1.52	1 281.241[1)]	0.000[1)]
t 值		0.081	13.036	24.324	17.380	10.506[1)]	$F=44.886$[2)],$P=0.000$[2)]	
P 值		0.936	0.000	0.000	0.000	0.000[1)]		

1)主效应的 F 值和 P 值;2)交互效应的 F 值和 P 值

表 4　2 组老年性骨质疏松症肾阳虚证患者腰椎骨密度

组别	样本量(例)	腰椎骨密度($\bar{x}\pm s$,g·cm^{-2})		t 值	P 值
		治疗前	治疗开始后 6 个月		
益骨汤联合太极拳组	40	0.63±0.12	0.86±0.25	−5.246	0.000
钙剂联合阿仑膦酸钠组	40	0.61±0.11	0.74±0.18	−3.897	0.000
t 值		−0.777	−2.464		
P 值		0.439	0.016		

表 5　2 组老年性骨质疏松症肾阳虚证患者生长激素血清含量

组别	样本量(例)	生长激素血清含量($\bar{x}\pm s$,ug·L^{-1})					F 值	P 值
		治疗前	治疗开始后 1 个月	治疗开始后 3 个月	治疗开始后 6 个月	合计		
益骨汤联合太极拳组	40	0.79±0.44	2.51±0.77	4.10±0.88	5.59±1.08	3.25±0.79	494.694	0.000
钙剂联合阿仑膦酸钠组	40	0.78±0.47	1.44±0.64	2.69±0.81	3.99±1.03	2.23±0.74	332.258	0.000
合计	80	0.79±0.45	1.97±0.88	3.40±1.09	4.79±1.32	2.74±0.94	790.502[1)]	0.000[1)]
t 值		−0.068	−6.742	−7.433	−6.751	−5.959[1)]	$F=69.456$[2)],	
P 值		0.946	0.000	0.000	0.000	0.000[1)]	$P=0.000$[2)]	

1)主效应的 F 值和 P 值;2)交互效应的 F 值和 P 值

3.5 IGF－Ⅰ血清含量 时间因素和分组因素存在交互效应;2组患者IGF－Ⅰ血清含量总体比较,差异有统计学意义,即存在分组效应;治疗前后不同时间点IGF－Ⅰ血清含量的差异有统计学意义,即存在时间效应;2组患者IGF－Ⅰ血清含量均呈上升趋势,但2组的上升趋势不完全一致;治疗前,2组患者IGF－Ⅰ血清含量比较,差异无统计学意义;治疗开始后1个月、3个月和6个月,益骨汤联合太极拳组IGF－Ⅰ血清含量均高于钙剂联合阿仑膦酸钠组(表6)。

4 讨 论

骨质疏松症被称为老年人发生骨折的“沉默杀手”,早期无明显的自觉症状,相当一部分患者是在体检时才被发现。骨量丢失只有达到12%时,患者才会发生骨痛,且多集中于腰背部疼痛[10]。该病是多种原因引起的一组骨病,骨组织有正常钙化,钙盐与基质呈正常比例,以单位体积内骨量减少为特点的一种全身代谢性疾病,易引起骨折[11]。脆性骨折是该病最常见的严重并发症,常见于脊柱和髋部,成为老年人致残及致死的重要因素之一。我国老年骨质疏松症患者的发病率呈逐年上升趋势,因此加强对老年骨质疏松症的防治就显得尤为重要。运动可以预防老年骨质疏松症[12-13]。在运动过程中,通过肌肉的收缩和舒张可增加肌肉对骨组织的应力负荷,改善骨组织的血液供应,促进骨营养吸收,从而有利于骨形成和骨重建[14-15]。太极拳是一种内外兼修、柔和、缓慢、刚柔相济的中国传统拳术,可以使运动者达到形神共养的目的,可协调周身,调畅气血,平衡阴阳;同时太极拳让腰部得到锻炼,改善腰部气血循环,使得肾气得以充养,从而发挥其抗骨质疏松的功效。

目前临床治疗骨质疏松症的药物有维生素D、钙剂及双膦酸盐类。阿仑膦酸钠是临床应用最广泛的治疗骨质疏松症的双膦酸盐类药物,该药能在一定程度上提高患者活动能力、减轻疼痛,从而改善其生活质量。但有研究证实,双膦酸盐类药物虽有一定的临床疗效,但有发生肝肾功能损害及低钙血症的风险[16]。最新的临床研究报道显示,无论是补充钙剂、维生素D,还是同时补充钙剂和维生素D,均不能降低50岁以上中老年人骨折的发生率,甚至大剂量补充维生素D还会增加发生骨折的风险[17]。

骨质疏松症属中医学“骨痹、骨萎”范畴[18]。中医认为“肾藏精,主骨,生骨髓”,《素问·六节藏象论》曰:“肾者,主蛰,封藏之本,精之处也;其华在发,其充在骨,为阴中之阴,通于冬气”。以上理论说明肾对骨的生长发育和维持骨的成分及结构正常具有重要作用。《素问·上古天真论》曰:“女子七岁肾气盛,齿更发长……八八则齿发去”。老年人肾精丢失不足,骨及骨髓营养不足则会出现骨髓病变,故临床上我们采用益骨汤治疗老年骨质疏松症,并取得了一定的疗效。益骨汤方中的山药滋养强壮、生地黄养阴生津,两药偏补肾阴;骨碎补补肾强骨、补骨脂温肾补阳,两药合用,具有补肾填精益髓的作用;丹参活血生新;仙茅、仙灵脾温补肾阳。诸药合用,共奏温肾壮阳、填精益髓的功效。

骨质疏松症与多种因子有关,其中GH和IGF－Ⅰ在骨骼生长发育过程中扮演重要角色。IGF－Ⅰ是一种促生长肽内激素,决定长骨生长、骨骼发育和骨量增加[19]。GH是由脑垂体前叶嗜酸粒细胞分泌的单链多肽,可以直接促进成骨细胞的生长和分化,也可间接的通过IGF－Ⅰ促进成骨细胞的生成和分化,同样IGF－Ⅰ也可增加成骨细胞活性和增殖,从而增加骨量[20]。

本研究结果显示,益骨汤口服联合太极拳锻炼与钙剂联合阿仑膦酸钠口服治疗老年性骨质疏松症肾阳虚证,均能在一定程度上缓解腰背部疼痛、改善患

表6 2组老年性骨质疏松症肾阳虚证患者胰岛素样生长因子－Ⅰ血清含量

组别	样本量(例)	胰岛素样生长因子－Ⅰ血清含量($\bar{x}\pm s$,ug·L^{-1})					F值	P值
		治疗前	治疗开始后1个月	治疗开始后3个月	治疗开始后6个月	合计		
益骨汤联合太极拳组	40	178.95±7.59	233.96±20.58	255.18±22.49	296.82±28.29	241.23±19.73	231.799	0.000
钙剂联合阿仑膦酸钠组	40	177.12±10.19	210.39±17.67	232.54±21.01	264.98±32.57	221.26±20.36	163.707	0.000
合计	80	178.04±8.97	222.18±22.45	243.86±24.44	280.89±34.28	231.24±22.54	380.659[1)]	0.000[1)]
t值		−0.907	−5.495	−4.652	−4.668	−4.466[1)]	$F=10.313$[2)],	
P值		0.367	0.000	0.000	0.000	0.000[1)]	$P=0.000$[2)]	

1)主效应的F值和P值;2)交互效应的F值和P值

者的临床症状和提高患者骨密度,但前者的临床疗效优于后者,其作用机制可能与其能提高患者血清 GH、IGF - Ⅰ含量有关。

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