UNIVERSITE DE NANTES

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FACULTE DE MEDECINE

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Année : 2021 N° 2021-126

THESE

pour le

DIPLOME D'ETAT DE DOCTEUR EN MEDECINE

Radiologie et Imagerie Médicale

par

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Né le 2 novembre 1993 à Vannes (56)

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Présentée et soutenue publiquement le 20 septembre 2021

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Evaluation of the new Viatorr® controllable expansion prosthesis for the creation of transjugular intrahepatic portosystemic shunt (TIPS) in comparison with the original Viatorr® stent graft.

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REMERCIEMENTS:

A Monsieur le Président du Jury,

Monsieur le Professeur Eric FRAMPAS
Professeur de Radiologie – CHU de Nantes

Merci de présider ce jury. J'ai eu la chance de travailler plusieurs semestres au sein de votre service et de bénéficier de vos enseignements ainsi que de votre bienveillance. Je vous témoigne ici toute ma reconnaissance.

Au Directeur de Thèse,

Monsieur le Docteur Arthur DAVID
Radiologue – CHU de Nantes

Merci d'avoir dirigé cette thèse, d'avoir partagé ton savoir. Tu as su me guider, à travers tes remarques pertinentes, vers la réussite de ce travail. Je te remercie pour tous les moments passés à l'hôpital.

Aux membres du Jury,

Madame le Docteur Isabelle ARCHAMBEAUD
Hépato-Gastro-Entérologue – CHU de Nantes
Je vous remercie d'avoir accepté de juger ce travail. Bien que n'ayant pas eu l'occasion de travailler à vos côtés, bénéficier de votre expertise dans le domaine de l'hépatologie est un honneur.

Monsieur de Professeur Emmanuel CANET
Professeur de Médecine Intensive et Réanimation (MIR) – CHU de Nantes
Je vous remercie d'avoir accepté de juger ce travail, de participer au jury. Je vous témoigne ma gratitude.

Monsieur de Professeur Emmanuel CORON
Professeur en Hépato-Gastro-Entérologie – CHU de Nantes
Je vous remercie d'avoir accepté de juger ce travail, de participer au jury. Veuillez trouver par la présente la marque de ma reconnaissance.

A mes formateurs,

Je vous remercie pour votre accueil et votre bienveillance à mon égard. Travailler et apprendre auprès de chacun d'entre vous a été un grand plaisir et un grand honneur.
Veuillez trouver ici l'expression de ma reconnaissance et de ma profonde sympathie.

Au service de Radiologie centrale de l'Hôtel Dieu (CHU de Nantes) :
Au Docteur Meyer, pour les fessées qu'il met à tous les internes (« attends, je te montre ») et aux fermetures du mardi soir.
Au Docteur Le Viol, à toutes ses vacations en musique douce.
Au Docteur Defrance, pour les ouvertures du mardi matin, les multiples avis thorax, les corrections de vacation qui finissent en discussion de vacances/WE.
Au Docteur Gilbert, la nouvelle dragonne.
Au Docteur Arrigoni, el profesor.
Aux Docteurs Renaud, Thiaubière, Nicolas, Mourrain-Langlois, Delemazure, Brioulet, Liberge, Morla, Toulgoat, Leauté, Bertrand-Vasseur, Laigle-Querat.
Aux anciens du CHU, les Docteurs PMHeudes, Kassam, Gardan.

Au service de Neuro-Radiologie du CHU de Nantes :
Au Professeur Hubert Desal.
Aux Docteurs Benjamin Daumas-Duport (alias BenDauDu), Elisabeth Auffray-Calvier, Alina Lintia-Gaultier, Romain Bourcier, Jesus Aguilar, Cédric Lenoble, Arnaud Pellerin, Lili Detraz.

Au service de Radiologie Pédiatrique du CHU de Nantes :
Aux Docteurs Marie-Pierre Quere, Thomas Lefrancois, Flavie Sadones, Pauline de Cambourg.

Au service de Radiologie de l'hôpital de Saint-Nazaire :
Aux Docteurs Jean-François Nouel (JF), Caroline Vergnes, Marc Fribourg, Nicolas Brecheteau, Hélène Tachy (Tachyyyyy).

Au service de Radiologie du CHD La Roche sur Yon :
Aux Docteurs Philippe Montigny, Marion Caza, Claire Kawski, Audrey Perreard, Marie-Pierre Garnier-Viarouge, Lydie Gosme, Monique Chevallier, Magdalena Sigheti, Diana Vintu, Salem Boukachabine, Bruno Gralepois, Annael Lahuec, Cécile Coussoou.

Au service de Radiologie interventionnel de l'Institut de Cancérologie de l'Ouest Gauducheau de Nantes :
Aux Docteurs Stéphanie Volpi (vendredi, c'est la journée de l'interne et les autres aussi), Frédéric Douane et Christophe Perret.
Et à l'équipe de manipulateurs radio : Adèle, Agathe, Gougou, Jeanne.

Aux co-internes, mes amis et ma famille,
Merci à tous. Vous avez tous grandement participé à ma réussite.

Aux co-internes,
A la meilleure promotion :
Vince, j'ai match samedi soir mais je viens après.
Guillaume, c'est buenz.
Marion, la Princesse.
Pich, « caaaaaalin. » N'oublie pas les 1.000 binouz que tu me dois.
Perraud, clubber disparu.

Aux autres co-internes devenus des amis : Zoé, Marinette, Rim Maaaaaaloum, Dumout, Jet-rhum, Ravanal, JuChate, Cheikh Seye, Hernandouille, Sylvain Lemoine, Mymy (MAssif), Lucie, DSL second, Maëva, Laure, Victor.

A mes amis,
A Johan, Jacques, Paul, Nicolas : débuter aux Valseuses pour finir au Bubble.

Martin, Aude, Camille, Justine : promo Paviot 2012.

A tous mes amis rencontrés pendant l'internat : Lise (archi-chaude), Adrien (Plancha bientôt ?), Juliette et Antoine Bab, Audrey et Nono (« caaaaalin » bis), Marie D, Audrey C, Fanny, Marie-Adé, Marie P, Thibault et Lauriane, Hugo, Erwan G.

A ceux qui ont enchainé externat et internat à Nantes (sympa la ville ?) : Nicolas M, Aymeric, Nicolas D, Bérénice, JJ, Dimitri, DLS premier.

Et surtout à ma famille,

A mes parents, prêts à me soutenir de jour comme de nuit, du début à la fin. Aux matchs au Roazhon Park ou à la Rabine, aux cafés des Nenettes, « on va voir la mer ? ».

A Elodie, jamais très loin quand il y a brunch.

Aux cousins, cousines ; « bon alors, tu finis quand ? » « Tu vas revenir à Vannes ? »

A grand-mère.

A patate.

TABLE DES MATIERES

ABBREVIATIONS

CT: Computed tomography

HE: Hepatic encephalopathy

MELD: Model for End Stage Liver Disease

PPG: Portosystemic pressure gradient

PTFE: Polytetrafluoroethylene

SD: Standard deviation

TIPS: Transjugular intrahepatic portosystemic shunt

VCX: Viatorr® Controlled Expansion

Vs: Versus

TITLE:

Evaluation of the new Viatorr® controllable expansion prosthesis for the creation of transjugular intrahepatic portosystemic shunt (TIPS) in comparison with the original Viatorr® stent graft.

KEY-WORDS

Transjugular intrahepatic portosystemic shunt (TIPS), Viatorr, Viatorr CX, Portal hypertension.

ABSTRACT

Background: A new Viatorr® Controlled Expansion (VCX) stent (Gore and Associates, USA) was introduced for transjugular intrahepatic portosystemic shunt (TIPS) placement in 2018, allowing for controlled diameter between 8 and 10 mm during implantation. Few published data are yet available on clinical outcomes. The purpose of the study was to retrospectively compare safety and efficacy of VCX versus original Viatorr stents.

Materiel and methods: Between February 2015 and march 2020, clinical and hemodynamical outcomes were retrospectively analyzed for 200 patients who underwent TIPS placement. For each patient, variceal rebleeding, recurrence of refractory ascites, overall hepatic encephalopathy (HE), stent dysfunction, stent revision and death within one-year following TIPS placement were recorded for data analysis.

Results: Three subgroups were identified: Viatorr stent dilated to 10 mm (n=55), Viatorr stent dilated to 8 mm (n=45) or VCX stent (n=100). Cumulative HE rates at 1 year were not statistically different between the three subgroups (36.4%, 31.1% and 25.3%, respectively) for overall HE. There were no significant differences in cumulative survival rates at one-year follow-up between the three subgroups of patients, 21.8%, 15.6% and 16.8%, respectively.

Conclusion: VCX stents showed similar efficacy in treating portal hypertension complications, with a non-significant decrease in HE and deaths post-TIPS.

I. INTRODUCTION

Transjugular intrahepatic portosystemic shunt (TIPS) is commonly used for the management of complications of portal hypertension, in particular in patients with variceal bleeding and refractory ascites (1).

Regarding stents in TIPS procedures, several studies have shown better patency rates and clinical outcomes with polytetrafluoroethylene (PTFE)-covered stents in comparison with bare stents (2-4). Nevertheless, the question of stent diameter is still open to debate. A previous randomized controlled trial demonstrated similar incidence of hepatic encephalopathy (HE) and cumulative survival rate using 8- or 10-mm diameter stents, but a significantly higher probability of remaining free of complications due to portal hypertension in the 10-mm than in the 8-mm stent group (5). However, a meta-analysis including 489 patients suggested that the use of 8-mm stents could result in higher survival and lower HE (6). Some authors proposed an underdilatation of 10-mm diameter Viatorr stents, but they observed a passive expansion of at six months following TIPS creation (7).

A new Viatorr® Controlled Expansion (VCX) stent (Gore and Associates, USA) was introduced for clinical practice in 2018, allowing for controlled diameter between 8 and 10 mm during implantation. However, few published data are yet available on clinical outcomes after TIPS creation with this device, especially compared with the conventional 10-mm diameter Viatorr® stent (8, 9).

The aim of the present study was therefore to compare the clinical outcomes of these two stents after TIPS creation.

II. MATERIEL AND METHODS

A. Study design and patients

This retrospective study was conducted in a single university hospital. Local ethics committee approval was obtained and a waiver for informed consent was given.

Two hundred consecutive patients undergoing TIPS procedure between February 2015 and March 2020 were included– 100 with conventional 10-mm diameter Viatorr® stent and 100 with controlled expansion VCX® stent.

The decision to treat complications of portal hypertension with TIPS Creation was made at the local weekly multidisplinary team meeting. The primary outcome for this study was post-procedural HE. Secondary outcomes included: hemodynamic characteristics, variceal rebleeding, recurrence of refractory ascites, stent dysfunction (stenosis, thrombosis, need to revision) and death.

B. TIPS procedure

All TIPS were performed under general anesthesia in a flat-panel-based detector angiographic suite (Innova® 4100, General Electric Healthcare) by 6 senior interventional radiologists, with at least 2 years of experience in TIPS creation, using the Rösch-Uchida portal vein access set (Cook).

A 10-Fr sheath was placed in the internal jugular vein using ultrasound guidance and then the hepatic vein was catheterized. The Rösch® needle was advanced into the portal vein under percutaneous real-time ultrasound guidance control,), as previously described (9).

Once access to the portal vein system was confirmed by blood aspiration and injection of iodine-containing contrast media, a portography was achieved and portal pressure was considered to determine the initial portosystemic pressure gradient (PPG). Variceal

embolization was performed at the discretion of the operator, when gastric/oesophageal varices were seen on initial portography, using preferentially N-butyl 2-cyanoacrylate (Glubran2®, GEM).

Dilatation of the intrahepatic tract was performed before the deployment of a PTFE-covered Viatorr® or VCX® (Gore), further dilated with 8-mm or 10-mm diameter angioplasty balloon (Ultraverse®, Bard).

A final portography was realized and final PPG was measured after TIPS placement. If hemodynamic success - defined as a reduction in the PPG to an absolute value ≤ 12 mm Hg - was achieved, further shunt dilation was not performed. Additional variceal embolization was performed if required.

C. Data collection and study endpoints

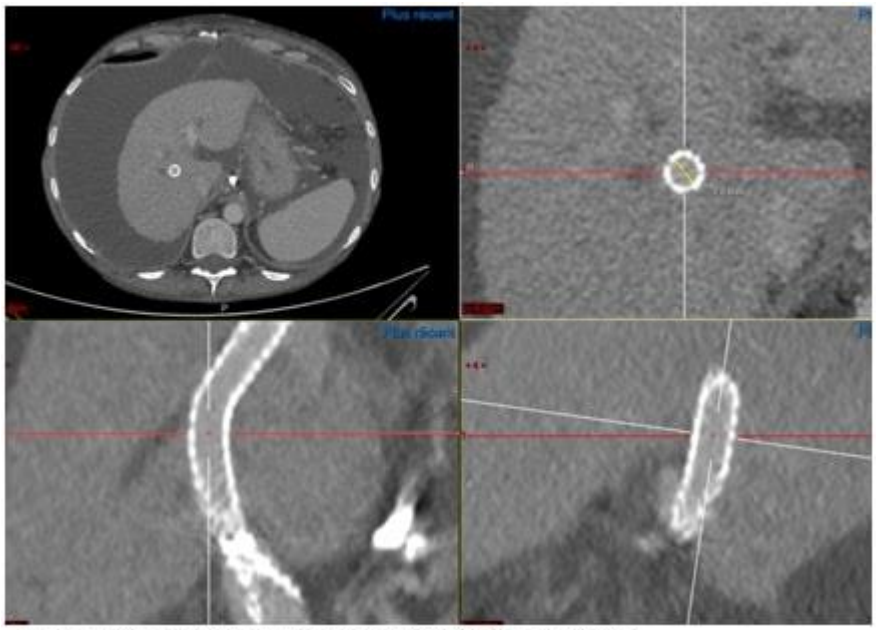
For each patient, the following pre-TIPS clinical data were retrospectively collected from the electronic medical chart: age, gender, etiology of liver cirrhosis, Child–Pugh score, Model for End Stage Liver Disease (MELD) score, previous HE grade I-II, previous portal vein thrombosis, indication of TIPS and degree of emergency.

Peri-procedural variables included the following: PSG before and after TIPS creation, variceal embolization, type and diameter of the stent graft, degree of post-dilatation,

The clinical variables reviewed during the one-year post-TIPS follow-up included: variceal rebleeding, recurrence of refractory ascites, overall HE, HE grade II-IV, TIPS dysfunction (including stent thrombosis and stenosis), TIPS revision and death.

Computed tomography (CT) analyses were performed on the latest post-TIPS exam retrieved from our picture archiving and communication system (Carestream Vue, Carestream Health). Stent diameter was measured in the midportion of the covered part within the intrahepatic

tract, on short-axis images obtained by multi-planar reconstruction during portal phase (Figure 1).



Case example of in vivo CT measurement of prosthesis diameter

D. Statistical analysis

Qualitative variables were expressed as raw numbers, proportions and percentages. Quantitative were reported as means ± standard deviation (SD) and ranges.

Comparisons of measures for quantitative variables were performed using the two-sided Student t-test. Comparisons of proportions for binary variables were performed using the chi-square or the exact Fisher test. The Kaplan-Meier method and a log-rank test were used for the comparison of survival curves between defined subgroups. P-values < 0.05 were considered statistically significant.

III. RESULTS

A. Patient description

During the review period, 200 patients were treated by TIPS creation, 100 using Viattor stent and 100 using VCX stents. Patient demographics and clinical characteristics are reported in Table 1, with comparable characteristics between groups for age, gender, cause of liver cirrhosis, MELD score, previous HE grade I-II and portal vein thrombosis. Only the Child-Pugh was significantly higher in the VCX group (9.2 ± 2.1 versus 8.1 ± 1.9, p =0.005).

Indications for TIPS procedure were variceal bleeding and refractory ascites in 75 and 39 patients in the Viatorr group, 63 and 40 patients in the VCX group (p=0.07 and p=0.88), respectively.

Table 1: Clinical characteristics of 200 patients who underwent TIPS placement

Characteristics	Viatorr (n=100)	Viatorr CX (n=100)	p	*Viatorr CX 8mm (n=95)*
Age	57.9 ± 10.5 [22.0-77.0]	59.2 ± 9.7 [32.0-78.0]	0.38	*59.3 ± 9.9 [32.0-78.0]*
Sex (male)	74 (74.0%)	76 (76.0)	0.74	*72 (75.8%)*
Cause of liver cirrhosis				
Alcohol	78 (78.0%)	91 (91%)	**0.01**	*86 (90.5%)*
Hepatitis C	5 (5.0%)	5 (5.0%)	-	*4 (4.2%)*
Hepatitis B	1 (1.0%)	0 (0.0%)	-	*0 (0.0%)*
NASH	13 (13.0%)	16 (16.0%)	0.55	*15 (15.8%)*
Other	16 (16.0%)	6 (6.0%)	0.02	*5 (5.3%)*
Child-Pugh score	8.1 ± 1.9 [5.0 – 14.0]	9.2 ± 2.1 [5.0 – 14.0]	**0.005**	*9.2 ± 2.2 [5.0 – 14.0]*
MELD score	13.9 ± 6.2 [2.0 – 35.0]	15.5 ± 6.8 [6.0 – 51.0]	0.09	*15.3 ± 6.8 [6.0 – 51.0]*
Previous HE I-II	18 (18.0%)	27 (27.0%)	0.13	*27 (28.4%)*
Portal vein thrombosis	14 (14.0%)	15 (15.0%)	0.84	*14 (14.7%)*
Indication				
Refractory ascites	39 (39%)	40 (40.0%)	0.88	*39 (41.1%)*
Variceal bleeding	75 (75.0%)	63 (63.0%)	0.07	*58 (61.1%)*
Prophylaxis of rebleeding	38 (38.0%)	20 (20.0%)		*19 (20.0%)*
Acute bleeding	37 (37%)	43 (43.0%)		*39 (41.1%)*
Other	6 (6.0%)	15 (15.0%)	0.04	*15 (15.8%)*
Degree of emergency				
Emergency setting	46 (46.0%)	52 (52.0%)	0.40	*47 (49.5%)*
Scheduled	54 (54.0%)	48 (48.0%)		*48 (50.5%)*

MELD (model for End-Stage liver Disease), HE (Hepatic Encephalopathy)

B. Procedural and hemodynamic outcomes

TIPS was successfully created in all 200 patients, with only one immediate complication (subcapsular hemorrhage requiring selective embolization). Variceal embolization was performed in 41 patients in the Viatorr group versus 58 patients in the VCX group (p=0.02). Hemodynamics outcomes are presented in Table 2.

Table 2: Evaluation of pressure measurements before and after the procedure, measurement of the pressure differential

PPG	Viatorr			Viatorr CX			
Post-dilatation	10-mm (n=55)	8-mm (n=45)		8-mm (n=95)		10-mm (n=5)	
Preprocedural PPG (mmHg)	16.8 ± 5.5 [5.0 - 32.0]	15.6 ± 5.4 [2.0 - 33.0]	p=0.32	16.0 ± 5.3 [3.0 - 27.0]	p=0.43	16.0 ± 6.6 [9.0 -23.0]	p=0.82
Post procedural PPG (mmHg)	7.1 ± 3.3 [1.0-14.0]	7.3 ± 4.3 [3.0-28.0]	p=0.80	7.7 ± 3.1 [2.0 - 16.0]	p=0.35	8.4 ± 2.1 [6.0-11.0]	p=0.26
Difference of PPG (mmHg)	9.6 ± 5.3 [1.0 – 25.0]	8.2 ± 4.2 [-2.0 – 18.0]	p=0.17	8.3 ± 5.1 [-4.0 – 19.0]	p=0.13	7.6 ± 4.7 [2.0 – 13.0]	p=0.41
Patients reaching the hemodynamic target of PPG≤12mmHg	52 (94.5%)	43 (95.6%)	p=1	90 (94.7%)	p=0.38	5 (100.0%)	p=1

*p-value for comparison with hemodynamic outcomes of Viatorr post-dilated to 10-mm
PPG (portosystemic pressure gradient)

In the Viatorr group, the stent was post-dilated with a 10-mm diameter angioplasty balloon in 55 patients and with an 8-mm diameter balloon in the remaining 45 patients. There was no difference in PPG between Viatorr stents dilated to 8-mm or to 10 mm. Fifty-two (94.5%) and 43 patients (95.6%) patients reached a reduction of the PPG below 12 mmHg with the Viatorr dilated to 10 mm or to 8 mm, respectively (p=1). In the VCX group, all 100 stents were initially dilated to 8-mm, and 10 patients had a final PPG over 12 mmHg. Among theses 10 patients, 5 had their stents further dilated to 10 mm of diameter, allowing a reduction of PPG below 12

mmHg. The difference of PPG was not statistically different between patients with Viatorr stents dilated to 10 mm and patients with VCX stents dilated to 8 mm or 10 mm of diameter.

C. Clinical outcomes

Table 3 summarizes clinical outcomes including overall HE, grade II-IV HE, variceal rebleeding, refractory ascites, stent dysfunction, stent revision and death. We found no statistically significant difference in these variables between subgroups of patients treated with Viatorr stent dilated to 10 mm, Viatorr stent dilated to 8 mm or VCX stent.

Cumulative HE rates at 1 year in the three subgroups were 36.4%, 31.1% and 25.3% for overall HE and 20.0%, 13.3% and 11.6% for grade II-IV HE respectively. In patients treated by TIPS creation for variceal bleeding, rebleeding rates were 20.5%, 16.1% and 20.7% respectively.

In patients treated for refractory ascites, recurrence rates were 31.6%, 15.0% and 25.6% respectively.

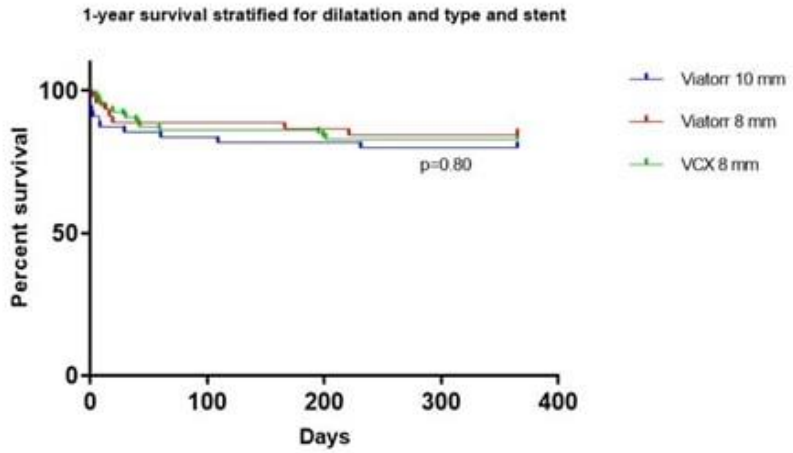
TIPS revision was performed in 10.9%, 15.6% and 12.6% respectively.

Table 3: Clinical outcomes of 200 patients who underwent TIPS creation

1-y outcomes	Viatorr		Viatorr CX	
Post-dilatation	10-mm (n=55)	8-mm (n=45)	8-mm (n=95)	p
HE	20/55 (36.4%)	14/45 (31.1%)	24/95 (25.3%)	0.35
HE grade II-IV	11/55 (20.0%)	6/45 (13.3%)	11/95 (11.6%)	0.36
Variceal rebleeding	9/44 (20.5%)	5/31 (16.1%)	12/58 (20.7%)	0.86
Refractory ascites	6/19 (31.6%)	3/20 (15.0%)	9/39 (23.1%)	0.47
Thrombosis	6/55 (10.9%)	2/45 (4.4%)	4/95 (4.2%)	0.22
Stenosis	1/55 (1.8%)	1/45 (2.2%)	7/95(7.4%)	0.07
Revision	6/55 (10.9%)	7/45 (15.6%)	12/95 (12.6%)	0.79
Desobstruction	4/55 (7.3%)	2/45 (4.4%)	4/95 (4.2%)	0.49
Angioplasty	0/55 (0.0%)	4/45 (8.9%)	5/95 (5.3%)	0.10
Reduction	2/55 (3.6%)	1/45 (2.2%)	3/95 (3.2%)	0.92
Death	12/55 (21.8%)	7/45 (15.6%)	16/95 (16.8%)	0.85

HE (Hepatic Encephalopathy)

There were no significant differences in cumulative survival rates at one-year follow-up between the three subgroups of patients, 21.8%, 15.6% and 16.8%, respectively (Table 3, Figure 2). Most common causes of deaths were variceal rebleeding (n=16/35, 45.7%) and hepatic encephalopathy (n=8/35, 22.9%).



Patients at risk	0 days	19 days	166 days	365 days
Viatorr 10 mm	55	48	46	44
Viatorr 8 mm	45	41	40	38
VCX 8 mm	94	88	41	78

Figure 2: cumulative survival rates at one-year follow-up between the three subgroups of patients.

D. CT analyses

One hundred and seven patients post-TIPS CT scans were available for stent diameter measurement (Table 4). Diameters are given in Table 4. Viatorr stents dilated to 10 mm had a significantly higher mean diameter (8.4 ± 0.7 mm) than Viatorr stent dilated to 8-mm (8.0 ± 0.6 mm) or VCX stent dilated to 8 mm diameter (7.7 ± 0.4 mm).

Table 4: Measuring of the diameter of prostheses in vivo

	CT-Diameter	p*
Viatorr with 10-mm post-dilatation (n=32)	8.4 ± 0.7 mm	-
Viatorr with 8-mm post-dilatation (n=29)	8.0 ± 0.6 mm	0.005
Viatorr CX with 8-mm post-dilatation (n=46)	7.7 ± 0.4 mm	<0.001

p-value for diameter comparison with Viatorr post-dilated to 10-mm

IV. DISCUSSION:

Our study report the clinical and hemodynamic outcomes of patients who underwent TIPS creation using a new controlled-expansion VCX stent, compared with those treated with conventional.

Viatorr stents, whether these had been dilated to 8 or 10 mm. VCX stents have been developed to allow stability and regularity of the effective diameter of the prosthesis. The results showed that the use of VCX stents was associated with similar clinical outcomes and PPG changes to fully or underdilated Viatorr stents.

HE is the most common complication after TIPS creation, with multiple influencing factors (including liver function, age, creatinemia). In our study, most post-TIPS HE were Grade 1 (17/34 for Viatorr, 13/24 for VCX), usually at an early stage, and regressing during hospitalization. HE symptoms were mostly manage with medical treatment only, shunt reduction was performed to treat refractory HE in 10.4% of post-TIPS HE: 8.8% for Viatorr, 12.5% for VCX. Several published investigations have reported a large variability in on post-TIPS HE rates with VCX stents. For example, Miraglia observed 22% HE incidence rate after TIPS with VCX stent, with a mean of 5.8 months of clinical follow-up, whereas Kloster and al found a cumulative HE incidence at 61% after one year of monitoring. Casadaban focused exclusively on HE with rates close to ours (8, 9, 12). These results are comparable with other retrospective studies (9, 11, 12). We can see a trend emerging, with fewer HE for VCX, which should require confirmation with a larger cohort.

In our cohort, we observed to 21.8% of deaths with the old 10 mm dilated stents. For VCX dilated to 8 mm, we find a survival rate of 83.2% at 1 year, similar to Miraglia et al (82%) and

Praktiknjo et al (85%) (9, 13).VCX remains a safe prosthesis in terms of mortality, despite the fact that we included more emergency procedures and that more variceal embolizations were performed in the VCX group. Praktiknjo et al, in a recent paper, showed a clear superiority of VCX dilated to 8 mm, compared to previous Viatorr Stent dilated to 8 mm in terms of mortality (13). In fact, they observed a significant reduction in mortality with VCX, but with relatively high mortality rates with Viatorr stents: 30% with Viatorr stents dilated to 8 mm, and 40% with stents dilated to 10 mm.

Covered TIPS was knows as an effective treatment of variceal bleeding, more effectively than drugs (14). In our study, we found no significant difference in post-TIPS variceal rebleeding rates, (20.7% for VCX-8 mm, 16.1% for Viatorr 8-mm and 20.5% for Viatorr 10-mm). This is slightly higher than the rates reported by Wang et al (10.1% of rebleeding at 1 year for VCX 8-mm) (15).

There is often a progressive improvement in ascites after TIPS implantation. Patients are called in 4 weeks after TIPS to reassess the ascites and determine the need for a paracentesis. For us, RA is as well controlled by the VCX 8-mm as by older models, whether 8-mm or 10- mm: ascites persists in 23.1% for VCX, 23.1% for older Viatorr. Our values remain quite distant from Miraglia 2017 who found that long-term need for paracentesis was greater in the 8-mm group, 58%, vs 31% for the 10-mm group (16).

In a large retrospective study, 10 mm diameter ePTFE covered stent lead to better control of refractory ascites, as compared to an 8 mm stent, without increasing the incidence of HE.

VCX stents have been developed to allow stability and regularity of the effective diameter of the prosthesis. VCX stent dilated to 8 mm diameter (7.7 ± 0.4 mm) is relatively close to Praktiknjo et al: 8.0 ± (7.8 – 9.2) mm for VCX (13). There was no significant passive expansion with time for Viatorr stents, (8.4 ± 0.7 mm), remaining smaller than the nominal stent diameter. The differences between Viatorr with 10-mm post-dilatation and VCX in-vivo diameters were significant but remained small in absolute terms.

Our results showed that the use of VCX stents was associated with similar hemodynamical outcomes to fully or underdilated Viatorr stents. We observed that 94.7% of patients treated by VCX dilated to 8-mm had a PPG ≤ 12 mmHg. This result is similar to those obtained previous stents dilated to 10-mm (94.5%) or 8-mm (95.6%). The lack of difference in clinical outcomes may be explained by those very little differences in stent diameters, leading to similar post-procedural PPG.

The present study has several limitations, mostly due to its retrospective and single-centre nature, with a relatively low number of patients. This predisposes to selection bias and especially for pre-procedure liver function. We were unable to study the impact of TIPS on right heart function, which remains a crucial clinical outcome.

However, the results of this study might lead to larger prospective multicenter studies.

The VCX-8 mm did not compromise shunt patency, and allow prevention of rebleeding as effective as the previous prostheses.

DISCLOSURE OF INTEREST

No potential conflict of interest relevant to this article was reported.

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NOM : **LE GAL** PRENOM : **Antoine**

Titre de Thèse : Évaluation de la nouvelle prothèse à expansion contrôlable Viatorr® pour la création d'un shunt portosystémique intrahépatique transjugulaire (TIPS) en comparaison avec l'endoprothèse originale Viatorr®.

RESUME

Contexte : Une nouvelle endoprothèse à expansion contrôlée (VCX) Viatorr® (Gore and Associates, USA) a été introduite pour la pose de shunt portosystémique intrahépatique transjugulaire (TIPS) en 2018, permettant un diamètre contrôlé entre 8 et 10 mm lors de l'implantation. Peu de données sont publiées sur les résultats cliniques. L'objectif de l'étude était de comparer rétrospectivement la sécurité et l'efficacité des stents VCX par rapport aux stents Viatorr originaux.

Matériel et méthodes : Entre février 2015 et mars 2020, les résultats cliniques et hémodynamiques ont été analysés rétrospectivement pour 200 patients ayant subi une pose de TIPS. Pour chaque patient, les ruptures de varices digestives, la récidive d'ascite réfractaire, l'encéphalopathie hépatique (HE), le dysfonctionnement de l'endoprothèse, la révision de l'endoprothèse et le décès dans l'année suivant la pose du TIPS ont été enregistrés pour l'analyse des données.

Résultats : Trois sous-groupes ont été identifiés : stent Viatorr dilaté à 10 mm (n=55), stent Viatorr dilaté à 8 mm (n=45) ou stent VCX (n=100). Les taux d'HE cumulés à 1 an n'étaient pas statistiquement différents entre les trois sous-groupes (36,4 %, 31,1 % et 25,3 %, respectivement) pour l'HE globale. Il n'y avait pas de différences significatives dans les taux de survie cumulatifs à un an de suivi entre les trois sous-groupes de patients, 21,8 %, 15,6 % et 16,8 %, respectivement.

MOTS-CLES

TIPS (transjugular intra-hepatic portosystemic shunt), Viatorr, Viatorr Cx, hypertension portale.