Retrospective Study

Risk Factors Affecting the Success Rate of Radiofrequency Thermocoagulation of Lumbar Sympathetic Nerve

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Background: Computed tomography (CT)-guided radiofrequency thermocoagulation of lumbar sympathetic nerve has been gradually applied to the treatment of many autonomic nerve disorders, such as plantar hyperhidrosis (PH) and diabetic peripheral neuropathy (DPN). The difference in the success rate of operation between the left and right sides is not yet studied.

Objective: This study aimed to explore a statistically significant difference between the success rate of left and right CT-guided radiofrequency thermocoagulation of lumbar sympathetic nerve and screen the risk factors affecting the success rate of the right surgery.

Study Design: This is a single-center retrospective cohort study.

Setting: The study was carried out in the Pain Department of the affiliated Hospital of Jiaxing College in Jiaxing, China.

Methods: A total of 86 patients who received CT-guided radiofrequency thermocoagulation of lumbar sympathetic nerve were included in this study approved by the Ethics Committee of the affiliated Hospital of Jiaxing University. Nonparametric and chi-square tests were used to compare the operation times, CT scan times, and success rate on the left and right sides. Binary multivariate logistic regression analysis was applied to screen the risk factors on the outcome variable.

Results: The bilateral operation time, CT scan times, and success rate differed significantly between the left and right sides ($P < 0.05$). After univariate analysis, 6 covariates (gender, body mass index, treatment history, operation time, CT scan times, and puncture needle type) were selected. Finally, the multivariate regression model screened out 2 risk factors: the operation time and puncture needle type.

Limitations: We look forward to increasing the sample size in follow-up studies and exploring relevant conclusions in randomized controlled trials.

Conclusion: This study proved that in CT-guided radiofrequency thermocoagulation of the lumbar sympathetic nerve, the difficulty of operation on the right side was significantly high, and the success rate was also lower than that on the contralateral side. Multivariate logistic regression analysis showed that operation time and type of puncture needle were risk factors affecting the success rate of the operation. These findings laid a foundation for the accomplishment of technical improvement and innovation in the future. A preliminary exploration was carried out to reduce the risk and complications and to improve the success rate of the operation.

Key words: Sympathetic nerve, thermocoagulation, logistic regression, risk factor

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The treatment of sympathetic hyperfunction diseases (such as hyperhidrosis and Raynaud's disease) has gradually entered the era of minimally invasive therapy (1). Chemical lumbar sympathectomy is one of the representative treatment methods in the early stage. As a commonly used lesion solvent, anhydrous ethanol provides an acceptable range of damage, causing many surgery-related complications (2). Computed tomography (CT)-guided radiofrequency thermocoagulation of lumbar sympathetic nerve introduces CT into lumbar sympathetic nerve assisted by puncture and accurate location during the operation. The destruction mode of thermocoagulation is safe and can be controlled compared with anhydrous ethanol. The research on radiofrequency thermocoagulation of the lumbar sympathetic nerve mainly focuses on evaluating the postoperative curative effect. Interestingly, several studies have reported the safety and short-term efficacy of radiofrequency thermocoagulation of the lumbar sympathetic nerve in treating hyperhidrosis and other diseases (3). Compared to chemical lumbar sympathetic modulation, radiofrequency thermocoagulation can achieve satisfactory results and significantly reduce the occurrence of operation-related complications and improve patient satisfaction.

Furthermore, studies on radiofrequency thermocoagulation of lumbar sympathetic nerve in diseases related to sympathetic hyperfunction vary according to the individuals and the differences in the spatial location and the number of ganglia of the lumbar sympathetic nerve. In long-term clinical work, we found that in the bilateral lumbar sympathetic radiofrequency in the same patient, the right side requires more time than the left side. Based on the objective clinical phenomena, this study aimed to explore the statistically significant difference between the left and right sides of lumbar sympathetic nerve surgery after radiofrequency ablation under CT guidance and screen the risk factors affecting the outcome variables through logistic regression. These processes would be helpful in clinical practice and optimize the lumbar sympathetic radiofrequency thermocoagulation.

Methods

Inclusion Criteria and Exclusion Criteria

This study was approved by the Ethics Committee of the affiliated Hospital of Jiaxing University in Jiaxing, China, and a total of 86 patients who underwent CT-guided radiofrequency thermocoagulation of lumbar sympathetic nerve in our hospital from October 2015 to October 2019 were included in this retrospective survey.

Inclusion criteria: 1) suffering severe clinical symptoms and significantly affecting the daily life of patients; 2) cannot be relieved after treatments of drugs or other conservative measures; 3) refuse to open and endoscopic lumbar sympathectomy, or cannot tolerate general anesthesia; 4) agreed to accept CT-guided radiofrequency thermocoagulation and signed the informed consent.

Exclusion criteria: 1) owning the previous history of lumbar trauma or surgery; 2) congenital or acquired scoliosis (severe hunchback or scoliosis); 3) preoperative thrombocytopenia or coagulation dysfunction; 4) a temperature difference of less than 2°C after anhydrous ethanol rescue; 5) combined with lumbar disc herniation; 6) severe allergy to the local anesthetic or related chemical agents; 7) unilateral or bilateral multi-segmental surgery.

Surgical Procedure

After entering the room, the venous access was opened to monitor oxygen saturation (SpO_2), non-invasive blood pressure (NIBP), and foot temperature (T). The patients laid in a prone position. The method of spinous process count was applied to find the L2-L3 intervertebral space, then 3 mm was considered as the interval for scanning until the best puncture plane was selected. The puncture path was drawn using the software of CT machine, and then the puncture depth and angle were determined. After that, the intersection point with the body surface was the puncture point, and the distance between the needle entry point and the midline was recorded. Finally, we used infrared rays to calibrate the puncture point of the body surface. According to the proposed puncture path under CT guidance, 21G radiofrequency puncture needle was inserted into the anterior lateral edge of the cone through the paraspinal space of L2-L3. If the image confirmed that the position and direction of the radiofrequency puncture needle were correct, the needle was entered directly along that path to the target. In contrast, in case of a deviation in the position and direction of the puncture needle, the needle was adjusted according to the CT scan images. Finally, the needle was guided to reach the puncture target under the CT guidance, and then, exercise and sensory tests were carried out before radiofrequency thermocoagulation. The parameters of the sensory test were set at 0.1-0.5 V and 50 Hz frequency. If discomfort, such as soreness, swelling, numbness, or tingling, was induced, the sensory tests were positive. Low-frequency current was used in the exercise test, and the parameters were set at 0.1-0.5 V and a frequency of 2 Hz; if it caused fibrillation and pulsation of the trunk muscle fibers in the corresponding segments, the exercise test was positive. After the exercise and sensory tests were negative, radiofrequency thermocoagulation was performed at 95° for 120 s and repeated for 2 cycles. The temperature > 2°C before and after the operation was considered successful. For the patients with the poor effect of radiofrequency thermocoagulation, 1-3 mL anhydrous ethanol was injected into the clinical process of non-intervention as an intraoperative remedy. The CT scan was performed again after needle withdrawal, the vital signs were stable, and the patient was returned to the ward safely after the operation.

Calculation of Sample Size

In this study, the success rate of the operation was considered as the main observation endpoint of the study. Pearson's chi-square test was used for statistical analysis (α = 0.05, power = 0.80, p1= 0.56; p2 = 0.34), and NCSS PASS 11.0 software was used to calculate the sample size. The sample size of this study was calculated as at least 81, and a total of 86 patients were included in the study.

Statistical Analysis

The demographic data (gender, age, body mass index (BMI), treatment history) and operation-related data (operation time, times of CT scan, and puncture segments) were analyzed. SPSS Version 26.0 (IBM, Chicago, IL) was used to analyze the data. Shapiro–Wilk test was used to determine whether the measurement data obeyed normal distribution and were expressed as mean ± standard deviation, while the non-normal distribution data were expressed by median (quartile interval). Paired sample t test was used to compare the differences among measurement data, and the chi-square test was used to compare the differences between counting data. We used the Wilcoxon test to analyze the non-normal distribution data.

Several candidate variables that might affect the outcome were included in the demographic data (age, gender, BMI, and treatment history) and operation-related data (puncture needle type, puncture segment, operation time, and times of CT scan) as covariates. Some variables, such as height, weight, and needle adjustment, are closely related to BMI and CT scan times, so none were included as candidate variables for univariate analysis. BMI is set as a binary variable with a binding value of 24.9 (4). The fourth classification data are based on the quartile; the setting of the third classification data was based on the limited range of p25 and p75 or combined with the actual data for simple classification; the remaining variables were adjusted to the second classification data. The candidate variables were screened by univariate analysis, and the *P*-value was adjusted to 0.2. In the univariate analysis, the candidate variables with $P < 0.2$ were included in the multifactor regression model. The importance of the variables to be included in the multifactor analysis was evaluated using categorical regression (CATREG); the corresponding variables were classified, and virtual variables were set, and the reference was adjusted according to the variable change correlation. In addition, a linear correlation was established between the candidate variables, and the logit transformation of the outcome variables was evaluated by Box–Tidwell test (5). The covariables included in the model were collinearly diagnosed using the variance expansion factor in the multiple regression model, the mediating variables with large interference were eliminated, and the significant outliers were eliminated by combining Cook's distance. The Hosmer–Lemeshow test was used to evaluate the fitting status of the regression model, and the -2 log-likelihood ratio was used to assess the overall significance of the model. Finally, a binary multifactor logistic regression model was established to screen the risk factors that affect the success rate of right radiofrequency thermocoagulation of lumbar sympathetic nerve under the CT guidance.

Results

Demographic Data

A total of 86 patients were included in this study. Table 1 lists the demographic data and some operation-related data, such as age, gender, height, weight, BMI, course of the disease, treatment history, and family history.

Operation Related Data

Data related to the operation are listed in Table 2. The operation time of CT-guided lumbar sympathetic radiofrequency thermocoagulation on the left and right sides was 15.00 (10.00-23.00) and 17.50 (12.00-

Table 1. *Demographics and operation related data in pain department.*

Parameter	No.	%
Population		
Total	86	100
Gender		
Female	42	48.8
Male	44	51.2
Age		
< 30	9	10.5
30-59	48	55.8
≥ 60	29	33.7
Height		
< 165	42	48.8
≥ 165	44	51.2
Weight		
< 59.5	43	50
≥ 59.5	43	50
BMI		
≤ 24.9	67	77.9
> 24.9	19	22.1
Course of disease		
< 2	18	20.9
2-9.9	23	26.7
10-16.9	23	26.7
≥ 17	22	25.6
Treatment history		
No	25	29.1
Yes	61	70.9
Drug	31	36
Acupuncture	18	20.9
Surgery	12	14
Family history		
No	73	84.9
Yes	13	15.1
Time of surgery		
< 12	19	22.1
12-28.24	46	53.5
≥ 28.25	21	24.4
CT scan times		
< 5	34	39.5
5-9	45	52.3
≥ 10	7	8.1
Type of puncture needle		
Straight needle	64	74.4
Bend needle	22	25.6

Table 1 (cont.). *Demographics and operation related data in pain department.*

Parameter	No.	%
Puncture segment		
L2	19	22.1
L3	67	77.9

BMI: body mass index.

Table 2. *Operation related data between 2 groups.*

Variable	Groups		*P* value
	Left	Right	
Operation time, median (IQR), min	15.00 (10.00-23.00)	17.50 (12.00-28.25)	< 0.05
CT scan times, median (IQR), time(s)	4.50 (3.00-6.00)	5.00 (4.00-7.00)	< 0.05
Rate of success [n (%)]	48 (55.81)	29 (33.72)	< 0.05

Operation time: the time from the beginning of the puncture to the time of pulling out the needle; CT scan times: the number of scanning sequences from the beginning of the puncture to the end of the radio frequency; Rate of success: the ipsilateral temperature difference of more than 2° before and after operation was recorded as a successful operation.

28.25), and the times of CT scan were 4.50 (3.00-6.00) and 5.00 (4.00-7.00), respectively. The success rate of the left side was significantly higher than that of the right side (left: 55.81%, right: 33.72%, $P < 0.05$).

Multivariate Logistic Regression Analysis

A total of 6 covariables were included in the model after the variable screening. These variables include gender, BMI, treatment history, operation time, times of CT scan, and puncture needle type. Among these, times of CT scan and operation time were set as virtual variables after classification. The first type was set as a reference, according to the results of the CATREG, and the variance inflation factor (VIF) was < 5. It was concluded that there was no multicollinearity among the variables. The Durbin–Watson test revealed that all the variables were independent, the percentage of the model prediction was about 83.5%, and the significance of the Hosmer-Lemeshow test was > 0.05. After excluding an obvious outlier, a total of 85 samples were included in the multifactor regression analysis. The results of logistic regression analysis suggested that the time of operation and the type of puncture needle were the risk factors affecting the success rate after the operation (Fig. 1).

When the operation time was between 12 and 28.5 min and < 12 min, the probability of effective operation was 0.123 (odds ratio (OR): 0.123, 95% confidence interval (CI): 0.025-0.602), and that of using curved needle compared to the straight needle was 4.217 (OR: 4.217, 95% CI: 1.003-17.728) (Table 3).

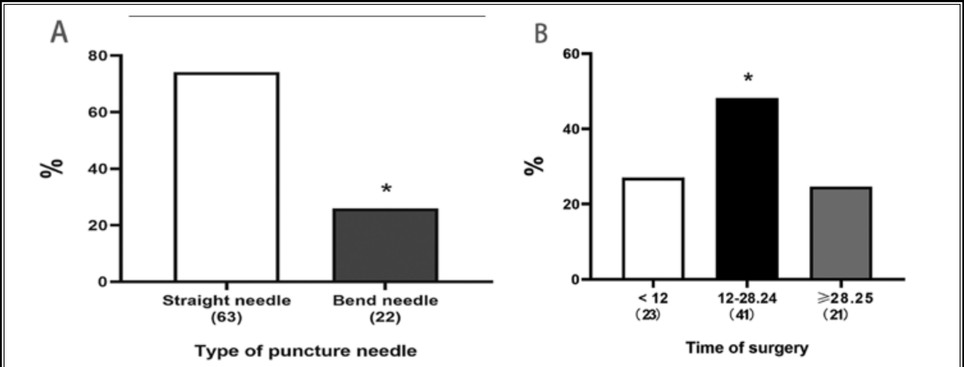

Fig 1. *Point prevalence of surgical outcome in type of puncture needle (A) and time of surgery (B). Patients were stratified according to the type of puncture needle and time of surgery. *P value < 0.05, which indicates significant difference between each category and the reference.*

Discussion

Lumbar sympathectomy is a surgical method for lumbar sympathetic nerve modulation. Currently, there are several methods to perform lumbar sympathetic nerve resection, including open surgery or endoscopy-directed amputation, chemical agent damage, or high-temperature thermocoagulation. These methods can cut off nerve conduction signals, improve vascular tension and glandular secretory function, and relieve pain (6). Sympathetic hyperfunction is related to the occurrence and development of many diseases, such as hyperhidrosis, Raynaud's disease, arteriosclerosis obliterans, and diabetic peripheral neuropathy (7-10). Abnormal vasoconstriction or gland secretion dysfunction of sympathetic innervation is crucial pathogenesis of sympathetic innervation and participates in the pathophysiological processes of all kinds of pain (11). It has been proven that sympathetic nerve modulation significantly improves the condition, provides a good short-term effect, and improves the quality of life of this disease caused by autonomic nerve dysfunction. Also, chronic painful diseases of lower extremities have attracted increasing social attention because of their lower quality of life and elevated medical expenses and social burden (12). In recent years, lumbar sympathetic nerve modulation has been extended to the treatment of chronic pain such as complex regional pain syndrome, phantom limb pain, and post-herpetic neuralgia (13-17). Presently, the types of diseases around lumbar sympathetic modulation are extensive, and technological innovation has become an irreversible trend.

Endoscope-assisted lumbar sympathectomy has gradually become the mainstream surgical treatment because of the maturity of endoscopic technology.

Table 3. *The correlation of different factors with postoperative curative effect.*

Variable	Multivariable Analysis		
	P value	Odds radio	95% CI
Gender			
Female	Reference		
Male	0.693	0.771	0.212-2.806
BMI			
≤ 24.9	Reference		
> 24.9	0.545	1.624	0.338-7.802
Treatment history			
No	Reference		
Yes	0.071	0.289	0.075-1.113
Type of puncture needle			
Straight needle	Reference		
Bent needle	0.049	4.217	1.003-17.728
Time of surgery			
< 12	Reference		
12-28.24	0.010	0.123	0.025-0.602
≥ 28.25	0.140	0.149	0.012-1.867
CT scan times			
< 5	Reference		
5-9	0.300	0.392	0.067-2.307
≥ 10	0.664	0.488	0.019-12.369

Values that are statistically significant are set in bold and italic.
BMI: body mass index; CI: confidence interval.

The postoperative effect is the most prominent advantage of this surgical method (18,19). However, elderly patients with cardiopulmonary insufficiency cannot tolerate surgery and general anesthesia compared to minimally invasive technology. Among these methods, the chemical destruction technique mainly depends on phenol or anhydrous alcohol to achieve sympathetic nerve destruction (2,20,21). Tsitskari et al (2) reported a satisfactory curative effect in a short time after the operation, but the recurrence rate was high after 1 year, and the abnormal diffusion after anhydrous alcohol injection may cause adverse reactions, such as injury to the surrounding tissue and involvement of the adjacent nerves (20).

Radiofrequency thermocoagulation of lumbar sympathetic nerve uses the bare end of the radiofrequency needle to produce a high temperature of > 90°C to destroy nerve fibers and myelin sheath locally (22). In idiopathic hypersympathetic diseases, the physical thermocoagulation of sympathetic fibers reduces the nerve impulse emission of the fiber bundle when the temperature of the bare segment of the radiofrequency needle, the radiofrequency duration, and the repetitive radiofrequency cycle are optimal. The resulting effect was similar to that of nerve resection under direct vision. In previous minimally invasive operations, the puncture location was identified under a C-arm machine guidance (23). However, the puncture needle's imaging under the C-arm machine was poor; the imprecise position of the needle tip necessitated repeated adjustment of the puncture angle and depth of the radiofrequency needle, which rendered it difficult to achieve the ideal therapeutic effect while prolonging the operation time. Zhu et al (24) used CT angiography to determine the safe path of the lumbar sympathetic block; the imaging effect was satisfactory. In this study, all punctures were performed under CT guidance to improve the accuracy and safety of puncture location.

In this study, the operation time, the times of CT scan, and the success rate of bilateral surgery were compared; the operation time of the right side was significantly longer than that of the left side, the times of CT scan increased significantly, and the success rate of bilateral operation was statistically significant between the 2 sides. These results suggested that the right lumbar sympathetic radiofrequency operation was more difficult than that of the left, with a low success rate.

The risk factors affecting the success rate of the right side were screened by multivariate logistic regression analysis. The sample independence test and linear hypothesis were completed after the candidate variables were identified. Directed acylic graph (DAG) described the correlation between the respective variables included in the study and the outcome variables. The univariate analysis preliminarily screened the covariates and finally adjusted the gender, BMI, treatment history, puncture needle type, operation time, and times of CT scan as covariates, excluding the multicollinearity among variables. After multifactor analysis with stepwise regression, CATREG was used to analyze the importance of the included variables, and the virtual variables were set up to adjust the reference. The multivariate regression analysis results showed that the operation time and the type of puncture needle were the risk factors affecting the success rate. When the operation time was 12-28.5 min and < 12 min, the probability of effective operation was 0.123, and that of using a curved needle during the operation was 4.217 compared to that of the straight needle.

Typically, 2-6 pairs of lumbar sympathetic ganglia in normal adults and 4-5 pairs are observed in most people. The left lumbar sympathetic nerve runs in the posterior medial side of the abdominal aorta and is located at the anterolateral edge of the lumbar cone, but in some patients, the abdominal aorta can approach the midline level. The method of CT localization via dual indication of abdominal aorta and cone is unreliable. Thus, the adjustment of the puncture needle should start from the anterolateral side of the cone and explore near the abdominal aorta. Owing to the large puncture space between the abdominal aorta and the outer edge of the left cone, when the lumbar sympathetic puncture is performed on the left side, the puncture needle is often controllable, the range of movement is large, space is exposed clearly, and the location can be reached under the guidance of CT. Moreover, the needle tip is blunt, the abdominal aorta tube wall is elastic, and the possibility of puncture bleeding under CT guidance is low. On the other hand, the right lumbar sympathetic nerve is located at the outer edge of the pyramid and the posterior medial side of the inferior vena cava, and the surgery is performed in the prone position. During the radiofrequency thermocoagulation of the lumbar sympathetic nerve on both sides, the left abdominal aorta cannot be deformed easily, and a clear CT image with a distinct boundary is acquired. The space between the abdominal aorta and the cone is large, but after compression on the right side, due to the thin wall and large capacity of the inferior vena cava, the abdominal wall is deformed after compression. Especially in the middle-aged and elderly patients, the abdominal wall is weak, the abdominal muscle group is not obvious, and the pressure is often flat, round, or irregular after fasting and fasting, and the surrounding boundary is not clear, and it is pushed to the side of the cone, close to or even close to the anterior lateral edge of the cone (Fig. 2A), such that the original puncture space is significantly reduced, and the puncture needle insertion angle is significantly limited. The puncture path drawing in advance, the selection of puncture angle, and the selection of puncture needle are demanding. If the ideal effect cannot be achieved after repeated punctures, then the injection of a small amount of anhydrous ethanol is the final measure (Fig. 2B). The psoas major muscle is attached to the outer edge of the cone, and the kidney is on the posterolateral side of the psoas major muscle. In the lumbar sympathetic radiofrequency, the ideal state is to avoid the kidney after puncture under the straight needle, penetrate the psoas major muscle, and fix the puncture needle to enter the anterior lateral edge of the cone. Herein, we attempted to use a straight needle to puncture according to the originally proposed puncture path; the white dotted line in the image is the drawn puncture path (Fig. 3A). If the straight needle puncture inevitably runs through the kidney, we changed the pre-puncture target and puncture angle (Fig. 3BF). If the adjusted puncture needle still could not reach the target accurately, and the needle tip could not walk between the inferior vena cava and the cone at a safe angle, the inferior vena cava could be damaged easily, and the possibility of massive hemorrhage can also not be excluded. In addition, repeated adjustment of the puncture angle and depth inevitably prolonged the operation time.

The results of the multivariate analysis were in agreement with the expectations. When the operation time was 12-28.25 min, compared to < 12 min, the probability of successful operation was 0.123. In this case, the operation time is a protective factor, but no significant difference was noted when it exceeds 28.25 min. We speculated that the insufficient number of samples included in the model might lead to the final model's instability. In addition, based on the results of this study, bending needle is a risk factor affecting the postoperative success rate, and the application of bending needle seems to affect the success rate of the right operation; however, few studies have reported about the application of bending needle in CT-guided lumbar sympathetic radiofrequency to explore the curative effect of bending needle in lumbar sympathetic radio frequency in future studies. In summary, the objective existence of anatomical factors may lead to a difficult, time-consuming, and low success rate of the right lumbar sympathetic radiofrequency operation. The results of multifactor regression analysis provided a research basis for us to improve the success rate.

Limitations

This is a single-center retrospective cohort study, and the reliability of the conclusions may need to be substantiated by multicenter, randomized, controlled trials. Secondly, there is a lack of sufficient sample size, and multiple diseases are included in this study. Moreover, a sub-analysis was not conducted in this study.

Conclusion

In this study, the left and right side effects of CT-guided radiofrequency thermocoagulation of the lumbar sympathetic nerve were analyzed systematically. The comparison between the left and right sides demonstrated that the right side requires a long operation time, CT scan times, and a low success rate. Logistic

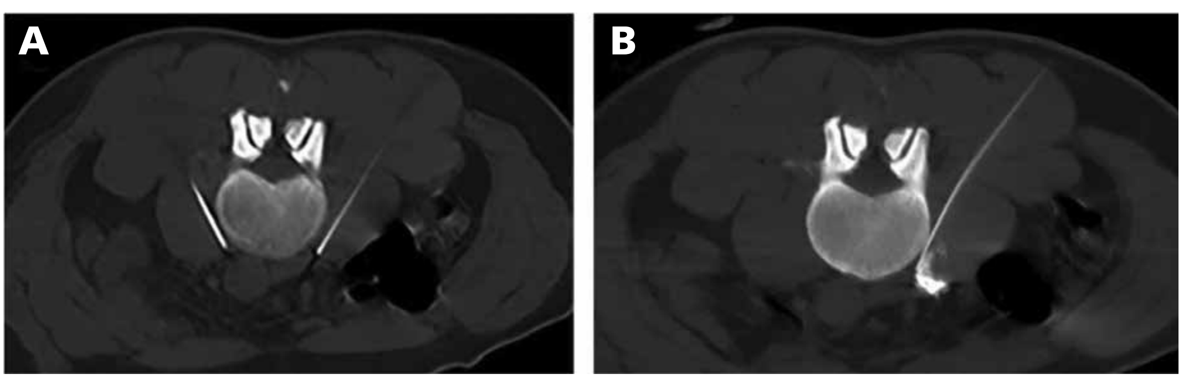

Fig. 2. *Failure to obtain the target and remedial measures. The puncture space narrowed due to the compression of the inferior vena cava (A). If the effect of radiofrequency is not good, 1–3 mL anhydrous ethanol is injected as a remedial measure (B).*

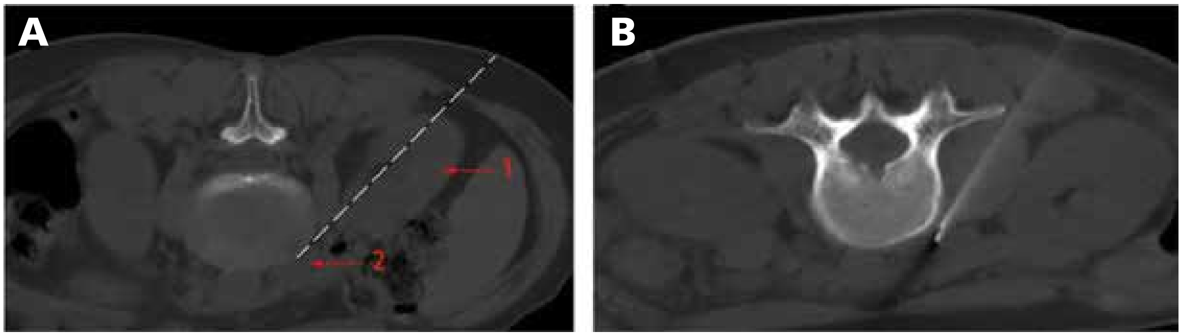

Fig. 3. *In this case, puncture under a straight needle is difficult and exhibits complications. The kidney (red arrow 1) will be damaged if we follow the hypothetical puncture path (A). The inferior vena cava (red arrow 2) is squeezed to the front of the pyramid. The puncture needle injures the compressed inferior vena cava (B).*

regression analysis revealed that the time of operation and the type of puncture needle were the factors affecting the success rate of the operation.

Author Contribution

Dr. Ge Luo, Dr. Jianjun Zhu, Dr. Ru Chen, Dr. Keyue Xie, Dr. Huadong Ni, Dr. Qiuli He, Dr. Jie Fu, Dr. Bing Huang, and Dr. Ming Yao assessed data and are responsible for the integrity and authenticity of the data. Dr. Ge Luo, Dr. Bing Huang, and Dr. Ming Yao designed the experimental scheme. Dr. Qiuli He, Dr. Jie Fu, Dr. Jianjun Zhu, and Dr. Ru Chen are responsible for summarizing the previous studies and collating the original data. Dr. Ge Luo, Dr. Keyue Xie, and Dr. Huadong Ni completed the first draft of the manuscript and statistical analysis. Dr. Bing Huang and Dr. Ming Yao revised the manuscript.

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