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A CLINICAL STUDY OF THE PREVENTION OF POST LUMBER DISCECTOMY EPIDURAL SCAR ADHESION WITH POLYLACTIC ACID MEMBRANE

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[Abstract] **Objective**: To observe the clinical effect of the polylactic acid membrane in the prevention of epidural scar adhesion. **Methods**: From July 1998 to April 2000, 62 inpatients with lumbar dics herniation were randomly assigned into two groups: an experimental group with 32 patients and a control group with 30 patients. All patients were treated with surgical fenestration, laminectomy and lumbar discectomy. Patients in the experimental group were implanted with a 0.1 mm polylactic acid membrane covering the interlaminar space. Patients in the control group were not implanted with any acid membrane to cover the interlaminar space. Two weeks after the surgery, the patients were examined for symptoms of local and systemic negative reactions. Six months after the surgery, the patients were reevaluated for any clinical symptoms and CT scans were employed to examine the epidural scars. **Results**: Two weeks after the surgery, neither the experimental group nor the control group showed any local or systemic adverse reactions. Body temperatures were within normal range. Wounds healed in Phase I. No abnormalities were detected during hepatic and renal function or blood routine examinations. Six months after the surgery, the curative effects of the experimental group and the control group were as follows: excellent in 27 and 24 patients, good in 4 and 4 patients, fair in 1 and 1 patients, and poor in 0 and 1 patients, respectively. There was no significant statistical difference between the two groups ($P>0.05$). The CT scans showed no adhesion between the epidural scar and the dural sac in all patients from the experimental group, while various degrees of adhesion were found in the patients from the control group. **Conclusion**: The polylactic acid membrane effectively prevented epidural scar adhesion with good biocompatibility without toxity. The value of its clinical application is promising.

[Key words:] Polylactic acid membrane, lumbar discectomy, epidural adhesion, prevention

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[text in English omitted]

The epidural scar adhesion after lumbar discectomy and lumbar laminectomy decompression is suspected to be an important cause responsible for postoperative recurrence of pain[1]. The epidural scar adhesion also causes indistinct local anatomical structure, which increases the risk in possible future operations. Therefore, the prevention of epidural scar adhesion has become a noteworthy clinical issue in lumbar surgery.

Currently, one method more widely studied is to place certain materials in the epidural space. From July 1998 to April 2000, based on animal experiments, we conducted a clinical study on the prevention of epidural scar adhesion with the polylactic acid membrane, which was jointly developed by the Chinese Academy of Science and West China Medical University.

1. Clinical data

1.1 General data

Admission standards: inpatients who showed clinical symptoms and body signs, or were diagnosed with lumbar disc herniation as a result of imaging examination, or showed obvious surgical indications but without any serious complications of internal disease nor any surgical contraindications, and whose liver, kidney and blood routine examinations showed normal results will be enrolled into the study.

This study consisted of 62 patients with 37 males and 25 females between ages of 29 and 71 (average age: 41). The history of illness ranged from 2 months to 12 years. The cardinal symptoms of these patients were lumbago with radiating ache and numbness in lower limbs. L_s or S_1 hypaesthesia was found in examinations. Straight leg-raising test showed positive signs with average of 40 degrees. Affected areas: L_s-S_1 in 26 cases; L_{4-s} in 30 cases, and double herniation in L_{4-5} and L_s-S_1 in 6 cases. CT scans found 7 cases of combined lateral recess stenosis. The patients were randomly assigned into two groups, 32 cases in the experimental group and 30 cases in the control group.

[footnote:]

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1.2 Surgical method

A back middle incision was made under the continuous and regular epidural anesthesia. We performed laminectomy, laminar fenestration or complete laminectomy as we deemed necessary for the case, and removed nucleus pulposus after incising anulus fibrosus. Lateral recess augmentation was performed for patients with combined lateral recess stenosis. Patients in the

experimental group were placed with a thin layer of polylactic acid membrane in proper size (thickness: 0.1 mm) covering the interlaminar space with the edge of the membrane tightly attached to separate the dural sac from the muscles on posterior surface. The patients in the control group were not placed with a layer of polylactic acid membrane. All surgeries were performed by the same surgeon.

1.3 Indications of postoperation observation

2 weeks following the surgery, we observed the patients' body temperature, adverse systemic reactions, local wound healing and primitive neurological signs such as straight leg-raising test and sensation in the innervation area, and re-examined the hepatic and renal functions.

6 months following the surgery, we classified the patients based on their clinical recovery according to the preset criteria. Cured patients: clinical symptoms disappeared completely; the test results of straight leg-raising were negative and the patients' activities were not limited. Patients with significant improvement: the symptoms of pain or numbness disappeared essentially; the test results of straight leg-raising were negative and the patients' activities were not limited. Patients with some improvement: had lumbar or leg pains, became worse during activities; the test results of straight leg-raising were positive and the patients' activities were moderately limited. Patients with no success: had obvious pains; the patient's activities were limited significantly; the test results of straight leg-raising were positive; CT scans on the treated area showed epidural scar adhesion.

1.3 Statistical method

We used SPSS10.0 statistics software to conduct a sequential test assessing the results of the clinical recovery of such patients 6 months after the surgery. A value of $P<0.05$ would make a statistical significance.

2. Results

2 weeks after the surgery, all 62 patients had normal body temperature without systemic reactions; the wounds showed Phase I healing. 2 patients in the experimental group and 1 patient in the control group showed radiating limb pain after 2 days, which was considered to be the result of a reactive oedema caused by nerve root dragging during the operation, and was relieved after case-specific treatment. The other patients had their pain obviously relieved after the operation. The results of straight leg-raising were largely normal. Numbness in the innervation area was obviously relieved. Blood and liver/kidney function re-examinations showed normal values. 6 months after the surgery, the experimental group had 27 cases cured, 4 cases significantly improved, and 1 case improved; the control group had 24 cases cured, 4 cases markedly improved, 1 case improved and 1 case failed. There is no statistical difference between the two groups ($P>0.05$). According to the CT scans, latent interspace between dural sac and back muscle scar could be seen in the experimental group. No adhesion between scar tissue and dural sac and nerve root was found. In the control group, there was a different degree of adhesion between scar tissue and the dural sac or nerve root.

3. Typical cases

Case 1: Female, 31 years old. This patient had pain in her left limb for 3 months, which aggravated with numbness for 1 week before admission. Examination: patient felt tenderness in Ls next to the lumbar when pressed, tenderness in spinous process when tapped and hypaesthesia in the left Ls nerve root innervation, and had weak tensile strength in hallucis back. Straight

leg-raising test indicated 50 degrees. Intensified test results were positive. Reflection of tendo calcaneus weakened. CT scans showed L_s-S_1 disc herniation oppressing left nerve root. The inpatient received Ls laminar fenestration and L_s-S_1 nucleus pulposus removal with polylactic acid membrane placed in. The stitches were removed after 11 days with Phase 1 wound healing. The symptom of pain and numbness disappeared after 2 weeks. The results of straight leg-raising test were negative. Blood and liver/kidney function re-examinations indicated normal values. CT scans showed no obvious hyperplasia of epidural scar at left laminar fenestration. A latent interspace could be seen between the dural sac and scar (Fig. 1a and 2b).

Case 2: male, 33 years old. This patient had recurring pain and numbness in his right limb for 1 year before admission. Examination: the patient had hypaesthesia in right S_1 nerve root innervation, and level 3 right flexor hallacis without reflection. Straight right leg-raising test indicated a result of 30 degrees and intensified test a result of 20. CT scans showed a herniation of the right central L_s-S_1 disc. The patient received a double laminar fenestration and nucleus pulposus removal without polylactic acid membrane inserted. The pain and numbness in left limb was obviously relieved after 2 days. The stitches were removed after 11 days with Phase 1 wound healing. The result of a straight leg-raising test showed 70 degrees without pain after 2 weeks. Blood and liver/kidney function re-examinations indicated normal values. 6 months after the surgery, a lumbago accompanied with pain in limbs emerged. The result of a straight leg-raising test indicated 60 degrees without obvious limitation to the patient’s activities. CT scans indicated an epidural scar adhesion at laminar fenestration (Fig. 2a and 2b).

4. Discussion

4.1 Mechanism of epidural scar adhesion

Wd do not completely understand the mechanism of epidural scar adhesion. Key, Ford et al (1948) suggested that damaged anterior anulus fibrosus caused postoperative epidural scar adhesion, while LaRocca et al (1974) believed that hematoma anulus fibrosus at posterior vertabral lamina was the cause. The latter theory had been widely accepted until 1990s when Songer et al[2] created a stereo theory that damaged anterior anulus fibrosus, posterior longitudinal ligament and musculus sacrospinalis wounded area all might have contributed to the adhesion around dura mater and never root, i.e. epidural scar. Muscle-like hematoma had been considered as the major source of epidural scar for a long period. However, many foreign researchers recently suggested that operative wound, local inflammation caused by chemicals in nucleus pulposus, and changes of vascular permeability would be the key factors [3]. Based on experiments, Wang Huan et al also held the opinion that the existence of hematoma was not important and inflammatory exudation caused by operative wound should be responsible for the epidural scar. We believe that the scar adhesion of dural sac anterior and lateral nerve root have a close relationship with inflammation. The risk of epidural scar adhesion may be reduced by completely removing the nucleus pulposus and flushing residual nucleus pulposus at lumbar disc to reduce local inflammation. Early postoperative activities of straight leg-raising can also help reduce occurrence of never root adhesion. According to our experiment, no obvious growth of scar tissues at ventral dural sac were observed in the CT scans in both the experimental and control groups, and an adhesion between dorsal epidural scar tissues and the dural sac was only seen in the control group.

Fig. 1. Case 1: Preoperative CT Scans of the lumbar disc herniation of L_s-S_1: (a) before the surgery, the left nerve roots were obviously compressed; (b) 6 months after the surgery, the epidural scar formation was not obvious and a space existed between the epidural sac and the scar. Fig. 2. Case 2: Preoperative CT Scans of the lumbar disc herniation of L_s-S_1: (a) before the surgery, a central lumbar disc herniation was shown in the direction of the posterior side, and the dural sac was obviously compressed; (b) 6 months after the surgery, bone defect in the laminar fenestration developed and the fibrous scar proliferated and protruded into the vertebral canal.

[text in English omitted]

4.2 Function mechanism of polylactic acid membrane

The theoretical basis of the current methods and materials for the prevention of epidural scar adhesion is, first of all, the functionality of a mechanic barrier, i.e. using physical methods to prevent contacts between scar and dura mater, and, secondly, the utilization of biochemical methods or other methods to prevent the growth of fibrocytes or formation of hematoma. According to the prevailing views, the fibrocytes will emerge on the third day after being wounded. After 5-6 days, collagen is produced. The formation of collagen fibers is active in the subsequent week, and then slows down gradually. Along with the conversion of collagen fiber granulation tissues into scar tissues, the scar will be fully developed after 4 weeks [5] and mature after 8-9 weeks. JIN Da-di and XIONG Min, et al [6, 7] both observed in their animal experiments that the polylactic acid membrane was kept intact in the first 3 weeks during which the fibrocytes were most active to secrete collagen. And after about 8 weeks when most of the membrane was absorbed, an extradural latent interspace was developed. The membrane mainly acted as a barrier separating fibroblast and hematoma from the dural sac. A scar developed at the dorsal side after the membrane was absorbed would become a natural barrier, thus creating a natural interspace outside the dura mater. They also observed in the animal experiments thesparse collagen and inactive fibroblast hyperplasia in the application of the polylactic acid membrane set. The membrane might also have the function of suppressing fibroblast hyperplasia and collagen secretion.

4.3 Evaluation of the effects of polylactic acid membrane

A large number of materials have been so far used to prevent epidural scar adhesion. It has been proven that gelatin sponge contributes to the formation of scar. Autologous free fat shows poor viability and the possibility of causing compressed cauda equina or nerve root [8]. The application of macromolecule sodium hyaluronate is also arguable. It is deemed to have limited effect only

on lateral adhesion in 2-4 weeks after the surgery [9]. ADCON-L, a material widely studied in recent years, is a kind of collagen stroma produced by combining absorbable gelatin and carbohydrate, which can act as a barrier as well as suppressing the activity of fibroblast. However, according to some researchers, ADCON-L will suppress the rehabilitation of dural sac and aggravate the leakage of cerebrospinal fluid [10]. With excellent biocompatibility, polylactic acid membrane can be degraded in vivo only with mild transient tissue reaction [11]. Lee et al [12] discovered through their experiments that polylactic acid membrane can prevent the formation of epidural scar adhesion. According to domestic reports, the homemade polylactic acid membrane can significantly suppress the formation of epidural scar adhesion [6, 13]. Our earlier experiment also indicated that polylactic acid membrane can effectively prevent epidural scar and postlaminectomy adhesion [7]. Based on our 6-month follow-up after the surgery, we believe that the polylactic acid membrane can effectively prevent the epidural scar adhesion with a good biocompatibility without toxity and irritation to never root during degradation. Its clinical application is promising.

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SURGICAL TREATMENT OF DIABETIC FOOT

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The symptoms of diabetic foot are commonly seen among elder diabetics. If it is not treated properly, there will be a high risk of disability. From Jan 1985 to Jan 2002, we adopted a comprehensive treatment to 34 patients and achieved good results. The following is our report:

1. Clinical information

This group consisted of 34 patients, with 18 males and 16 females between ages 43-78. The patients had diabetic history between 8-35 years. Blood sugar level 2 hours after meals was 13-21 mmol/L. Ulcer area: 2 cases on heel, 8 cases on sole, 14 cases on foot sides, 6 cases in toes, 4 cases on dorsum, 12 cases of trauma, 14 cases of scratch, 2 cases of bedsore, 1 case of etching by anthelotics, 1 case of laser treatment, 1 case of scald and 3 cases of unknown causes. Ulcer scope: from 1.0cm×1.5cm to 5.0cm×7.0cm. 4 cases are Grade I ulcer, 20 cases Grade II, 9 cases Grade IV and 1 case Grade V. After admission, the patient began to control their diet and blood sugar. The blood sugar 2 hours after meals was maintained between 9-12 mmol/L during peri-operative period. Vasodilators and neural nutritious drugs were applied plus effective antibiotics to prevent overload on the affected foot. We debrided the wound thoroughly; removed necrotic and inactive tissues; performed full drainage; protected the granulation tissue; and wet dressed the wound with 0.1% peroxyacetic acid normal saline or mupirocin ointment.

11 cases healed after the treatment; 13 cases cured after free skin grafting; 9 cases healed after local rotation skin flap rehabilitation supplemented with skin grafting and 1 case received amputation; 33 cases were followed-up for 1 year and 28 cases experienced foot function

recovery; 1 case found eguinus; 4 cases found atrophia, among which 3 cases found recurrence (2 cases in heel and 1 case on lateral side) and could not heal for a long time.

2. Discussion

According to Thom, the sugar blood of diabetics during peri-operative period controlled below 8.78 mmol/L will result in less intraoperative or postoperative complications. GONG Min, et al believe that a fasting blood sugar<7.8 mmol/L and postprandial blood sugar<11.1 mmol/L is safer for surgery. CHEN Bao-xing thinks that blood sugar control should vary from different age groups. And DENG Shang-Ping believes that a fasting blood sugar<8.9 mmol/L and blood sugar 2 hours postprandialy<12.2 mmol/L is more suitable for elder patients. The blood sugar of the patients 2 hours after meals in this group was controlled below 11 mmol/L, and 12 mmol/L for elder patients. No serious problems found in intraoperation or postoperation. The wound healed very well.

Surgical treatment: according to Wagner Grading System, most ulcers below Grade I can autogenously heal with proper local treatment; ulcers of Grade II usually requires debridement, drainage and skin grafting with high risk of reoccurrence after healing. Among the 13 cases in this group received free skin grafting, 3 cases or 23% reoccurred; ulcers of Grade IV had local skin and soft tissue gangrene, tendon ligament exposure, destruction of bone and possible formation of sequestra, requiring surgery to remove necrotic tissues and local rotation skin flap rehabilitation. Most wounds healed over extended period with high risk of deformity (5 cases in this group or 55%). For ulcers of Grade V, i.e. complete necrosis, it essentially requires amputation.

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