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Effect analysis of sacral canal therapy combined with Fufang Wulingzhi Tangjiang in the treatment of residual root pain after lumbar surgery

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Abstract. – OBJECTIVE: To observe the clinical effect of a combination of traditional Chinese and western medicine (sacral canal therapy combined with compound Fufang Wulingzhi Tangjiang) in the treatment of residual root pain after lumbar surgery.

PATIENTS AND METHODS: From January 2019 to December 2020, 538 patients with residual root pain due to lumbar degenerative diseases were treated in our hospital [open decompression discectomy (ODD), Percutaneous Endoscopic Lumbar Discectomy (PELD) or Transforminal Lumbar Interbody Fusion (TLIF)]. They were randomly divided into control group (basic treatment + celecoxib), observation group 1 (basic treatment + compound Fufang Wulingzhi Tangjiang), observation group 2 (basic treatment + sacral canal therapy) and observation group 3 (basic treatment + sacral canal therapy + Fufang Wulingzhi Tangjiang). Follow-up 3-12 months. The therapeutic effect, VAS score, JOA score, treatment cost, complications, serum interleukin-6 (IL-6), interleukin-1 (IL-1) and tumor necrosis factor-a (TNF-α) were recorded and compared before treatment, 1 week after treatment, 2 weeks after treatment, 1 month after treatment, and the last follow-up.

RESULTS: The treatment effect, VAS score, JOA, and treatment cost in the observation group were better than those in the control group ($p < 0.05$). There were significant differences in the above-mentioned indexes between the observation group 3 and the control group, observation group 1, and observation group 2 ($p < 0$ 01). Inflammatory factors (IL-6, IL1, TNF-α) in the observation group were lower than those in the control group ($p < 0$ 05). Inflammatory factors in observation group 3 were significantly lower than those in the control group, observation group 1, and observation group 2 ($p < 0$ 01).

CONCLUSIONS: Sacral canal injection combined with Fufang Wulingzhi Tangjiang can be effective in the treatment of postoperative root pain of lumbar degenerative diseases, which can reduce inflammatory factors such as IL-6, IL-1β and TNF-α. It has the advantages of quick effect, short treatment time, low cost, high safety, in line with the concept of ERAS, easily accepted by patients and their families, and worthy of further popularizing and applying in clinic.

Key Words:
Lumbar degenerative disease, Lumbar surgery, Residual root pain, Sacral canal therapy, Fufang Wulingzhi Tangjiang.

Abbreviations

FBSS: Failed Back Surgery Syndrome; IL-1β: interleukin-1β; IL-6: interleukin-6; JOA: Japanese Orthopedic Association Score; LDD: lumbar degenerative diseases; LDH: lumbar disc herniation; LS: lumbar spinal stenosis; LS: lumbar spondylolisthesis; ODD: open decompression discectomy; ODI: Oswestry Disability Index; PELD: Percutaneous Endoscopic Lumbar Discectomy; TNF-α: tumor necrosis factor-a; TCM: Traditional Chinese Medicine; TLIF: Transforminal Lumbar Interbody Fusion; VAS: Visual Analog Score.

Introduction

With the continuous improvement of medical standards and people's quality of life, increasing patients with lumbar degenerative diseases (LDD) such as lumbar disc herniation (LDH), Lumbar spinal stenosis (LSS) and lumbar spondylolisthesis (LS) were treated by surgery. Although surgery can significantly improve the symptoms, but there were still some patients with postoperative residual root pain, low back discomfort, lower

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limb numbness, and other symptoms, sometimes even more than the preoperative degree. It seriously influenced the daily life and quality of life of patients, so how to alleviate postoperative pain was the key to improve the quality of life of patients after the operation, but there was no unified treatment plan up to date. Clinical treatment methods mainly include conservative treatment, surgical treatment, and interventional therapy[1]. Based on the application of self-made compound Fufang Wulingzhi Tangjiang in the treatment of lumbar postoperative root pain in our hospital[2], Fufang Wulingzhi Tangjiang was combined with traditional western medicine therapy sacral canal injection to treat lumbar postoperative root pain, and the effect was satisfactory.

Patients and Methods

General Data

A total of 3,840 patients with single-level lumbar degenerative diseases (LDH, LSS, or LS) were treated in our hospital from January 2019 to December 2020 [open decompression discectomy (ODD), Percutaneous Endoscopic Lumbar Discectomy (PELD) or Transforminal Lumbar Interbody Fusion (TLIF)]. 538 cases with postoperative residual root pain were randomly divided into control group (basic treatment + celecoxib), observation group 1 (basic treatment + Fufang Wulingzhi Tangjiang), observation group 2 (basic treatment + sacral canal injection) and observation group 3 (basic treatment + sacral canal injection + Fufang Wulingzhi Tangjiang). There was no significant difference in each group. See Table I for details.

Inclusion Criteria

– Combined with the patient's history, symptoms, and imaging examinations, it was clearly diagnosed as LDH, LSS, or LS. The diagnostic criteria of western medicine refer to the diagnostic criteria of the fourth edition of practical Orthopaedics[3]. The diagnostic criteria of Traditional Chinese Medicine (TCM) refer to the Diagnostic and therapeutic criteria of TCM, and TCM syndrome differentiation accords with Qi deficiency and blood stasis syndrome. There is general weakness, dark complexion, low back pain, fixed pain, refusal to press, purple tongue or ecchymosis, thin mass and astringent pulses.
– Patients with poor response after more than 3 months of systemic conservative treatment.
– No previous lumbar surgery history.
– No obvious surgical contraindications.
– Single segment, ODD, PELD or TLIF were performed, and postoperative symptoms of root pain occurred.
– Patients and their families had good compliance and were willing to cooperate with the treatment and follow-up.

Exclusion Criteria

– Previous lumbar surgery.
– 2 or more levels of lumbar surgery.
– Surgical treatment of lumbar fractures or tumors.
– Patients with type 2 diabetes.
– Root pain caused by iatrogenic factors: such as incomplete decompression or wrong decompression segment caused by preoperative diagnosis errors and missed diagnosis, nerve root compression or injury caused by improper internal fixation position.
– Internal fixation, loosening, or fracture during follow-up.
– Patients or family members had poor compliance and were unwilling to cooperate with treatment and follow-up.
– Patients with a history of psychological disorders.

Table I. Real time PCR primers.

	Gender			Disease type			Surgery		
	Male	Female	Average age (year)	LDH	LSS	LS	ODD	PELD	TLIF
Control Group	70	65	68.41 ± 5.39	68	49	18	19	71	45
Observation Group 1	71	69	68.89 ± 4.30	63	57	20	11	82	47
Observation Group 2	69	55	69.82 ± 3.70	53	47	24	9	69	46
Observation Group 3	78	61	69.98 ± 4.50	62	59	18	22	68	49
X^2/F	1.195		2.389		3.990		11.677		
p	0.754		0.068		0.678		0.232		

Treatment Processing

Routine preoperative preparation was performed in each group, and each operation was performed by the same doctor with senior professional title. Traditional Chinese medicine, orthopedics, routine treatment, and nursing were given after operation. Within 48 hours after the operation, routine antibiotics were used to prevent infection, hormone, and mannitol to reduce swelling and relieve pain. Functional exercise of the bilateral quadriceps femoris and ankle pump was performed on the first postoperative day, and the functional exercise of low back muscle was appropriately performed on the third postoperative day. Getting out of bed moderately with waist brace 5-7 postoperative days. After the symptoms of root pain, routine treatment was given, such as hormone and mannitol, local physiotherapy (electroacupuncture, intermediate frequency pulse, electrotherapy), and so on.

Control group: on the basis of routine treatment, celecoxib was given orally on the first day of root pain (0.2 g per tablet, Pfizer Pharmaceutical Co., Ltd., approval number: J20120063). 0.2 g, twice a day. Continuous administration for 2 weeks.

Observation group 1: on the basis of routine treatment, Fufang Wulingzhi Tangjiang[2] was given orally on the first day of root pain (main ingredients: Wulingzhi 80 g, frankincense 20 g, myrrh 20 g, Radix aconitum 30 g, Radix Aconiti 30 g, peppermint, water 10 mL. Preparation method: the above 6 flavors, except peppermint water, the other 5 flavors with appropriate amount of water, detected for 2 times, 2 h for the first time, boiled for 1.5 h for the second time, combined with 2 decoctions, filtered, filtrate concentrated two crude drug 2 g/mL, added 600 g sucrose and 3 g sodium benzoate, boiled to dissolve, and filtered. Adding boiling water to 1,000 ml, mix well, divide, and sterilize. Prepared by Li Shizhen Pharmaceutical Group Co., Ltd). Took 10-15 ml 3 times a day for 2 weeks.

Observation group 2: on the basis of routine treatment, sacral canal injection (0.9% sodium chloride 10 ml, 0.9% sodium chloride 10 ml + triamcinolone acetonide 1 ml) was given on the first day of root pain, and sacral canal injection was performed again 1 and 2 weeks later.

Observation group 3: on the basis of routine treatment, Fufang Wulingzhi Tangjiang (10-15 ml, 3 times a day for 2 weeks) + sacral canal injection (0.9% sodium chloride 10 ml, 0.9% sodium chloride 10 ml + triamcinolone acetonide 1 ml) was given on the first day of root pain, and sacral canal injection was performed again 1 and 2 weeks later.

Observation Index

1. Modified Macnab evaluation criteria: 1 week after treatment, 2 weeks after treatment, 1 month after treatment and the last follow-up. Excellent: symptoms completely disappeared, returned to the original work and life; Good: slight symptoms, mild restriction of activity, no effect on work and life; Fair: symptoms were relieved, activities were limited, affecting normal work and life; Poor: there was no difference before and after treatment, or even aggravated.
2. Visual Analog Score (VAS), Japanese Orthopedic Association Score (JOA), and Oswestry Disability Index (ODI): pre-operation, 1 week after treatment, 2 weeks after treatment, 1 month after treatment and the last follow-up.
3. Total cost of treatment (treatment-related costs from symptom onset to last follow-up).
4. Serum inflammatory factors (interleukin-6 (IL-6), interleukin-1β(IL-1β) and tumor necrosis factor-a (TNF-α)): before treatment, 1 week after treatment, 2 weeks after treatment, and 1 month after treatment.
5. Complications.

Statistical Analysis

Measurement data were expressed as the mean standard deviation (x±s). All data were analyzed *via* SPSS 23.0 software (IBM Corp., Armonk, NY, USA). Count data were compared with the Chi-square test. The independent sample F test was used for intragroup comparisons. $p < 0.05$ was considered statistically significant, and $p < 0.01$ was deemed highly significant.

Results

Modified Macnab Evaluation Criteria

1 week after treatment, the modified Macnab evaluation criteria in observation group 3 were better than those in other groups ($p < 0.05$), and the modified Macnab evaluation criteria of 2 weeks after treatment, 1 month after treatment and the last follow-up were significantly better than those in other groups ($p < 0.01$) (Table II).

Table II. Modified Macnab evaluation criteria.

	1 week after treatment				2 weeks after treatment				1 month after treatment				The last follow-up			
	Excellent	Good	Fair	Poor	Excellent	Good	Fair	Poor	Excellent	Good	Fair	Poor	Excellent	Good	Fair	Poor
Control group	22	25	59	29	28	28	58	21	29	42	53	11	43	57	29	6
Observation group 1	25	33	55	27	30	37	59	14	40	47	48	5	51	52	36	1
Observation group 2	23	27	49	25	30	34	51	9	30	34	52	8	30	34	52	8
Observation group 3	31	36	60	12	38	43	57	1	53	44	42	0	67	59	13	0
F	2.682				4.176				6.521				16.446			
p	0.046				0.006				0.0002				≤ 0.001			

Table III. VAS.

	Before treatment	1 week after treatment	2 weeks after treatment	1 month after treatment	The last follow-up
Control group	7.35 ± 1.28	7.36 ± 0.99	6.45 ± 1.53	4.53 ± 0.81	3.04 ± 1.59
Observation group 1	7.50 ± 1.44	6.77 ± 1.04	3.97 ± 0.94	3.04 ± 1.20	1.52 ± 0.90
Observation group 2	7.37 ± 1.40	6.88 ± 1.13	3.79 ± 1.08	3.79 ± 1.08	3.58 ± 0.93
Observation group 3	7.51 ± 1.57	6.47 ± 1.32	2.37 ± 0.87	1.56 ± 0.88	0.95 ± 0.59
F	0.287	16.027	266.936	183.082	150.506
p	0.835	≤ 0.001	≤ 0.001	≤ 0.001	≤ 0.001

VAS

There was no significant difference in VAS before treatment ($p < 0.05$). 1 week after treatment, there was a significant difference among all groups ($p < 0.01$), and there was a significant difference between the control group and observation group 1, 2, and 3 ($p < 0.01$). There was no significant difference between observation group 1 and observation group 2 ($p > 0.05$), and there was a significant statistical difference between observation group 3 and the control group, observation group 1, and observation group 2 ($p < 0.01$). 2 weeks after treatment, there was a significant difference among all groups ($p < 0.01$). There was a significant difference between the control group and observation group 1, 2, and 3 ($p < 0.01$). There was no significant difference between observation group 1 and observation group 2 ($p > 0.05$), and there was a significant statistical difference between observation group 3 and the control group, observation group 1, and observation group 2 ($p < 0.01$). 1 month after treatment and the last follow-up, there were significant differences among all groups ($p < 0.01$), and there were significant differences between each group ($p < 0.01$) (Table III).

JOA

There was no significant difference in JOA before treatment ($p < 0.05$). 1 week after treatment, there was a significant difference among all groups ($p < 0.01$), and there was a significant difference between the control group and observation groups 1, 2, and 3 ($p < 0.01$). There was no significant difference between observation group 1 and observation group 2 ($p > 0.05$), and there was a significant statistical difference between observation group 3 and the control group, observation group 1, and observation group 2 ($p < 0.01$). 2 weeks after treatment, there was a significant difference among all groups ($p < 0.01$). There was a significant difference between the control group and observation groups 1, 2, and 3 ($p < 0.01$). There was no significant difference between observation group 1 and observation group 2 ($p > 0.05$), and there was a significant statistical difference between observation group 3 and the control group, observation group 1, and observation group 2 ($p < 0.01$). 1 month after treatment and the last follow-up, there were significant differences among all groups ($p < 0.01$), and there were significant differences between each group ($p < 0.01$) (Table IV).

Total Costs of Treatment

There was no significant difference in total cost among all groups ($p > 0.05$) (Table V).

Serum Inflammatory Factors

There was no significant difference in serum inflammatory factors (IL-6, IL-1β, TNF-α) before treatment ($p < 0.05$). 1 week after treatment, there was a significant difference among all groups ($p < 0.01$), and there was a significant

Table IV. JOA.

	Before treatment	1 week after treatment	2 weeks after treatment	1 month after treatment	The last follow-up
Control group	7.09 ± 4.09	13.77 ± 6.92	14.82 ± 7.14	16.69 ± 6.98	17.58 ± 6.23
Observation group 1	7.83 ± 4.08	15.19 ± 7.34	16.84 ± 7.22	19.20 ± 6.29	20.65 ± 5.79
Observation group 2	7.24 ± 4.26	15.43 ± 7.08	16.70 ± 6.74	18.37 ± 6.67	19.04 ± 6.91
Observation group 3	7.40 ± 4.24	17.57 ± 6.77	19.09 ± 6.24	20.89 ± 5.91	23.46 ± 4.69
F	0.723	5.741	9.111	10.039	24.271
p	0.539	0.001	≤ 0.001	≤ 0.001	≤ 0.001

Table V. Total cost of treatment.

	Total cost (Thousand Yuan)
Control group	2.57 ± 0.26
Observation group 1	2.54 ± 0.26
Observation group 2	2.55 ± 0.26
Observation group 3	2.56 ± 0.27
F	0.220
p	0.882

difference between the control group and observation groups 1, 2, and 3 ($p < 0.01$). There was no significant difference between observation group 1 and observation group 2 ($p > 0.05$), and there was a significant statistical difference between observation group 3 and the control group, observation group 1, and observation group 2 ($p < 0.01$). 2 weeks after treatment, there was a significant difference among all groups ($p < 0.01$). There was a significant difference between the control group and observation groups 1, 2, and 3 ($p < 0.01$). There was no significant difference between observation group 1 and observation group 2 ($p > 0.05$), and there was a significant statistical difference between observation group 3 and the control group, observation group 1, and observation group 2 ($p < 0.01$). 1 month after treatment and the last follow-up, there were significant differences among all groups ($p < 0.01$), and there were significant differences between each group ($p < 0.01$). See Tables VI, VII, and VIII for details.

Complications

During the follow-up period, there were no treatment-related complications in all groups.

Discussion

At present, posterior lumbar surgery is the main treatment for LDD such as LDH and LSS, and the curative effect is positive, but there are still some patients with postoperative low back pain and/or lower limb root pain symptoms, sometimes aggravated after temporary relief, at the point that even in the normal site before operation numbness, pain and other neurological symptoms appear, leading to the syndrome that some scholars call Failed Back Surgery Syndrome (FBSS)[4,5].

Postoperative root pain is characterized by persistent pain in the nerve root innervation area of the lower limbs, which can be due to many reasons. At present, it is mainly considered related to the following factors: (1) Incomplete decompression or wrong decompression level caused by misdiagnosis and missed diagnosis; (2) Nerve root edema and demyelination caused by nerve root traction during operation; (3) Postoperative

Table VI. IL-6 (pg/mL).

	Before treatment	1 week after treatment	2 weeks after treatment	1 month after treatment
Control group	77.03 ± 6,54	53.67 ± 5.93	49.52 ± 5.19	45.21 ± 5.50
Observation group 1	76.08 ± 5.31	51.52 ± 5.94	45.78 ± 5.88	41.74 ± 3.94
Observation group 2	75.97 ± 4.52	51.93 ± 4.55	46.35 ± 5.80	43.72 ± 4.08
Observation group 3	77.35 ± 6.37	48.09 ± 4.06	43.29 ± 4.56	37.73 ± 4.82
F	1.896	27.473	30.778	66.249
p	0.129	≤ 0.001	≤ 0.001	≤ 0.001

Table VII. IL-1β (pg/mL).

	Before treatment	1 week after treatment	2 weeks after treatment	1 month after treatment
Control group	20.82 ± 2.70	19.98 ± 2.09	16.29 ± 2.28	14.29 ± 2.02
Observation group 1	21.16 ± 2.90	17.19 ± 1.88	14.22 ± 1.89	11.92 ± 1.99
Observation group 2	21.46 ± 2.97	17.38 ± 2.08	14.40 ± 1.56	12.62 ± 1.18
Observation group 3	21.38 ± 2.92	16.57 ± 1.55	12.95 ± 1.20	10.75 ± 0.96
F	1.339	84.273	81.056	114.310
p	0.261	≤ 0.001	≤ 0.001	≤ 0.001

Table VIII. TNF-α (pg/mL).

	Before treatment	1 week after treatment	2 weeks after treatment	1 month after treatment
Control group	5.12 ± 0.70	4.30 ± 0.67	3.80 ± 0.42	3.75 ± 0.44
Observation group 1	5.11 ± 0.62	3.67 ± 0.52	3.32 ± 0.38	2.84 ± 0.35
Observation group 2	5.23 ± 0.67	3.74 ± 0.59	3.40 ± 0.39	2.98 ± 0.29
Observation group 3	5.10 ± 0.60	3.04 ± 0.43	2.98 ± 0.30	2.13 ± 0.28
F	1.122	116.066	109.142	187.756
p	0.340	≤ 0.001	≤ 0.001	≤ 0.001

scar formation and nerve root adhesion around the nerve; (4) The nerve root was squeezed or injured due to the improper position of internal fixation. Most scholars[5-7] believe that root pain is caused by scar formation and nerve root adhesion. At present, there is no unified treatment plan, and the commonly used ones include conservative treatment (drugs, local physiotherapy), minimally invasive interventional surgery, and reopen surgery. Patients and their families generally have doubts about reoperation (minimally invasive intervention, reopening). Daniell and Osti[4] showed that patients who have undergone 2, 3, or even 4 operations have a success rate of less than 30%, 15%, and 5%, respectively.

A large number of domestic and foreign literature[8,9] reported that sacral canal has achieved a good clinical effect in the treatment of low back pain. Wei et al[10] showed that in sacral canal treatment, the liquid formed a liquid peeling effect through the epidural space during the injection of drugs, which loosened the nerve root adhesion to a certain extent, reduced the nerve root edema and adhesion, controlled the aseptic inflammation in the spinal canal, and improved symptoms. The results of our study were the same as the above conclusions. The serum levels of TNF-α, IL-1β, and IL-6 in observation groups 2 and 3 decreased significantly at 1 week, 2 weeks, and 1 month after treatment, and were consistent with the decrease of VAS and the increase of JOA at 1 week, 2 weeks and 1 month after treatment. It suggested that sacral canal injection can reduce the expression of serum inflammatory factors and improve VAS and JOA. The combined effect of sacral canal injection + oral compound Fufang Wulingzhi Tangjiang was better than that of sacral canal injection alone, and the difference was statistically significant ($p < 0.01$).

Traditional Chinese medicine believes that LDD (LDH, LSS, LS) belongs to the category of "low back pain" and "arthrosporous". Due to various factors such as abnormal posture, lumbar strain, fall injury, improper exertion, and so on, qi and blood stasis are caused by spinal and lumbar muscle injury, leading to obstruction of meridians, resulting in pain[11]. It can be seen that qi stagnation and blood stasis are the keys to post-operative root pain, therefore the treatment should activate qi, promote blood circulation and warming, and reactivate meridians[1].

The self-made compound Fufang Wulingzhi Tangjiang in our hospital was composed of Wulingzhi, frankincense, myrrh, Aconitum radix, Aconiti radix, and other drugs, which had the effect of dispelling blood stasis and relieving pain, warming and activating meridians, focusing on solving the blood stasis and wind-cold blocking collaterals after lumbar surgery. Wulingzhi dispelled blood stasis and relieved pain, frankincense promoted blood circulation, relieved swelling, and promoted muscle myrrh dispelled blood stasis. Aconitum Radix and Aconiti Radix dispelled wind, dehumidification, warmed menstruation and relieve pain[12]. Frankincense-myrrh is a commonly used compatible drug for promoting blood circulation and removing qi and blood stasis. Frankincense was warm, good at promoting blood circulation and relieving pain, myrrh had strong bitterness, good at dispersing blood and removing blood stasis[13].

Clinical trials and a large number of animal experiments have confirmed that frankincense extract and various monomer components have significant anti-inflammatory effects[14,15]. In our study, the serum levels of TNF-α, IL-1 β, and IL-6 in observation group 1 and 3 decreased significantly at 1 week, 2 weeks, and 1 month after treatment, which was consistent with the decrease of VAS and the increase of JOA at 1 week, 2 weeks and 1 month after treatment. It was suggested that Fufang Wulingzhi Tangjiang could reduce the expression of inflammatory fac-

tors and improve the VAS and JOA of patients. The combined effect of sacral canal injection + oral compound Fufang Wulingzhi Tangjiang was better than that of oral compound Fufang Wulingzhi Tangjiang alone, and the difference was statistically significant ($p < 0.01$).

Conclusions

Sacral canal injection combined with Fufang Wulingzhi Tangjiang can be effective in the treatment of postoperative root pain of lumbar degenerative diseases, which can reduce inflammatory factors such as IL-6, IL-1β and TNF-α. It has the advantages of quick effect, short treatment time, low cost, high safety, in line with the concept of ERAS, easily accepted by patients and their families, and worthy of further popularizing and applying in clinic.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Ethics Approval

This research was approved by Hubei 672 Orthopedics Hospital of Integrated Chinese and Western Medicine Ethics Committee (Wuhan, China; permit No. HB6720425) and was in conformity with the guidelines of the National Institute of Health.

Informed Consent

Written informed consent was formally obtained from all participants.

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Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' Contribution

W. Xie, J. Tang and X.-G. Li made substantial contributions to the study conception and design, acquisition of data, and the analysis and interpretation of data. C.-J. Wu, Y. Li, Q.-L. Lu, and X.-W. Gan contributed to drafting the manuscript and critically revising the manuscript for important intellectual content. W. Xie and J. Tang prepared the manuscript. All authors read and approved the final manuscript.

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