A New Choice for the Use of the Stents for Transjugular Intrahepatic Portosystemic Shunt Creation: Viabahn ePTFE covered stent/bare metal stent combination

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Research article

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Abstract

Background

Compare the clinical outcome of structure and function between insertion of transjugular intrahepatic portosystemic shunt (TIPS) created with the Viabahn ePTFE covered stent/bare metal stent (BMS) combination and Fluency ePTFE covered stent/BMS combination.

Methods

101 consecutive patients undergone TIPS procedure from February 2016 to August 2018 in our center were analyzed retrospectively, 64 subjects were enrolled in Viabahn group and 37 were Fluency group. We caculated the TIPS geometry characteristics and evaluated the related occurrence of shunt dysfunction, survival, overt hepatic encephalopathy (OHE) and variceal rebleeding.

Results

The technical success rate was 100%. After TIPS insertion, the rate of shunt dysfunction during the first 3 months was significantly different between Viabahn group and Fluency group, which were respectively 1.6% and 13.5% ($p = 0.024$). And multivariate analysis indicated that the angle of portalvenous inflow (α) (HR = 1.060, 95%CI = 1.009–1.112, $p = 0.020$) was the only predictor of shunt dysfunction. Besides, after 3 months following TIPS insertion, the α angle distinctly increased from 20.9°±14.3° to 26.9°±20.1° ($p = 0.005$) in Fluency group but stayed unchanged in Viabahn group (from 21.9°±15.1° to 22.9°±17.6°, $p = 0.798$).

Conclusions

The occurence of shunt dysfunction was related to the angle of portalvenous inflow (α), because of the slighter effect on α angle, after TIPS inplanation, Viabahn ePTFE covered stent/BMS combination was more stable in structure and promised higher short-term stent patency compared to Fluency ePTFE covered stent/BMS combination.

Background

Currently, transjugular intrahepatic portosystemic shunt (TIPS) is mainly used for the treatment of complications caused by portal hypertension, especially uncontrollable or recurrent variceal hemorrhage and refractory ascites [1–4]. Besides, TIPS is also applicable to gastric variceal hemorrhage, ectopic variceal bleeding, hepatic hydrothorax, hepatorenal syndrome, portal thrombosis and Budd-Chiari syndrome (BCS) [5–7]. However, the occurence of hepatic encephalopathy (HE) and shunt dysfunction following TIPS insertion has always been a troublesome complication.

Accumulated evidence has shown that compared to bare metal stent (BMS), expanded polytetrafluoroethylene (ePTFE) covered stent not only can significantly reduce stent restenosis rate, but also prove to be effective in respect of reducing the rebleeding and improving the survival [8, 9]. And the guidelines has already recommended it as routine material in TIPS procedure [3]. Indeed, the use of ePTFE covered stent has entirely rendered TIPS procedure a brand new future.

The Viatorr ePTFE covered stent (WL Gore, Flagstaff AZ) was approved by the Food and Drug Administration (FDA) for a TIPS application in December of 2004 [10]. Compared to BMS, it promises better shunt efficacy, patency rates, and survival [11, 12]. In China, the use of Fluency ePTFE covered stent/BMS combination gains great popularity for Viatorr ePTFE covered stent was not available on market until recently and it's rather expensive. And several studies have confirmed the safety and feasibility of Fluency ePTFE covered stent/BMS combination, but the stent patency seems a little lower than Viatorr ePTFE covered stent [13, 14].

In general, Fluency ePTFE covered stent is not perfectly compatible with soft BMS for its high hardness. However, we found that Viabahn ePTFE covered stent with greater flexibility might just make a better complement with BMS to result in better effect.

Methods

The study was conducted according to the Standards of Practice Guidelines of the Cardiovascular and Interventional Radiological Society and conducted under an approval by the Institutional Review Board. The study was conducted according to the Declaration of Helsinki and an informed consent to undergo TIPS and to participate in this research was signed by each patient.

Patients

We conducted a retrospective study on 101 consecutive patients undergone TIPS procedure February 2016 to August 2018 in our center.

The inclusion criteria was portal hypertension diagnosed by clinical symptoms, laboratory and imaging tests. Uncontrollable or recurrent variceal hemorrhage and refractory ascites were all indications for TIPS implantation. And the exclusion criteria consist of chronic heart, lung, or renal hypofunction, complication of overt hepatic encephalopathy (OHE), extensive primary or metastatic hepatic malignancy before TIPS insertion, follow-up time of less than one year and patients with incomplete data.

According to the actual application of ePTFE covered stents, 101 subjects belonging to two groups were recruited: Viabahn group (n = 64) and Fluency group (n = 37). The baseline characteristics of all patients were displayed in Table 1.

TIPS Procedure

A standardized TIPS technique has been detailed described previously [15–18]. After the catheterization of the right or middle hepatic vein was performed through the right internal jugular vein with a transjugular liver access set (RUPS-100; Cook Inc.), a pressure measurement was obtained. An intrahepatic tract was created by the puncture needle between the hepatic vein and one of the branches of portal vein, and then the guidewire and catheter were advanced into the portal vein. At this time, portography was performed and a pressure measurement was obtained subsequently. After the parenchymal tract was pre-baloon dilated, an 8 mm bare stent (E-Luminexx or Lifestent; Bard Inc.) combined with an ePTFE covered stent (Fluency; Bard Inc. or Viabahn; Gore Inc.) was implanted between the hepatic vein and the portal vein. Portal pressure gradient (PPG) value was obtained then. The length of the covered stent inside the portal vein was less than 1 cm. Cyanoacrylate was utilized to embolize gastric varices via angiography once found.

The angle of deviation of the blood flow at the portal venous inflow (α) and central venous outflow (β) were mesured by two radiologists on portography and CT image, The angles were calculated according to Fig. 1, which has been detailed described previously [19].

Postoperative Management

After the procedure, all patients were required to stay in hospital for several days and strict vital signs monitoring was needed. In addition, they received symptomatic treatments, such as analgesia, antibiotic prophylaxis, and routine treatments to improve liver function. Anticoagulation was not routinely recommended except in patients with portal vein thrombosis (PVT) [20].

Follow Up

After TIPS implantation, laboratory testings (including blood test, liver and kidney function and coagulation function) and imaging examinations (such as ultrasound, CT or MRI) were reexamined at 1, 3, 6, 12 months in the first year and once a year here after. Phone calls were made regularly to keep up with the prognosis and complications of the patients and they were kept in detailed records [21].

During the follow up, if a maximum shunt flow velocity of ≤ 50 cm/s or ≥ 250 cm/s or an absence of blood signal was found by ultrasonography, or clinical symptoms (such as rebleeding and ascites) relapsed, then there would be a reason to suspect shunt dysfunction [2, 22]. Transjugular-route portal venography was then performed on this kind of patients, and shunt dysfunction was confirmed by a shunt stenosis of > 50%, and stent revision (recanalization, balloon dilation or creation of a parallel shunt) was needed once diagnosis was confirmed [3, 4]. The OHE was evaluated and graded based on the West Haven criteria [23].

Statistical Analyses

Continuous variables were expressed as mean ± standard deviation and compared using the independent sample t test or paired t test, categorical variables were expressed as frequencies and compared using Fisher exact test or the chi-squared test. Actuarial probabilities were calculated with Kaplan-Meier curves and compared using the log-rank tests. Independent predictors were identified with Cox regression model. Differences were considered significant at $P < 0.05$. The statistical analyses were performed with IBM SPSS statistics version 22.0 (IBM, Inc., Chicago, IL, USA).

Results

Immediate condition following TIPS implantation

TIPS procedure was successfully completed in all patients, and the technical success rate was 100%. After TIPS creation, the PPG of all patients reduced at least 40%, and 92 (91%) patients even decreased to below 12 mmHg. Specifically, the average PPG in Viabahn group fell from 27.1 ± 5.2 mmHg to 9.6 ± 2.4 mmHg, and in Fluency group fell from 26.1 ± 5.5 mmHg to 10.2 ± 2.6 mmHg. No life-threatening complications such as hemoperitoneum, liver or renal failure was discovered during the perioperative period of TIPS procedure in all patients [24, 25].

TIPS Geometry

The α, β angle of both groups the time when and 3 months after TIPS implantation were displayed in Table 2. There was no statistical difference in the baseline value between the two groups. However, after 3 months following TIPS insertion, the α angle in Fluency group significantly increased from 20.9°±14.3° to 26.9°±20.1° ($p = 0.005$), compared to an unconspicuous change from 21.9°±15.1° to 22.9°±17.6° ($p = 0.798$) in Viabahn group. As to β angle, there were no significant changes found in Fluency group (12.0 ± 8.2 vs. 12.1°±9.9°, $p = 0.956$) and Viabahn group (7.8°±9.5° vs. 8.2°±9.0°, $p = 0.709$) between immediately and 3 months post-TIPS. The typical cases were shown in Fig. 2.

Shunt Dysfunction, Survival, OHE and Variceal Rebleeding after TIPS implantation

The median follow-up time of Viabahn group was 19.5 (range: 12–30) months and that of Fluency group was 30 (range: 14–44) months. The shunt dysfunction, survival, OHE and variceal rebleeding of all patients were demonstrated in Table 3, Kaplan-Meier curves during the follow up were shown in Fig. 3.

Shunt Dysfunction

In the first year following TIPS insertion, shunt dysfunction occured in 14 patients, including 8 (12.5%) in Viabahn group and 6 (16.2%) in Fluency group ($p = 0.541$), which indicated no statistical difference. After 3 months, however, significant difference was found demonstrated by the shunt dysfunction of 1 (1.6%) patient in Viabahn group and 5 (13.5%) patients in Fluency group, $p = 0.024$ (Table 3). The same pattern

was also observed in Kaplan-Meier analysis (Fig. 3). In terms of the occurence of shunt dysfunction during the follow-up, the univariate analysis showed that higher MELD score, lower international normalized ratioare (INR) and lager α angle were related. The multivariate analysis showed that only α angle (HR = 1.060, 95%CI = 1.009–1.112, p = 0.020) was identified as independent predictors of variceal rebleeding (Table 4).

Survival, Ohe And Variceal Rebleeding

During the follow-up time in one year, 6 patients died in Viabahn group, including 3 liver failure (respectively 2 weeks, 2 months and 5 months after TIPS procedure), 3 variceal rebleeding (respectively 4 months, 9 months and 12 months after TIPS procedure); 4 patients died in Fluency group, including 2 liver failure (respectively 2 weeks and 1 month after TIPS procedure), 1 variceal rebleeding (2 months after TIPS procedure), and 1 hepatic encephalopathy (4 months after TIPS procedure). The survival rate of one year was respectively 90.6% in Viabahn group and 89.2% in Fluency group (p = 1.000).

After TIPS insertion, the occurence of OHE within one year were respectively 13 (20.3%) patients in Viabahn group and 10 (27.0%) patients in Fluency group (p = 1.000). In addition, we noticed that the occurence of OHE mainly developed during first 3 months in both groups. More concretely, the occurence of OHE within 3 months following TIPS insertion were respectively 11/13 (84.6%) in Viabahn group and 8/10 (80.0%) in Fluency group.

Liver And Kidney Function

During the follow up, the changing trends of Child-Pugh score, total bilirubin, albumin and serum creatinine of all patients were depicted in Fig. 4. As demonstrated, every index of the baseline level and that of 0.1, 1, 3, 6, 12 months after TIPS implantation do not differ between the two groups statistically. On the whole, the liver and kidney function indices got slightly worse in a short time after TIPS insertion, but they slowly restored to baseline level in one month. Over time here after, the Child-Pugh score manifested a progressively downward trend, which fell from 7.5 ± 1.5 before TIPS procedure to 6.6 ± 1.4 one year after (p = 0.002).

Discussion

The development of shunt dysfunction mainly attributes to pseudointimal hyperplasia and thrombosis [26, 27]. Back when BMS was widely utilized, shunt dysfunction occurred commonly due to bile leakage and extended liver parenchyma growth into the shunt via the mesh of bare stents. Over the years, the incidence of shunt dysfunction has been effectively reduced for the widespread use of ePTFE covered stent [28].

Viatorr ePTFE covered stent, made specifically for TIPS procedure, mainly consists of a 5–9 cm-long PTFE-covered intrahepatic segment and a 2 cm-long uncovered portal segment. But Fluency and Viabahn ePTFE covered stents that we commonly use in China are completely covered by PTFE inside out with no bare portal part [29]. Therefore, the placement of Fluency ePTFE covered stents are always performed in association with a longer BMS for the lack of portal part [30, 31]. And so far, there has been several researches confirming the feasibility of Fluency ePTFE covered stent/BMS combination [32–34].

When it comes to the era of covered stents, the occurrence of shunt dysfunction mostly results from the stenosis of stents' ends near portal vein and hepatic vein, which correlates with the position of stent placement, the diameter and flexibility of the stents [35, 36]. And some researches have verified that the larger the angle of portalvenous inflow is, it is more likely for shunt dysfunction to occur [25], which is similar to our conclusion. In this study, we found the angle of portalvenous inflow (HR = 1.060, 95%CI = 1.009–1.112, p = 0.020) was the only predictor of shunt dysfunction.

As a result of the hard texture of Fluency ePTFE covered stent, longitudinal deformation would take place in the early stage as the stent rebounces after placement, which leads to the increasement of the angle of portalvenous inflow, and it may even cause the twists in the softer BMC outside because of excessive tension.[37] Viabahn ePTFE covered stents are softer, compared to Fluency ePTFE covered stents, and the tension towards the bare stents outside is rather less, so longitudinal deformation is less likely to occur. Thus, the angle of portalvenous inflow would increase after TIPS inplanation in Fluency group but not change in Viabahn group, which is verified in this study, after 3 months following TIPS insertion, the angle of portalvenous inflow distinctly increased from 20.9°±14.3° to 26.9°±20.1° (p = 0.005) in Fluency group but stayed unchanged in Viabahn group (from 21.9°±15.1° to 22.9°±17.6°, p = 0.798).

Therefore, Viabahn ePTFE covered stents rather than Fluency ePTFE covered stents are more suitable to function in combination with bare stents, and shunt dysfunction is less likely to occur. And it turned out as expected, we noticed in our data that the incidence rate of shunt dysfunction within 3 months in Viabahn group was far less than that in Fluency group(1.6% vs. 11.5%, p = 0.024). This in turn also suggests that Viabahn ePTFE covered stent/BMS combination is worth more widespread application in a situation where Viatorr ePTFE covered stent is hard to obtain in China.

Other studies have indicated that Fluency ePTFE covered stent/BMS combination did not differ from Viatorr stent concerning survival, OHE and variceal rebleeding [32–34]. And there also exists no significant diference between different kinds of ePTFE covered stents in our study. The Child-Pugh score and some related laboratory indices of both groups got a little worse after 3 days following TIPS placement, but gradually restored and tend to baseline level in one month. And in 3, 6, 12 months, we found that the Child-Pugh score fell below baseline level and showed a downward trend over time, where more and more patients developed from Child-Pugh B and C to Child-Pugh A. This kind of phenomenon was similar to that of other studies [38], which suggests that Viabahn ePTFE covered stent/BMS combination could not only ensure the safety, but also help to restore the poor liver and kidney functions of cirrhotic patients after TIPS implantation [39].

Although as data suggested, Viabahn ePTFE covered stent/BMS combination may be the best shot in TIPS creation currently, it must be pointed out that Viabahn ePTFE covered stent is produced only in 2.5 cm, 5 cm and 10 cm types. Among these three standards, it seems that only 5 cm-long stent is fit for establishing a passway between the hepatic vein and the portal vein, which leaves only the choice of 4 cm or 6 cm-long other stents such as Fluency ePTFE covered stent when necessary in some patients. And while TIPS insertion, Fluency ePTFE covered stent should be placed to stay in a vertical position as much as possible and 4 cm rather than 6 cm stent is preferred, which could prevent the influence of longitudinal deformation at most. Another limitation of our study is that we conducted a non-randomized retrospective study, and so there may existed certain selection bias.

Conclusion

The occurence of shunt dysfunction was related to the angle of portalvenous inflow (α), because of the slighter effect on α angle, after TIPS inplanation, Viabahn ePTFE covered stent/BMS combination was more stable in structure and promised higher short-term stent patency compared to Fluency ePTFE covered stent/BMS combination.

Abbreviations

TIPS, transjugular intrahepatic portosystemic shunt; BMS, bare metal stent; OHE, overt hepatic encephalopathy; BCS, Budd-Chiari syndrome; ePTFE, expanded polytetrafluoroethylene; FDA, Food and Drug Administration; PVT, portal vein thrombosis.

Declarations

Ethics approval and consent to participate

The study was conducted according to the Standards of Practice Guidelines of the Cardiovascular and Interventional Radiological Society and conducted under an approval by the Institutional Review Board. The study was conducted according to the Declaration of Helsinki and Written consent was obtained from participants in UKCTOCS for use of data and samples in future ethically approved secondary studies.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during this study may be available from the corresponding author on reasonable request.

Competing interests

All the authors declare no conflict of interest.

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Authors' contributions

All authors were involved in study design. Liu J, Meng J, Zhou C and Shi Q were involved in data collection. Liu J and Meng J drafted the manuscripts and figures. Liu J, Yang C, Ma J and Chen M performed the statistical analysis. Xiong B critically revised the manuscript and all authors read and approved the final manuscript.

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Tables

Table 1. Baseline characteristics of patients included in the study

Variables	Viabahn (n=64)	Fluency (n=37)	P values
Age (years)	51.1±11.3	53.7±10.9	0.268
Sex (male)	42	27	0.296
Aetiology			0.879
Hepatitis B virus	38	21	
Hepatitis C virus	9	5	
Alcohol misuse	4	4	
Others	13	7	
Comorbidity			
Hypertension	5	4	0.721
Diabetes	9	6	0.778
Hepatocellular carcinoma	3	3	0.666
TIPS indications			0.536
Variceal hemorrhage	56	34	
Refractory ascites	8	3	
laboratory parameters			
Total bilirubin (mg/dL)	1.35±0.70	1.32±0.70	0.857
Albumin (g/L)	31.2±6.5	31.5±6.0	0.812
Alanine aminotransferase (U/L)	27.7±14.2	36.5±32.0	0.120
Aspartate aminotransferase (U/L)	38.9±32.1	45.8±40.8	0.349
Creatinine (mg/dL)	0.75±0.24	0.73±0.21	0.667
Blood urea nitrogen (mmol/L)	5.83±3.00	5.78±2.45	0.942
Prothrombin time (seconds)	16.5±2.3	17.0±2.8	0.365
International normalized ratio	1.36±0.24	1.41±0.30	0.316
Hemoglobin (g/L)	80.0±24.3	79.2±14.3	0.872
Platelet count (10^9/L)	88.4±67.6	102.6±92.5	0.378
Serum Na (mmol/L)	138.4±4.6	137.9±7.0	0.654
Child-Pugh score	7.4±1.6	7.5±1.5	0.600
Child-Pugh class			0.948
A	19	12	
B	40	22	
C	5	3	
MELD score	11.3±3.2	11.1±3.1	0.827
MELD-Na score	12.2±4.5	12.4±4.1	0.836

Imaging evaluation			
Portal vein diameter (mm)	15.2±3.5	15.8±3.6	0.433
Splenic vein diameter (mm)	12.1±2.5	12.3±3.3	0.832
Spontaneous portosystemic shunt	12	3	0.122
Pre-TIPS PP(mmHg)	33.8±6.2	33.9±5.7	0.954
Pre-TIPS PPG(mmHg)	27.1±5.2	26.1±5.5	0.412

Abbreviation: MELD, model for end-stage liver disease; PVT, portal vein thrombosis; TIPS, transjugular intrahepatic portosystemic shunt; PP, portal pressure; PPG, portal pressure gradient.

Table 2. The angle of deviation of the blood flow

Variables	The angle of deviation of the blood flow		P value
	Immediately post-TIPS	3 months post-TIPS	
Viabahn group (α angle, °)	22.5±12.1	22.8±14.2	0.798
Fluency group (α angle, °)	23.0±15.3	28.2±19.5	**0.005**
P value	0.888	0.186	
Viabahn group (β angle, °)	22.0±10.8	20.7±11.1	0.317
Fluency group (β angle, °)	22.3±12.8	24.1±12.9	0.337
P value	0.925	0.257	

Table 3. Results of treatment and complications, including shunt dysfunction, survival, variceal rebleeding and overt hepatic encephalopathy during the follow-up

iables	Viabahn (n=64)	Fluency (n=37)	P values
ınt Dysfunction			
-3 months	1 (1.6%)	5 (13.5%)	**0.024**
-6 months	5 (7.8%)	5 (13.5%)	0.491
-12 months	8 (12.5%)	6 (16.2%)	0.541
ıth			
-3 months	2 (3.1%)	3 (8.1%)	0.453
-6 months	4 (6.3%)	4 (10.8%)	0.460
-12 months	6 (9.4%)	4 (10.8%)	1.000
iceal Rebleeding			
-3 months	1 (1.6%)	2 (5.4%)	0.552
-6 months	3 (4.7%)	2 (5.4%)	1.000
-12 months	7 (10.9%)	4 (10.8%)	1.000
ert Hepatic Encephalopathy			
-3 months	11 (17.2%)	8 (21.6%)	0.605
-6 months	13 (20.3%)	9 (24.3%)	0.863
-12 months	13 (20.3%)	10 (27.0%)	0.468

Table 4. Univariate and multivariate analysis of factors associated with post-TIPS shunt dysfunction.

ıbles	Shunt dysfunction			Multivariate analysis		
	Yes (n=14)	No (n=87)	P values	HR	95% CI	P values
;	12 (85.7%)	57 (65.5%)	0.215	-	-	-
(y)	51.6±9.5	52.1±11.5	0.859	-	-	-
	1.31±0.10	1.39±0.28	0.056	-	-	-
D score	10.1±1.7	11.4±3.3	0.041	-	-	-
gle (°)	33.6±16.8	21.6±14.9	0.007	1.060	1.009-1.112	0.020

Figures

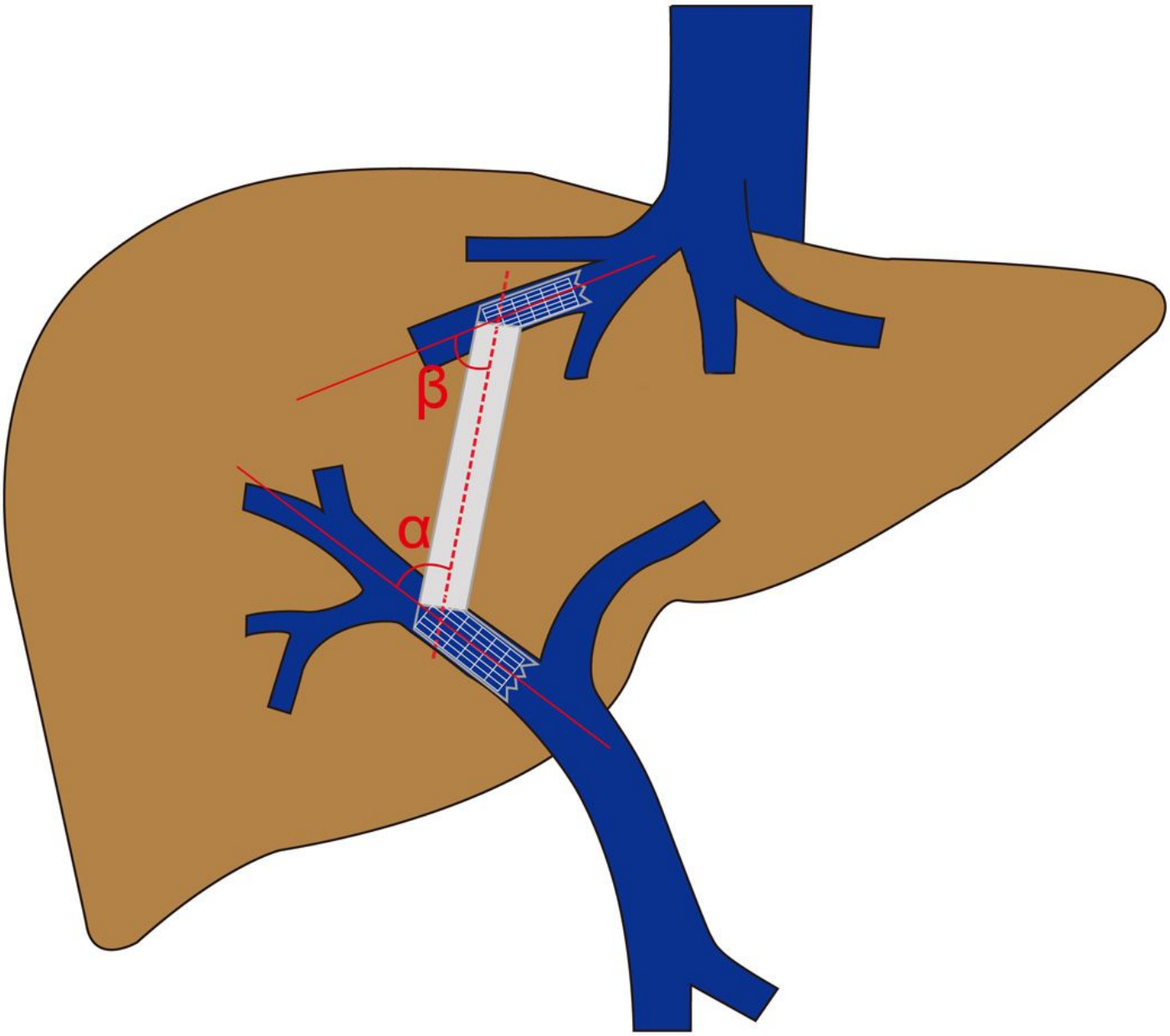

Figure 1

Illustration demonstrating the the angle of deviation of the blood flow at the portal venous inflow (α) and central venous outflow (β).

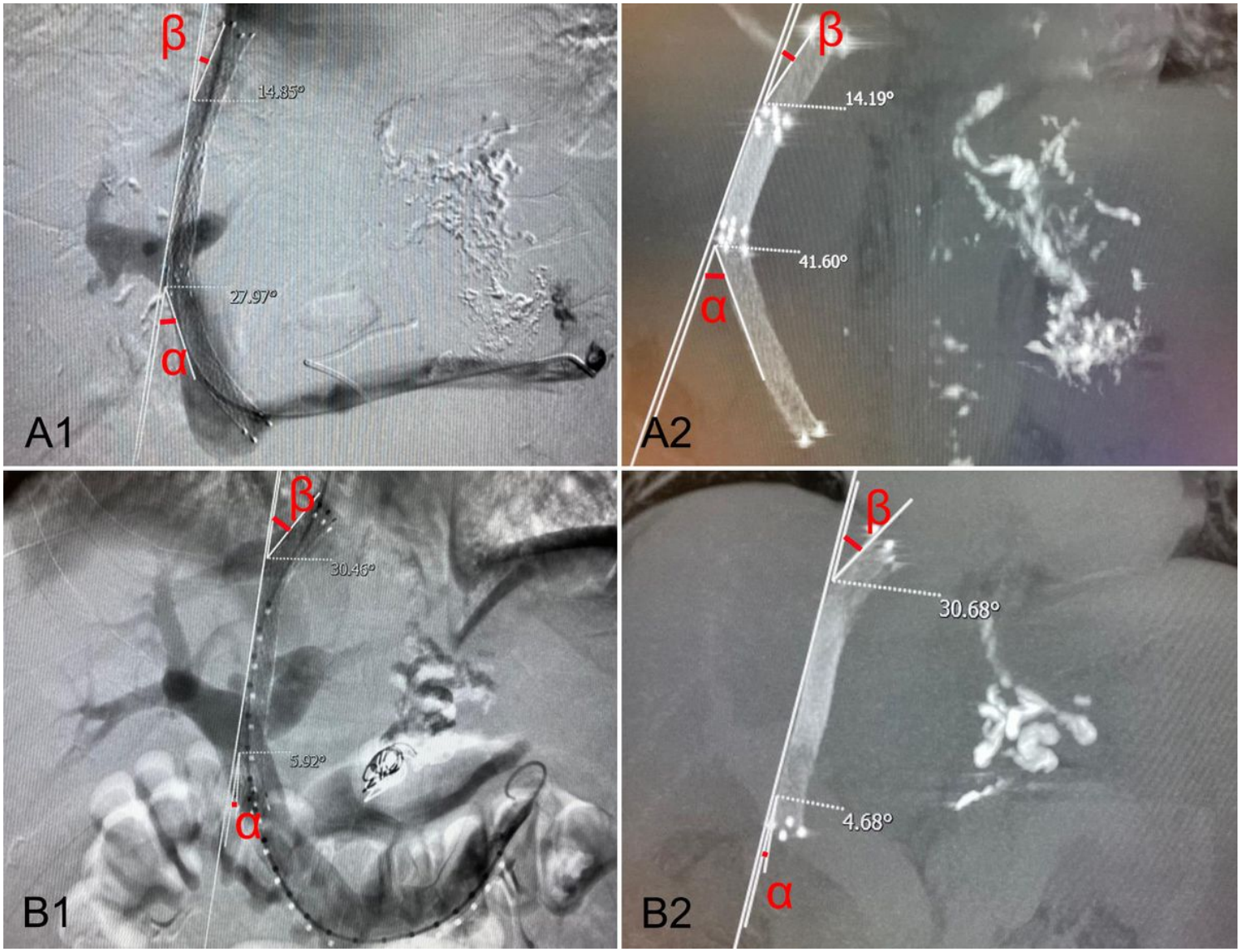

Figure 2

A. A 73-year-old male with variceal hemorrhage underwent TIPS created with the Fluency ePTFE covered stent/BMS combination. When TIPS insertion(A1), the α and β angle were respectively 28° and 15°; and 3 months later (A2), the α angle increased to 42° but β angle remained unchanged. B. A 38-year-old male with variceal hemorrhage received TIPS created with the Viabahn ePTFE covered stent/BMS combination. When TIPS insertion(B1), the α and β angle were respectively 6° and 30°; and 3 months later(B2), the α and β angle were respectively 5° and 31°, basically unchanged.

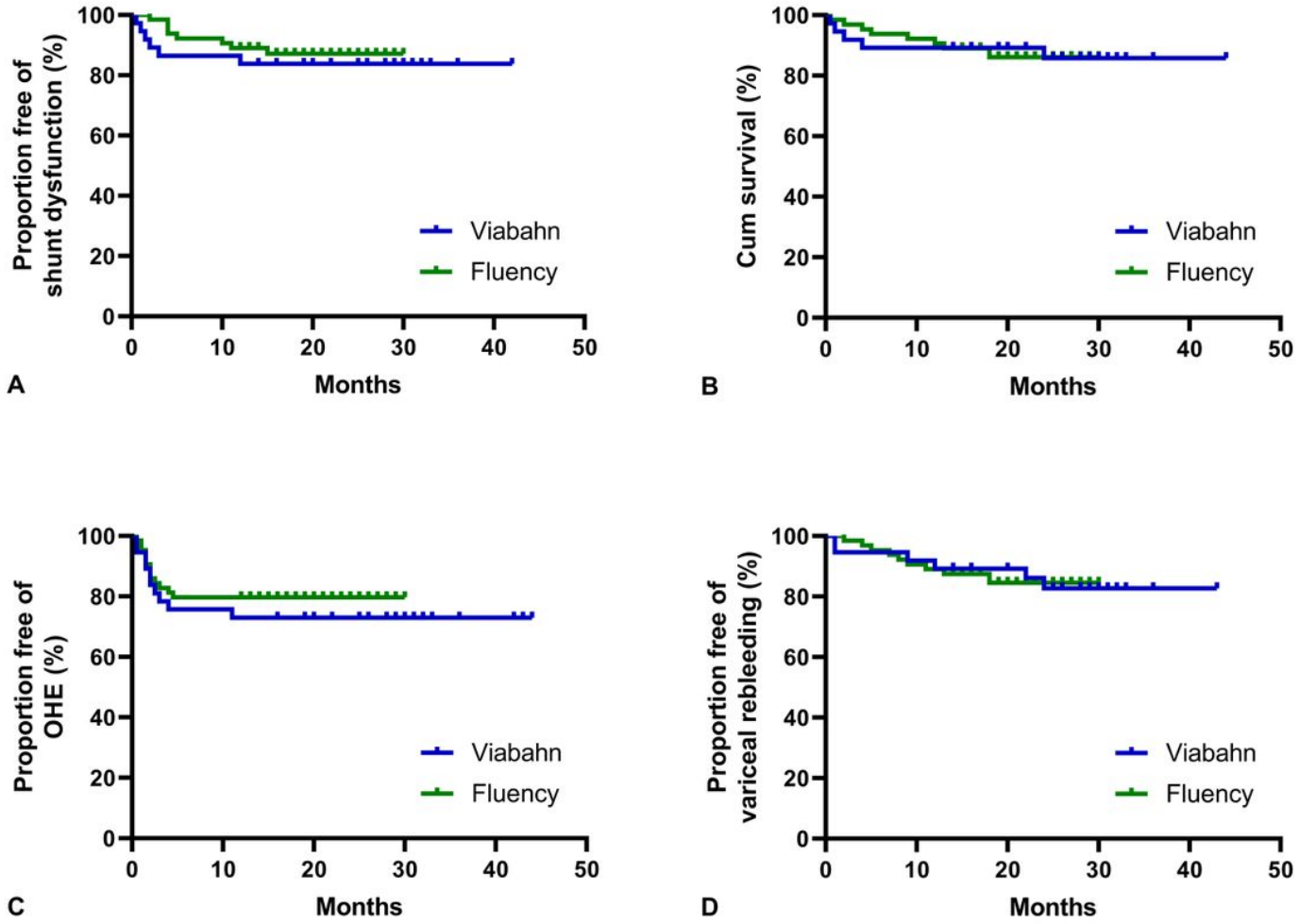

Figure 3

Kaplan-Meier curve of post-TIPS cumulative shunt dysfunction (A), survival (B), OHE (C) and variceal rebleeding (D) , the log-rank p values of which were respectively 0.551, 0.979, 0.454 and 0.948.

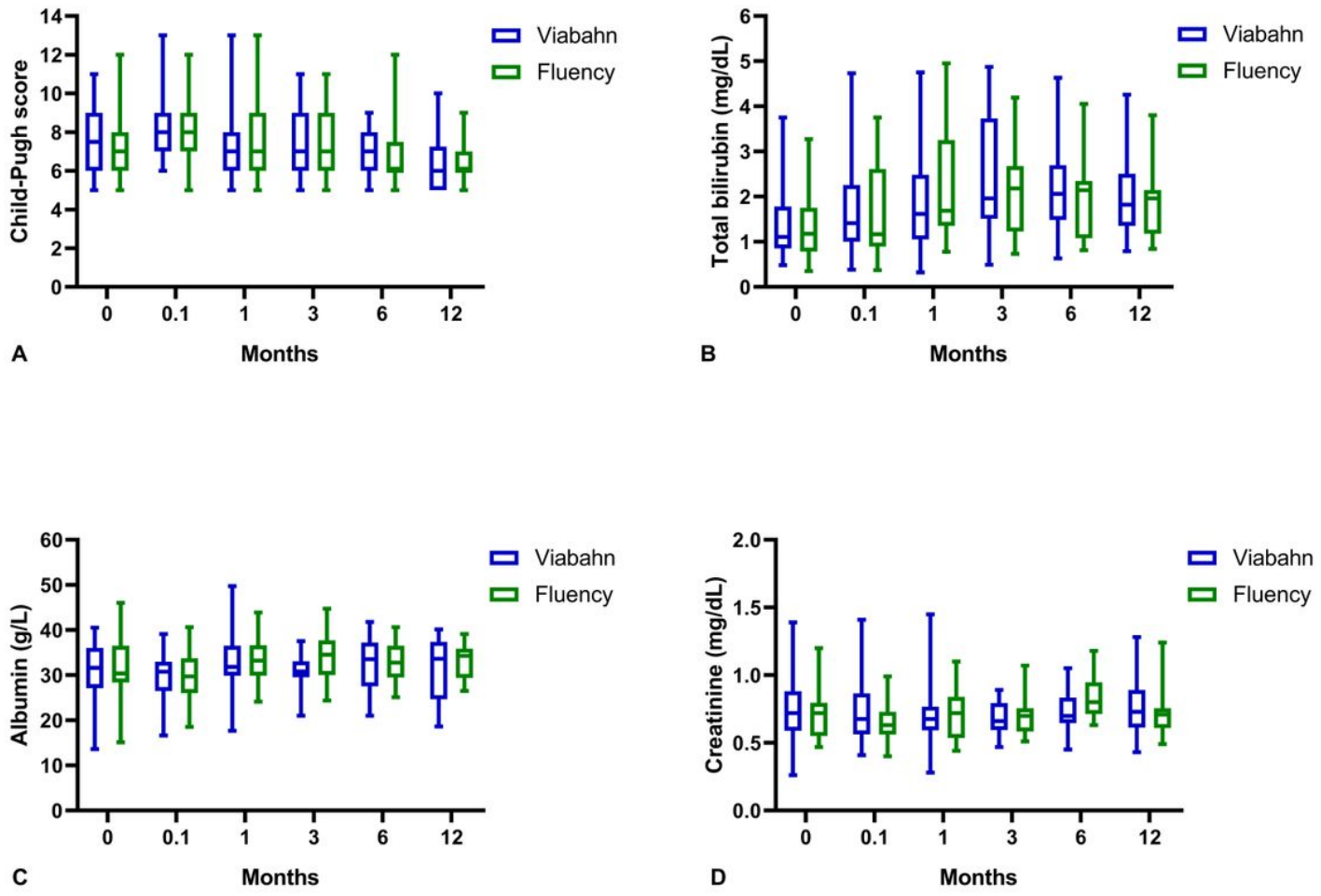

Figure 4

Shown in the box plots were the changing trends of liver and kidney function indices in two groups of patients. Before TIPS implantation and 0.1, 1, 3, 6, 12 months later, the average Child-Pugh score in Viabahn group and Fluency group were respectively 7.4±1.6 vs. 7.6±1.5 (p=0.526), 8.1±1.8 vs. 8.4±1.9 (p=0.383), 7.5±2.2 vs. 7.5±2.2 (p=0.925), 7.4±1.8 vs. 7.8±1.9 (p=0.556), 6.7±1.9 vs. 7.0±1.9 (p=0.586), 6.7±1.4 vs. 6.4±1.4 (p=0.562), which indicated no significant difference. Similarly, these two groups did not differ from each other concerning total bilirubin, albumin and serum creatinine both before and after TIPS insertion(p 0.05). On the whole, the Child-Pugh score, total bilirubin and serum creatinine of all patients increased at first and then decreased, while albumin presented an opposite trend.