

微创经椎间孔腰椎间融合术联合中药封包疗法 治疗腰椎滑脱症的临床研究

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摘要 目的: 观察微创经椎间孔腰椎间融合术(transforaminal lumbar interbody fusion, TLIF)联合中药封包疗法治疗腰椎滑脱症的临床疗效和安全性。方法: 回顾性分析 116 例手术治疗的腰椎滑脱症患者的病例资料。28 例采用开放 TLIF 治疗(TLIF 组)、31 例采用开放 TLIF 联合中药封包治疗(TLIF 联合组)、27 例采用微创 TLIF 治疗(MIS-TLIF 组)、30 例采用微创 TLIF 联合中药封包治疗(MIS-TLIF 联合组)。微创 TLIF 采用 CN12M009 Quadrant 系统进行手术, 中药封包疗法所用药物为消炎散。比较各组的并发症发生情况、手术时间、术中出血量、术后引流量、住院时间、疼痛视觉模拟量表(visual analogue scale, VAS)评分、Oswestry 功能障碍指数(Oswestry disability index, ODI)评分、外周静脉血肌酸激酶(creatinine kinase, CK)含量及多裂肌横截面积和灰度值。多裂肌横截面积和灰度值采用 Image J v2.1 软件在腰椎 T2WI MRI 上进行测量。结果: 所有患者均获得随访, 随访时间 12~24 个月。术后 TLIF 组 2 例患者出现神经损伤表现, 使用神经营养药物治疗后逐渐好转; 各组均未发生椎间隙感染、脑脊液漏、下肢深静脉血栓、内固定材料断裂或松动、椎间隙高度丢失、椎体间 Cage 下陷及移位等并发症。至末次随访时, 所有患者腰椎滑脱均已复位, 融合椎体均已获得骨性愈合。TLIF 组和 TLIF 联合组手术时间比较, MIS-TLIF 组和 MIS-TLIF 联合组手术时间比较, 组间差异均无统计学意义; TLIF 组和 TLIF 联合组手术时间均比 MIS-TLIF 组和 MIS-TLIF 联合组长($P=0.000, P=0.000; P=0.000, P=0.000$)。TLIF 组和 TLIF 联合组术中出血量比较, MIS-TLIF 组和 MIS-TLIF 联合组术中出血量比较, 组间差异均无统计学意义; TLIF 组和 TLIF 联合组术中出血量均比 MIS-TLIF 组和 MIS-TLIF 联合组多($P=0.000, P=0.000; P=0.000, P=0.000$)。TLIF 组和 TLIF 联合组术后引流量比较, MIS-TLIF 组和 MIS-TLIF 联合组术后引流量比较, 组间差异均无统计学意义; TLIF 组和 TLIF 联合组术后引流量均比 MIS-TLIF 组和 MIS-TLIF 联合组多($P=0.000, P=0.000; P=0.000, P=0.000$)。TLIF 组比 TLIF 联合组住院时间长($P=0.013$), MIS-TLIF 组比 MIS-TLIF 联合组住院时间长($P=0.024$), TLIF 组和 TLIF 联合组住院时间均比 MIS-TLIF 组和 MIS-TLIF 联合组长($P=0.000, P=0.000; P=0.000, P=0.000$)。手术前后不同时间 VAS 评分的差异有统计学意义, 即存在时间效应($F=1\ 635.341, P=0.000$)。与术前相比, 4 组患者术后 2 d、7 d、14 d、6 个月、12 个月时的 VAS 评分均减小($P=0.004, P=0.000, P=0.000, P=0.001; P=0.002, P=0.000, P=0.000, P=0.000; P=0.001, P=0.000, P=0.000, P=0.000; P=0.008, P=0.000, P=0.000, P=0.000; P=0.000, P=0.000, P=0.000, P=0.004$)。4 组 VAS 评分总体上比较, 组间差异有统计学意义, 即存在分组效应($F=129.520, P=0.000$)。术前 4 组 VAS 评分比较, 差异无统计学意义; 术后 2 d 时, MIS-TLIF 组和 MIS-TLIF 联合组 VAS 评分均小于 TLIF 组和 TLIF 联合组($P=0.000, P=0.000; P=0.000, P=0.000$); TLIF 组与 TLIF 联合组比较、MIS-TLIF 组与 MIS-TLIF 联合组比较, 组间差异均无统计学意义; 术后 7 d、14 d、6 个月、12 个月时, MIS-TLIF 联合组 VAS 评分均小于 MIS-TLIF 组($P=0.000; P=0.000; P=0.000; P=0.000$), MIS-TLIF 组 VAS 评分均小于 TLIF 联合组($P=0.000; P=0.000; P=0.000; P=0.003$), TLIF 联合组的 VAS 评分均小于 TLIF 组($P=0.000; P=0.000; P=0.000; P=0.006$); 时间因素与分组因素存在交互效应($F=18.500, P=0.000$)。手术前后不同时间 ODI 评分的差异有统计学意义, 即存在时间效应($F=2\ 857.334, P=0.000$)。与术前相比, 4 组患者术后 2 d、7 d、14 d、6 个月、12 个月时的 ODI 评分均减小($P=0.013, P=0.000, P=0.000, P=0.003; P=0.008, P=0.000, P=0.000, P=0.001; P=0.003, P=0.000, P=0.000, P=0.002; P=0.005, P=0.000, P=0.000, P=0.000; P=0.000, P=0.000, P=0.000, P=0.031$)。4 组 ODI 评分总体上比较, 组间差异有统计学意义, 即存在分组效应($F=173.869, P=0.000$)。术前 4 组 ODI 评分比较, 差异无统计学意义; 术后 2 d 时, MIS-TLIF 组和 MIS-TLIF 联合组的 ODI 评分均小于 TLIF 组和 TLIF 联合组($P=0.000, P=0.003; P=0.000, P=0.000$); TLIF 组与 TLIF 联合组比较、MIS-TLIF 组与 MIS-TLIF 联合组比较, 组间差异均无统计学意义; 术后 7 d、14 d、6 个月、12 个月时, MIS-TLIF 联合组 ODI 评分均小于 MIS-TLIF 组($P=0.000; P=0.000; P=0.003; P=0.000$), MIS-TLIF 组 ODI 评分均小于 TLIF 联合组($P=0.000; P=0.000; P=0.006; P=0.000$), TLIF 联合组的 ODI 评分均小于 TLIF 组($P=0.004; P=0.000; P=0.002; P=0.000$)。时间因素与分组因素存在交互效应($F=23.108, P=0.000$)。手术前后不同时间外周静脉血 CK 含量的差异有统计学意义, 即存在

时间效应($F=5\ 355.427, P=0.000$)。与术前相比,4 组患者术后 2 d、7 d、14 d、6 个月时外周静脉血 CK 含量均增加($P=0.002, P=0.000, P=0.000, P=0.000; P=0.002, P=0.000, P=0.000, P=0.007; P=0.000, P=0.000, P=0.000, P=0.012; P=0.008, P=0.000, P=0.000, P=0.000$)。4 组外周静脉血 CK 含量总体上比较,组间差异有统计学意义,即存在分组效应($F=662.238, P=0.000$)。术前及术后 6 个月时 4 组外周静脉血 CK 含量比较,差异均无统计学意义;术后 2 d 时, MIS-TLIF 组和 MIS-TLIF 联合组的 CK 含量均小于 TLIF 组和 TLIF 联合组($P=0.002, P=0.006; P=0.000, P=0.000$); TLIF 组与 TLIF 联合组比较、MIS-TLIF 组与 MIS-TLIF 联合组比较,组间差异均无统计学意义;术后 7 d、14 d 时, MIS-TLIF 联合组的 CK 含量均小于 MIS-TLIF 组($P=0.000; P=0.000$), MIS-TLIF 组的 CK 含量均小于 TLIF 联合组($P=0.000; P=0.009$), TLIF 联合组的 CK 含量均小于 TLIF 组($P=0.008; P=0.000$)。时间因素与分组因素存在交互效应($F=133.581, P=0.000$)。手术前后不同时间多裂肌横截面积的差异有统计学意义,即存在时间效应($F=4\ 633.716, P=0.000$)。与术前相比,4 组患者术后 14 d、6 个月、12 个月时多裂肌横截面积均减小($P=0.002, P=0.000, P=0.000, P=0.000; P=0.001, P=0.000, P=0.000, P=0.025; P=0.001, P=0.000, P=0.000, P=0.000$)。4 组多裂肌横截面积总体上比较,组间差异有统计学意义,即存在分组效应($F=849.382, P=0.000$)。术前 4 组多裂肌横截面积比较,差异无统计学意义;术后 14 d、6 个月、12 个月时, MIS-TLIF 联合组的多裂肌横截面积均大于 MIS-TLIF 组($P=0.006; P=0.000; P=0.000$), MIS-TLIF 组的多裂肌横截面积均大于 TLIF 联合组($P=0.000; P=0.000; P=0.000$), TLIF 联合组的多裂肌横截面积均大于 TLIF 组($P=0.000; P=0.000; P=0.000$)。时间因素与分组因素存在交互效应($F=155.619, P=0.000$)。手术前后不同时间多裂肌灰度值的差异有统计学意义,即存在时间效应($F=2\ 679.510, P=0.000$)。与术前相比,4 组患者术后 14 d、6 个月、12 个月时多裂肌灰度值均减小($P=0.009, P=0.000, P=0.000, P=0.000; P=0.008, P=0.000, P=0.000, P=0.000; P=0.004, P=0.000, P=0.000, P=0.024$)。4 组多裂肌灰度值总体上比较,组间差异有统计学意义,即存在分组效应($F=453.201, P=0.000$)。术前 4 组多裂肌灰度值比较,差异无统计学意义;术后 14 d、6 个月、12 个月时, MIS-TLIF 联合组的多裂肌灰度值均大于 MIS-TLIF 组($P=0.002; P=0.000; P=0.000$), MIS-TLIF 组的多裂肌灰度值均大于 TLIF 联合组($P=0.000; P=0.000; P=0.000$), TLIF 联合组的多裂肌灰度值均大于 TLIF 组($P=0.000; P=0.000; P=0.000$)。时间因素与分组因素存在交互效应($F=56.039, P=0.000$)。结论:采用微创 TLIF 联合中药封包疗法治疗腰椎滑脱症具有安全性好、创伤小、住院时间短、术后疼痛轻、恢复快等优点,值得临床推广应用。

关键词 腰椎滑脱;腰椎;脊柱融合术;椎间孔;外科手术,微创性;热敷;临床试验

Clinical study on minimally invasive transforaminal lumbar interbody fusion combined with traditional Chinese medicine packet therapy for treatment of lumbar spondylolisthesis

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ABSTRACT Objective: To observe the clinical curative effects and safety of minimally invasive transforaminal lumbar interbody fusion (TLIF) combined with traditional Chinese medicine (TCM) packet therapy in the treatment of lumbar spondylolisthesis. **Methods:** The medical records of 116 patients with lumbar spondylolisthesis were analyzed retrospectively. Twenty-eight patients were treated with open TLIF (TLIF group), thirty-one patients were treated with open TLIF combined with TCM packet therapy (TLIF combined-treatment group), twenty-seven patients were treated with minimally invasive TLIF (MIS-TLIF group), while the others were treated with MIS-TLIF combined with TCM packet therapy (MIS-TLIF combined-treatment group). CN12M009 Quadrant system was used for MIS-TLIF surgery, and Xiaoyan San (消炎散) was used for TCM packet therapy. The complications, operative times, intraoperative blood loss, postoperative drainage, hospital stay, pain visual analogue scale (VAS) scores, Oswestry disability index (ODI) scores, peripheral venous blood creatine kinase (CK) contents and cross sectional areas (CSA) and gray values of multifidus were compared between the 4 groups. The CSA and gray values of multifidus were measured by using Image J v2.1 software on T2-weighted MRI of lumbar spine. **Results:** All patients in the 4 groups were followed up for 12-24 months. Nerve injuries were found in 2 patients in TLIF group after surgery, and the patients improved gradually after treatment with neurotrophic drugs. No complications such as intervertebral space infection, cerebrospinal fluid leakage, lower extremity deep venous thrombosis, breakage or loosening of internal fixators, loss of interspace height loss and sag and displacement of intervertebral cage were found in all of the groups. All patients obtained reduction of lumbar spondylolisthesis and bone union of fused vertebra at last follow-up. There was no statistical difference in operative time between TLIF group and TLIF combined-treatment group and between MIS-TLIF group and MIS-TLIF combined-treatment group. The operative time was longer in TLIF group and TLIF combined-

treatment group compared to MIS - TLIF group and MIS - TLIF combined - treatment group ($P = 0.000, P = 0.000; P = 0.000, P = 0.000$). There was no statistical difference in intraoperative blood loss between TLIF group and TLIF combined - treatment group and between MIS - TLIF group and MIS - TLIF combined - treatment group. The intraoperative blood loss were more in TLIF group and TLIF combined - treatment group compared to MIS - TLIF group and MIS - TLIF combined - treatment group ($P = 0.000, P = 0.000; P = 0.000, P = 0.000$). There was no statistical difference in postoperative drainage between TLIF group and TLIF combined - treatment group and between MIS - TLIF group and MIS - TLIF combined - treatment group. The postoperative drainage were more in TLIF group and TLIF combined - treatment group compared to MIS - TLIF group and MIS - TLIF combined - treatment group ($P = 0.000, P = 0.000; P = 0.000, P = 0.000$). The hospital stay was longer in TLIF group compared to TLIF combined - treatment group ($P = 0.013$) and was longer in MIS - TLIF group compared to MIS - TLIF combined - treatment group ($P = 0.024$), and was longer in TLIF group and TLIF combined - treatment group compared to MIS - TLIF group and MIS - TLIF combined - treatment group ($P = 0.000, P = 0.000; P = 0.000, P = 0.000$). There was statistical difference in VAS scores between different timepoints before and after the surgery, in other words, there was time effect ($F = 1635.341, P = 0.000$). The VAS scores decreased in all of the 4 groups at 2, 7, 14 days and 6 and 12 months after the surgery compared to pre - surgery ($P = 0.004, P = 0.000, P = 0.000, P = 0.001; P = 0.002, P = 0.000, P = 0.000, P = 0.000; P = 0.001, P = 0.000, P = 0.000, P = 0.000; P = 0.008, P = 0.000, P = 0.000, P = 0.000; P = 0.000, P = 0.000, P = 0.000, P = 0.004$). There was statistical difference in VAS scores between the 4 groups in general, in other words, there was group effect ($F = 129.520, P = 0.000$). There was no statistical difference in VAS scores between the 4 groups before surgery. The VAS scores were lower in MIS - TLIF group and MIS - TLIF combined - treatment group compared to TLIF group and TLIF combined - treatment group at 2 days after the surgery ($P = 0.000, P = 0.000; P = 0.000, P = 0.000$). There was no statistical difference in VAS scores between TLIF group and TLIF combined - treatment group and between MIS - TLIF group and MIS - TLIF combined - treatment group. At 7, 14 days and 6 and 12 months after the surgery, the VAS scores were lower in MIS - TLIF combined - treatment group compared to MIS - TLIF group ($P = 0.000; P = 0.000; P = 0.000; P = 0.000$), and were lower in MIS - TLIF group compared to TLIF combined - treatment group ($P = 0.000; P = 0.000; P = 0.000; P = 0.003$), and were lower in TLIF combined - treatment group compared to TLIF group ($P = 0.000; P = 0.000; P = 0.000; P = 0.006$). There was interaction between time factor and grouping factor ($F = 18.500, P = 0.000$). There was statistical difference in ODI scores between different timepoints before and after the surgery, in other words, there was time effect ($F = 2857.334, P = 0.000$). The ODI scores decreased in all of the 4 groups at 2, 7, 14 days and 6 and 12 months after the surgery compared to pre - surgery ($P = 0.013, P = 0.000, P = 0.000, P = 0.003; P = 0.008, P = 0.000, P = 0.000, P = 0.001; P = 0.003, P = 0.000, P = 0.000, P = 0.002; P = 0.005, P = 0.000, P = 0.000, P = 0.000; P = 0.000, P = 0.000, P = 0.000, P = 0.031$). There was statistical difference in ODI scores between the 4 groups in general, in other words, there was group effect ($F = 173.869, P = 0.000$). There was no statistical difference in ODI scores between the 4 groups before surgery. At 2 days after the surgery, the ODI scores were lower in MIS - TLIF group and MIS - TLIF combined - treatment group compared to TLIF group and TLIF combined - treatment group ($P = 0.000, P = 0.003; P = 0.000, P = 0.000$), and there was no statistical difference in ODI scores between TLIF group and TLIF combined - treatment group and between MIS - TLIF group and MIS - TLIF combined - treatment group. At 7, 14 days and 6 and 12 months after the surgery, the ODI scores were lower in MIS - TLIF combined - treatment group compared to MIS - TLIF group ($P = 0.000; P = 0.000; P = 0.003; P = 0.000$), and were lower in MIS - TLIF group compared to TLIF combined - treatment group ($P = 0.000; P = 0.000; P = 0.006; P = 0.000$), and were lower in TLIF combined - treatment group compared to TLIF group ($P = 0.004; P = 0.000; P = 0.002; P = 0.000$). There was interaction between time factor and grouping factor ($F = 23.108, P = 0.000$). There was statistical difference in peripheral venous blood CK contents between different timepoints before and after the surgery, in other words, there was time effect ($F = 5355.427, P = 0.000$). The peripheral venous blood CK contents increased in all of the 4 groups at 2, 7, 14 days and 6 months after the surgery compared to pre - surgery ($P = 0.002, P = 0.000, P = 0.000, P = 0.000; P = 0.002, P = 0.000, P = 0.000, P = 0.007; P = 0.000, P = 0.000, P = 0.000, P = 0.012; P = 0.008, P = 0.000, P = 0.000, P = 0.000$). There was statistical difference in peripheral venous blood CK contents between the 4 groups in general, in other words, there was group effect ($F = 662.238, P = 0.000$). There was no statistical difference in peripheral venous blood CK contents between the 4 groups before surgery and at 6 months after the surgery. At 2 days after the surgery, the peripheral venous blood CK contents were lower in MIS - TLIF group and MIS - TLIF combined - treatment group compared to TLIF group and TLIF combined - treatment group ($P = 0.002, P = 0.006; P = 0.000, P = 0.000$) and there was no statistical difference between TLIF group and TLIF combined - treatment group and between MIS - TLIF group and MIS - TLIF combined - treatment group. At 7 and 14 days after the surgery, the peripheral venous blood CK

contents were lower in MIS - TLIF combined - treatment group compared to MIS - TLIF group ($P = 0.000$; $P = 0.000$), and were lower in MIS - TLIF group compared to TLIF combined - treatment ($P = 0.000$; $P = 0.009$), and were lower in TLIF combined - treatment group compared to TLIF group ($P = 0.008$; $P = 0.000$). There was interaction between time factor and grouping factor ($F = 133.581$, $P = 0.000$). There was statistical difference in the CSA of multifidus between different timepoints before and after the surgery, in other words, there was time effect ($F = 4633.716$, $P = 0.000$). The CSA of multifidus decreased in all of the 4 groups at 14 days and 6 and 12 months after the surgery compared to pre - surgery ($P = 0.002$, $P = 0.000$, $P = 0.000$, $P = 0.000$; $P = 0.001$, $P = 0.000$, $P = 0.000$, $P = 0.025$; $P = 0.001$, $P = 0.000$, $P = 0.000$, $P = 0.000$). There was statistical difference in the CSA of multifidus between the 4 groups in general, in other words, there was group effect ($F = 849.382$, $P = 0.000$). There was no statistical difference in the CSA of multifidus between the 4 groups before surgery. At 14 days and 6 and 12 months after the surgery, the CSA of multifidus were greater in MIS - TLIF combined - treatment group compared to MIS - TLIF group ($P = 0.006$; $P = 0.000$; $P = 0.000$), and were greater in MIS - TLIF group compared to TLIF combined - treatment group ($P = 0.000$; $P = 0.000$; $P = 0.000$), and were greater in TLIF combined - treatment compared to TLIF group ($P = 0.000$; $P = 0.000$; $P = 0.000$). There was interaction between time factor and grouping factor ($F = 155.619$, $P = 0.000$). There was statistical difference in the gray values of multifidus between different timepoints before and after the surgery, in other words, there was time effect ($F = 2679.510$, $P = 0.000$). The gray values of multifidus decreased in all of the 4 groups at 14 days and 6 and 12 months after the surgery compared to pre - surgery ($P = 0.009$, $P = 0.000$, $P = 0.000$, $P = 0.000$; $P = 0.008$, $P = 0.000$, $P = 0.000$, $P = 0.000$; $P = 0.004$, $P = 0.000$, $P = 0.000$, $P = 0.024$). There was statistical difference in the gray values of multifidus between the 4 groups in general, in other words, there was group effect ($F = 453.201$, $P = 0.000$). There was no statistical difference in the gray values of multifidus between the 4 groups before surgery. At 14 days and 6 and 12 months after the surgery, the gray values of multifidus were greater in MIS - TLIF combined - treatment group compared to MIS - TLIF group ($P = 0.002$; $P = 0.000$; $P = 0.000$), and were greater in MIS - TLIF group compared to TLIF combined - treatment group ($P = 0.000$; $P = 0.000$; $P = 0.000$), and were greater in TLIF combined - treatment group compared to TLIF group ($P = 0.000$; $P = 0.000$; $P = 0.000$). There was interaction between time factor and grouping factor ($F = 56.039$, $P = 0.000$).

Conclusion: The combination therapy of minimally invasive TLIF and TCM packet therapy has such advantages as high safety, less trauma, short hospital stay, less postoperative pain and fast recovery in treatment of lumbar spondylolisthesis, so it is worthy of popularizing in clinic.

Key words spondylolysis; lumbar vertebrae; spinal fusion; intervertebral foramen; surgical procedures, minimally invasive; hot compress; clinical trial

Harms 等^[1]于 1982 年首先介绍并应用经椎间孔腰椎间融合术(transforaminal lumbar interbody fusion, TLIF)治疗腰椎退行性疾病,该手术与传统后路腰椎间融合术相比,可有效减少神经系统并发症,但术中仍需像传统后路腰椎间融合术一样广泛剥离软组织,无法实现微创。为此,Foley 等^[2]于 2003 年创新性地提出了微创 TLIF,借助特殊器械与内镜进行减压、椎间融合和内固定,明显减少了肌肉损伤,降低了术后腰背痛的发生率^[3]。中药封包是将中医外治与现代药物透皮技术相结合的技术,在红外线与磁场相互作用下,将中药封包内中药的有效活性物质转化为离子状态,穿透皮肤,从而达到治疗目的^[4]。

本研究拟通过回顾性研究比较 TLIF、TLIF 联合中药封包、微创 TLIF 及微创 TLIF 联合中药封包 4 种治疗方案对于腰椎滑脱症的临床疗效,探讨微创 TLIF 联合中药封包治疗腰椎滑脱症的可行性。

1 临床资料

1.1 一般资料 纳入研究的患者共 116 例,均为

2009 年 3 月至 2015 年 1 月在湖南中医药大学第二附属医院住院治疗的腰椎滑脱症患者。28 例采用开放 TLIF 治疗(TLIF 组)、31 例采用开放 TLIF 联合中药封包治疗(TLIF 联合组)、27 例采用微创 TLIF 治疗(MIS - TLIF 组)、30 例采用微创 TLIF 联合中药封包治疗(MIS - TLIF 联合组)。4 组患者的基线资料比较,差异均无统计学意义,有可比性(表 1)。

1.2 诊断标准 采用《临床诊疗指南·骨科分册》中腰椎滑脱症的诊断标准^[6]。

1.3 纳入标准 ①符合上述诊断标准;②采用 TLIF 或 TLIF 联合中药封包或微创 TLIF 或微创 TLIF 联合中药封包治疗;③治疗均由同一组医师完成,所用器械和药物相同;④治疗及随访资料完整,随访 12 个月以上。

1.4 排除标准 ①合并严重骨质疏松者;②影像学检查提示关节突关节、椎板及椎管等结构异常者;③近期服用过止痛药物者。

2 方法

2.1 临床治疗 TLIF 组和 TLIF 联合组行传统开放

表 1 4 组腰椎滑脱症患者基线资料比较

组别	例数	性别(例)		年龄 ($\bar{x} \pm s$, 岁)	病程 ($\bar{x} \pm s$, 月)	滑脱程度 ¹⁾ (例)		滑脱节段(例)			滑脱类型(例)	
		男	女			I 度	II 度	L ₃	L ₄	L ₅	退行性 滑脱	真性 滑脱
TLIF 组	28	10	18	51.14 ± 6.50	23.39 ± 21.71	15	13	2	16	10	18	10
TLIF 联合组	31	14	17	49.17 ± 6.87	22.87 ± 22.53	19	12	2	20	9	19	12
MIS - TLIF 组	27	10	17	48.13 ± 7.74	21.56 ± 19.65	20	7	1	17	9	20	7
MIS - TLIF 联合组	30	14	16	49.93 ± 8.00	22.76 ± 19.60	19	11	2	20	8	22	8
检验统计量		$\chi^2 = 0.024$		$F = 0.949$	$F = 0.047$	$\chi^2 = 2.524$		$\chi^2 = 1.360$			$\chi^2 = 1.620$	
P 值		0.099		0.419	0.987	0.471		0.986			0.655	

1) 滑脱程度采用 Meyerding 分级法^[5]

TLIF 手术, MIS - TLIF 组和 MIS - TLIF 联合组采用 CN12M009 Quadrant 系统行 TLIF 手术。

术后 4 组患者均常规给予抗生素、脱水药物和神经营养药物。48 h 后撤除引流装置, 术后 7 ~ 8 d 在腰部支具保护下下床活动。TLIF 联合组和 MIS - TLIF 联合组 48 h 时后开始中药封包治疗。所用药物为消炎散, 药物组成包括大黄 30 g、栀子 30 g、泽泻 15 g、黄柏 50 g、血竭 15 g、丹皮 15 g、姜黄 15 g、乳香 15 g、没药 15 g、香附 15 g、延胡索 15 g、白芷 10 g。治疗时先对伤口换药, 再用一次性无菌生物半透膜(3M Health Care, 型号: 9546HP, 规格: 10 cm × 11.5 cm) 覆盖切口, 然后将含消炎散的磁疗包放置在 HNXY001C 型中医封包综合治疗仪(湖南省健缘医疗科技有限公司)内进行治疗, 每天 1 次, 每次 30 min。治疗结束后取下封包, 撕掉生物半透膜, 再换药 1 次。TLIF 组和 MIS - TLIF 组仅每天换药 1 次, 不进行中药封包治疗。

2.2 试验指标观察 比较各组的并发症发生情况、手术时间、术中出血量、术后引流量、住院时间、疼痛视觉模拟量表(visual analogue scale, VAS)评分、Oswestry 功能障碍指数(Oswestry disability index, ODI)评分、外周静脉血肌酸激酶(creatinine kinase, CK)含量及多裂肌横截面积和灰度值。多裂肌横截面积和灰度值采用 Image J v2.1 软件在腰椎 T2WI MRI 上进行测量。

2.3 数据统计分析 采用 SPSS 19.0 软件进行数据统计分析。4 组患者性别、滑脱程度、滑脱节段、滑脱类型的组间比较采用 χ^2 检验, 年龄、病程的组间比较采用单因素方差分析, 治疗前后不同时间点 4 组患者 VAS 评分、ODI 评分、外周静脉血 CK 含量、多裂肌横截面积、多裂肌灰度值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

所有患者均获得随访, 随访时间 12 ~ 24 个月。

术后 TLIF 组 2 例患者出现神经损伤表现, 使用神经营养药物治疗后逐渐好转; 各组均未发生椎间隙感染、脑脊液漏、下肢深静脉血栓、内固定材料断裂或松动、椎间隙高度丢失、椎体间 Cage 下陷及移位等并发症。至末次随访时, 所有患者腰椎滑脱均已复位, 融合椎体均已获得骨性愈合。典型病例图片见图 1。

TLIF 组和 TLIF 联合组手术时间比较, MIS - TLIF 组和 MIS - TLIF 联合组手术时间比较, 组间差异均无统计学意义; TLIF 组和 TLIF 联合组手术时间均比 MIS - TLIF 组和 MIS - TLIF 联合组长 ($P = 0.000, P = 0.000; P = 0.000, P = 0.000$)。TLIF 组和 TLIF 联合组术中出血量比较, MIS - TLIF 组和 MIS - TLIF 联合组术中出血量比较, 组间差异均无统计学意义; TLIF 组和 TLIF 联合组术中出血量均比 MIS - TLIF 组和 MIS - TLIF 联合组多 ($P = 0.000, P = 0.000; P = 0.000, P = 0.000$)。TLIF 组和 TLIF 联合组术后引流量比较, MIS - TLIF 组和 MIS - TLIF 联合组术后引流量比较, 组间差异均无统计学意义; TLIF 组和 TLIF 联合组术后引流量均比 MIS - TLIF 组和 MIS - TLIF 联合组多 ($P = 0.000, P = 0.000; P = 0.000, P = 0.000$)。TLIF 组比 TLIF 联合组住院时间长 ($P = 0.013$), MIS - TLIF 组比 MIS - TLIF 联合组住院时间长 ($P = 0.024$), TLIF 组和 TLIF 联合组住院时间均比 MIS - TLIF 组和 MIS - TLIF 联合组长 ($P = 0.000, P = 0.000; P = 0.000, P = 0.000$)。见表 2。

手术前后不同时间 VAS 评分的差异有统计学意义, 即存在时间效应 ($F = 1635.341, P = 0.000$)。与术前相比, 4 组患者术后 2 d、7 d、14 d、6 个月、12 个月时的 VAS 评分均减小 ($P = 0.004, P = 0.000, P = 0.000, P = 0.001; P = 0.002, P = 0.000, P = 0.000, P = 0.000; P = 0.001, P = 0.000, P = 0.000, P = 0.000; P = 0.008, P = 0.000, P = 0.000, P = 0.000$;

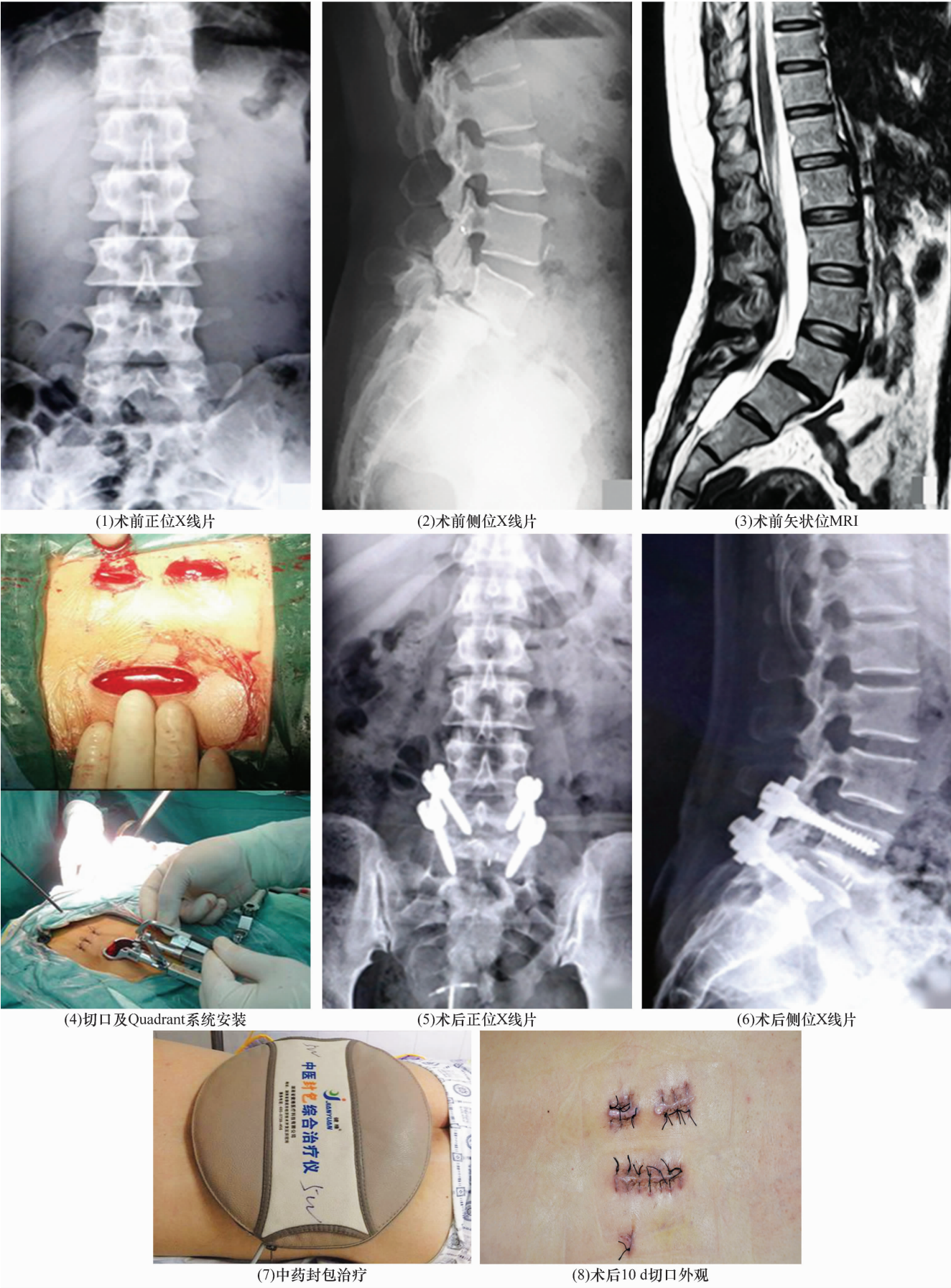


图1 腰椎滑脱症微创 TLIF 联合中药封包治疗前后图片

患者,女,53 岁,L₅ I 度滑脱,采用微创 TLIF 联合中药封包治疗

$P=0.000, P=0.000, P=0.000, P=0.004$)。4 组 VAS 评分总体上比较,组间差异有统计学意义,即存在分组效应($F=129.520, P=0.000$)。术前 4 组 VAS 评分比较,差异无统计学意义;术后 2 d 时, MIS-TLIF 组和 MIS-TLIF 联合组 VAS 评分均小于 TLIF 组和 TLIF 联合组($P=0.000, P=0.000; P=0.000, P=0.000$); TLIF 组与 TLIF 联合组比较、MIS-TLIF 组与 MIS-TLIF 联合组比较,组间差异均

无统计学意义;术后 7 d、14 d、6 个月、12 个月时, MIS-TLIF 联合组 VAS 评分均小于 MIS-TLIF 组($P=0.000; P=0.000; P=0.000; P=0.000$), MIS-TLIF 组 VAS 评分均小于 TLIF 联合组($P=0.000; P=0.000; P=0.000; P=0.003$), TLIF 联合组的 VAS 评分均小于 TLIF 组($P=0.000; P=0.000; P=0.000; P=0.006$);时间因素与分组因素存在交互效应($F=18.500, P=0.000$)。见表 3。

表 2 4 组腰椎滑脱症患者围手术期指标及住院时间比较 $\bar{x} \pm s$

组别	例数	手术时间(min)	术中出血量(mL)	术后引流量(mL)	住院时间(d)
TLIF 组	28	142.60 ± 15.54	270.53 ± 15.68	184.60 ± 16.04	14.32 ± 4.30
TLIF 联合组	31	139.60 ± 12.63	256.31 ± 16.68	163.52 ± 13.86	12.28 ± 2.60
MIS-TLIF 组	27	102.93 ± 12.43	135.50 ± 12.27	74.63 ± 13.52	10.23 ± 3.63
MIS-TLIF 联合组	30	100.31 ± 11.20	142.35 ± 15.43	78.57 ± 10.23	8.24 ± 1.62
<i>F</i> 值		340.022	1 318.654	115.921	83.644
<i>P</i> 值		0.000	0.000	0.000	0.000

表 3 4 组腰椎滑脱症患者手术前后 VAS 评分比较 $\bar{x} \pm s$, 分

组别	例数	术前	术后 2 d	术后 7 d	术后 14 d	术后 6 个月	术后 12 个月	<i>F</i> 值	<i>P</i> 值
TLIF 组	28	7.83 ± 0.79	4.73 ± 0.64	2.80 ± 0.71	2.13 ± 0.63	1.53 ± 1.17	2.23 ± 1.65	18.550	0.000
TLIF 联合组	31	7.63 ± 0.72	4.73 ± 0.78	2.27 ± 0.78	1.37 ± 0.76	0.83 ± 0.65	0.83 ± 0.30	15.100	0.000
MIS-TLIF 组	27	7.60 ± 0.77	3.23 ± 0.50	1.47 ± 0.68	0.60 ± 0.50	0.48 ± 0.09	0.32 ± 0.13	14.450	0.000
MIS-TLIF 联合组	30	7.60 ± 0.81	3.13 ± 4.34	1.03 ± 0.32	0.67 ± 0.25	0.38 ± 0.13	0.23 ± 0.08	12.730	0.000
<i>F</i> 值		604.950	381.350	938.040	617.050	1.710	0.799		
<i>P</i> 值		0.875	0.000	0.000	0.000	0.000	0.000		

手术前后不同时间 ODI 评分的差异有统计学意义,即存在时间效应($F=2 857.334, P=0.000$)。与术前相比,4 组患者术后 2 d、7 d、14 d、6 个月、12 个月时的 ODI 评分均减小($P=0.013, P=0.000, P=0.000, P=0.003; P=0.008, P=0.000, P=0.000, P=0.001; P=0.003, P=0.000, P=0.000, P=0.002; P=0.005, P=0.000, P=0.000, P=0.000; P=0.000, P=0.000, P=0.000, P=0.031$)。4 组 ODI 评分总体上比较,组间差异有统计学意义,即存在分组效应($F=173.869, P=0.000$)。术前 4 组 ODI 评分比较,差异无统计学意义;术后 2 d 时, MIS-TLIF 组和 MIS-TLIF 联合组的 ODI 评分均小于 TLIF 组和 TLIF 联合组($P=0.000, P=0.003; P=0.000, P=0.000$); TLIF 组与 TLIF 联合组比较、MIS-TLIF 组与 MIS-TLIF 联合组比较,组间差异均无统计学意义;术后 7 d、14 d、6 个月、12 个月时, MIS-TLIF 联合组 ODI 评分均小于 MIS-TLIF 组($P=0.000; P=0.000; P=0.003; P=0.000$), MIS-TLIF 组 ODI 评分均小于 TLIF 联合组($P=0.000; P=0.000; P=0.006; P=0.000$), TLIF 联合组的 ODI 评分均小于 TLIF 组($P=0.004; P=0.000; P=0.002; P=0.000$)。时间因素与分组因素存在交互效应($F=23.108, P=0.000$)。见表 4。

表 4 4 组腰椎滑脱症患者手术前后 ODI 评分比较 $\bar{x} \pm s$, 分

组别	例数	术前	术后 2 d	术后 7 d	术后 14 d	术后 6 个月	术后 12 个月	<i>F</i> 值	<i>P</i> 值
TLIF 组	28	60.13 ± 8.83	53.97 ± 3.62	40.27 ± 4.29	28.53 ± 4.00	16.53 ± 2.62	8.80 ± 6.57	21.540	0.000
TLIF 联合组	31	62.40 ± 6.57	53.67 ± 4.40	31.33 ± 1.99	22.40 ± 2.65	14.20 ± 1.32	6.67 ± 1.32	17.780	0.000
MIS-TLIF 组	27	63.07 ± 7.98	41.13 ± 5.32	22.90 ± 2.33	16.20 ± 2.06	10.02 ± 2.80	6.47 ± 1.72	12.180	0.000
MIS-TLIF 联合组	30	63.20 ± 6.57	43.30 ± 4.81	20.00 ± 4.14	11.47 ± 1.89	9.50 ± 2.03	5.80 ± 0.81	11.360	0.000
<i>F</i> 值		696.960	624.330	399.090	296.190	696.080	236.120		
<i>P</i> 值		0.882	0.000	0.000	0.000	0.000	0.000		

手术前后不同时间外周静脉血 CK 含量的差异有统计学意义,即存在时间效应($F = 5\,355.427, P = 0.000$)。与术前相比,4 组患者术后 2 d、7 d、14 d、6 个月时外周静脉血 CK 含量均增加($P = 0.002, P = 0.000, P = 0.000, P = 0.000; P = 0.002, P = 0.000, P = 0.000, P = 0.007; P = 0.000, P = 0.000, P = 0.000, P = 0.012; P = 0.008, P = 0.000, P = 0.000, P = 0.000$)。4 组外周静脉血 CK 含量总体上比较,组间差异有统计学意义,即存在分组效应($F = 662.238, P = 0.000$)。术前及术后 6 个月时 4 组外周静脉血 CK 含量比较,差异均无统计学意义;术后 2 d 时,

MIS-TLIF 组和 MIS-TLIF 联合组的 CK 含量均小于 TLIF 组和 TLIF 联合组($P = 0.002, P = 0.006; P = 0.000, P = 0.000$); TLIF 组与 TLIF 联合组比较、MIS-TLIF 组与 MIS-TLIF 联合组比较,组间差异均无统计学意义;术后 7 d、14 d 时, MIS-TLIF 联合组的 CK 含量均小于 MIS-TLIF 组($P = 0.000; P = 0.000$), MIS-TLIF 组的 CK 含量均小于 TLIF 联合组($P = 0.000; P = 0.009$), TLIF 联合组的 CK 含量均小于 TLIF 组($P = 0.008; P = 0.000$)。时间因素与分组因素存在交互效应($F = 133.581, P = 0.000$)。见表 5。

表 5 4 组腰椎滑脱症患者手术前后外周静脉血 CK 含量比较 $\bar{x} \pm s, U \cdot L^{-1}$

组别	例数	术前	术后 2 d	术后 7 d	术后 14 d	术后 6 个月	F 值	P 值
TLIF 组	28	69.37 ± 46.66	804.43 ± 69.09	648.57 ± 44.95	540.90 ± 22.27	71.31 ± 22.35	43.220	0.000
TLIF 联合组	31	66.40 ± 19.16	815.03 ± 68.40	560.57 ± 36.42	459.90 ± 31.49	69.30 ± 31.12	36.280	0.000
MIS-TLIF 组	27	74.40 ± 25.70	551.77 ± 43.62	445.10 ± 20.90	364.63 ± 20.27	77.17 ± 23.41	31.740	0.000
MIS-TLIF 联合组	30	65.00 ± 20.52	526.20 ± 15.36	369.63 ± 16.62	277.00 ± 33.80	69.51 ± 31.53	28.360	0.000
F 值		435.270	1 411.850	1 390.220	1 324.050	1 223.490		
P 值		0.766	0.000	0.000	0.000	0.056		

手术前后不同时间多裂肌横截面积的差异有统计学意义,即存在时间效应($F = 4\,633.716, P = 0.000$)。与术前相比,4 组患者术后 14 d、6 个月、12 个月时多裂肌横截面积均减小($P = 0.002, P = 0.000, P = 0.000, P = 0.000; P = 0.001, P = 0.000, P = 0.000, P = 0.025; P = 0.001, P = 0.000, P = 0.000, P = 0.000$)。4 组多裂肌横截面积总体上比较,组间差异有统计学意义,即存在分组效应($F = 849.382, P = 0.000$)。术前 4 组多裂肌横截面积比

较,差异无统计学意义;术后 14 d、6 个月、12 个月时, MIS-TLIF 联合组的多裂肌横截面积均大于 MIS-TLIF 组($P = 0.006; P = 0.000; P = 0.000$), MIS-TLIF 组的多裂肌横截面积均大于 TLIF 联合组($P = 0.000; P = 0.000; P = 0.000$), TLIF 联合组的多裂肌横截面积均大于 TLIF 组($P = 0.000; P = 0.000; P = 0.000$)。时间因素与分组因素存在交互效应($F = 155.619, P = 0.000$)。见表 6。

表 6 4 组腰椎滑脱症患者手术前后 MRI 上多裂肌横截面积比较 $\bar{x} \pm s, mm^2$

组别	例数	术前	术后 14 d	术后 6 个月	术后 12 个月	F 值	P 值
TLIF 组	28	634.11 ± 29.20	399.20 ± 29.64	420.35 ± 15.23	446.54 ± 20.70	77.640	0.000
TLIF 联合组	31	628.64 ± 50.95	436.17 ± 46.07	459.90 ± 31.49	501.81 ± 23.28	74.520	0.000
MIS-TLIF 组	27	638.80 ± 39.62	477.22 ± 32.22	500.34 ± 23.37	537.41 ± 18.63	61.340	0.000
MIS-TLIF 联合组	30	626.17 ± 37.17	520.15 ± 38.27	532.21 ± 32.17	561.42 ± 25.28	53.240	0.000
F 值		1 535.020	1 434.650	1 359.200	1 313.250		
P 值		0.852	0.000	0.000	0.000		

手术前后不同时间多裂肌灰度值的差异有统计学意义,即存在时间效应($F = 2\,679.510, P = 0.000$)。与术前相比,4 组患者术后 14 d、6 个月、12 个月时多裂肌灰度值均减小($P = 0.009, P = 0.000, P = 0.000, P = 0.000; P = 0.008, P = 0.000, P = 0.000, P = 0.000; P = 0.004, P = 0.000, P = 0.000, P = 0.024$)。

4 组多裂肌灰度值总体上比较,组间差异有统计学意义,即存在分组效应($F = 453.201, P = 0.000$)。术前 4 组多裂肌灰度值比较,差异无统计学意义;术后 14 d、6 个月、12 个月时, MIS-TLIF 联合组的多裂肌灰度值均大于 MIS-TLIF 组($P = 0.002; P = 0.000; P = 0.000$), MIS-TLIF 组的多裂肌灰度值均大于

TLIF 联合组 ($P=0.000$; $P=0.000$; $P=0.000$), TLIF 联合组的多裂肌灰度值均大于 TLIF 组 ($P=0.000$; $P=0.000$; $P=0.000$)。时间因素与分组因素存在交互效应 ($F=56.039$, $P=0.000$)。见表 7。

表 7 4 组腰椎滑脱症患者手术前后 MRI 上多裂肌灰度值比较 $\bar{x} \pm s$

组别	例数	术前	术后 14 d	术后 6 个月	术后 12 个月	F 值	P 值
TLIF 组	28	55.20 \pm 5.07	16.50 \pm 4.88	20.64 \pm 4.32	29.57 \pm 3.09	99.080	0.000
TLIF 联合组	31	50.33 \pm 7.37	21.33 \pm 0.60	24.87 \pm 3.25	33.78 \pm 2.06	67.600	0.000
MIS-TLIF 组	27	49.55 \pm 5.86	28.46 \pm 0.20	35.66 \pm 4.51	39.60 \pm 0.15	59.630	0.000
MIS-TLIF 联合组	30	53.03 \pm 6.37	33.52 \pm 0.37	42.38 \pm 5.21	45.22 \pm 0.64	48.090	0.000
F 值		690.360	666.080	540.060	589.030		
P 值		0.756	0.000	0.000	0.000		

4 讨论

自从 Foley 在 2003 年首次提出微创 TLIF 技术并应用到临床后,目前已被广泛应用^[7]。本研究中微创 TLIF 采用的是 Quadrant 系统,它是在 X-TUBE 操作技术基础上发展起来的微创脊柱外科撑开系统^[8],由蛇形臂、套管及 2 个冷光源组成。术中管道两侧弧形叶片撑开,配合冷光源,可清晰显示手术视野,可在直视下完成减压、复位、融合和内固定等操作。张伟彬等^[9]使用 X-tube 系统行微创 TLIF 与后侧椎间融合术治疗单节段腰椎间盘突出症,结果表明微创 TLIF 在减少组织损伤及术后恢复方面明显优于后侧椎间融合术。林阳^[10]对于微创 TLIF 和 TLIF 的 Meta 分析结果表明,二者的远期疗效及安全性相当,但微创 TLIF 具有出血少、下床活动早、住院时间短等优势。本研究的结果也显示,微创 TLIF 较 TLIF 能有效缩短手术时间、减少术中和术后出血、缩短住院时间,而且对肌肉组织的损伤更小、术后疼痛更轻微、功能恢复更快。

本研究中药封包治疗所采用的消炎散为湖南中医药大学第二附属医院骨伤科的经验方。方中大黄、栀子能清热凉血、逐瘀通经,泽泻泻热利水,黄柏清热燥湿,血竭、姜黄、丹皮活血化瘀、消肿止痛,乳香、没药活血、散血,香附、延胡索活血化瘀、行气止痛,白芷芳香通痹,诸药合用,具有活血散瘀、行气止痛、消肿生肌的功效。

脊柱周围的肌肉主要包括多裂肌、最长肌和髂肋肌,多裂肌是躯干肌中的重要肌群,主要起稳定脊柱的作用,也是腰椎后路手术中受影响最大的肌肉组织^[11-12]。CK 主要存在于骨骼肌、心肌、胎盘及脑组织中,当肌肉组织受到创伤时,肌细胞破坏或细胞膜通透性增加,CK 释放入血,当其释放速度大于灭活速度时,可引起外周血中含量增高。从手术前后外周血

CK 含量、多裂肌横截面积和灰度值的变化来看,与 TLIF 相比,微创 TLIF 对多裂肌的损伤更小,而联合应用中药封包治疗可能有助于术后多裂肌损伤的修复。

本研究的结果提示,采用微创 TLIF 联合中药封包疗法治疗腰椎滑脱症具有安全性好、创伤小、住院时间短、术后疼痛轻、恢复快等优点,值得临床应用。

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《中医正骨》杂志 2015 年重点专栏目录(一)

2015 年第 3 期——胫骨平台骨折专栏

- 1 胫骨平台骨折的分类与手术治疗进展
(述评专家: 温州医科大学附属义乌医院 陈红卫教授)
- 2 应用三柱分型理论治疗复杂胫骨平台骨折
- 3 劈开腓肠肌内侧头的改良后内侧入路在胫骨平台后柱骨折内固定术中的应用
- 4 不同手术方式治疗胫骨平台骨折畸形愈合的体会
- 5 联合入路双钢板固定结合自制接骨丹治疗 Schatzker V、VI 型胫骨平台骨折

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2015 年第 7 期——膝骨关节炎专栏

- 1 探索建立系统的膝骨关节炎中医临床科研范式和理论体系
(述评专家: 中国中医科学院望京医院 陈卫衡教授)
- 2 膝骨关节炎中医诊疗专家共识(2015 年版)
- 3 透骨消痛胶囊中补肾柔肝药和活血祛风药治疗骨关节炎作用方式的计算机模拟比较
- 4 加味青娥丸治疗膝骨关节炎的作用机制研究
- 5 壮药骨痹方烫熨联合运动疗法治疗膝骨关节炎的

临床研究

- 6 重组人 II 型肿瘤坏死因子受体-抗体融合蛋白关节腔注射联合中药熏洗治疗膝骨关节炎的临床研究
- 7 核转录因子- κ B 在骨关节炎炎症反应中的作用
- 8 口服补肾活血通络方治疗膝骨关节炎
- 9 关节镜下清理术联合关节腔内注射玻璃酸钠治疗膝骨关节炎

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