

GORE® VIATORR®

TIPS Endoprosthesis
with Controlled Expansion

TIME TO RETHINK TIPS

Earlier TIPS increases survival and reduces complications, helping improve the quality of life for liver disease patients.

Together, improving life





Consider the evidence for earlier TIPS

Advanced by compelling evidence and the next generation endoprosthesis, earlier TIPS is helping physicians increase survival in high-risk liver disease patients.

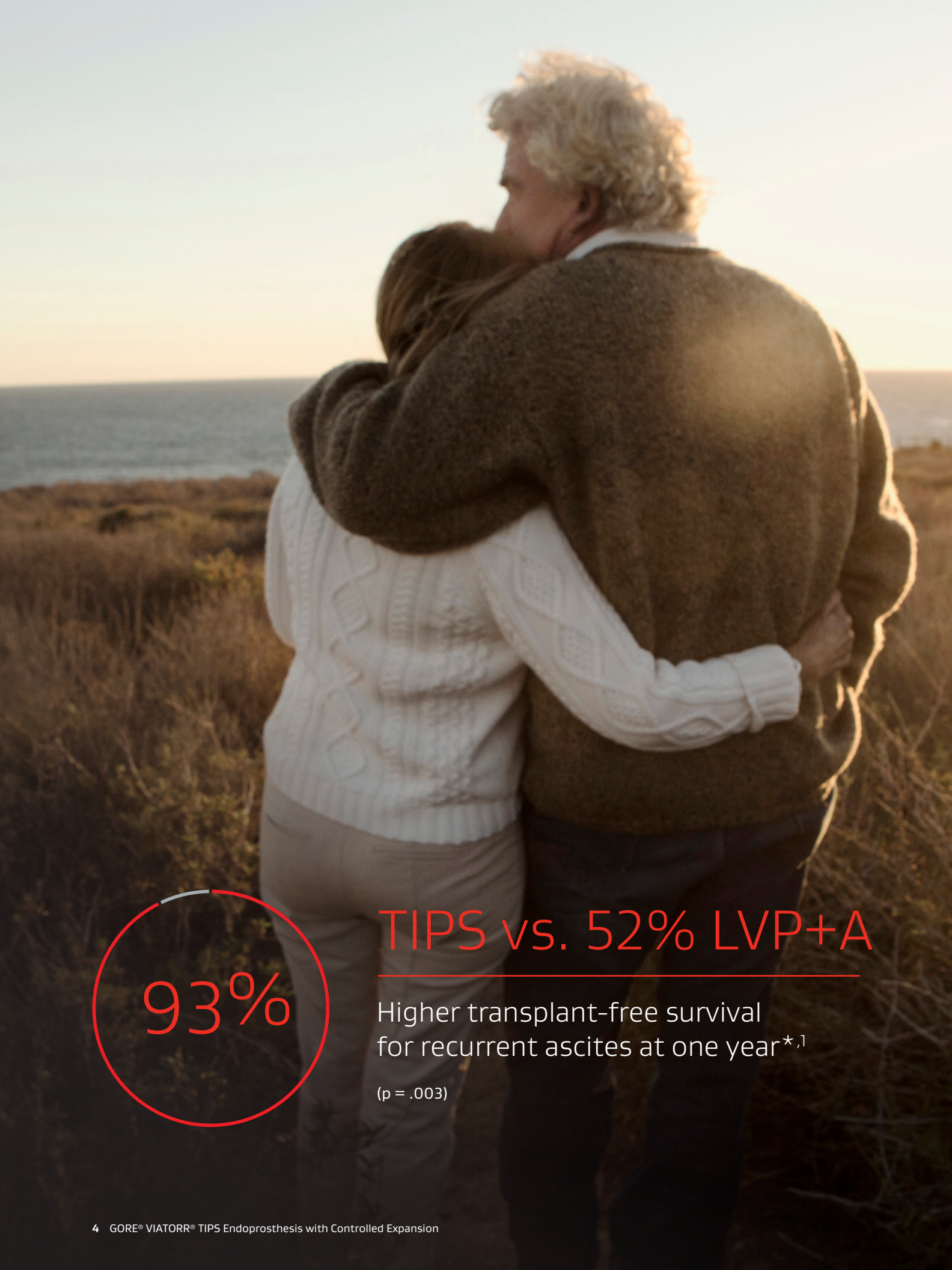
Higher transplant-free survival for recurrent ascites at one year^{*,1}

93% TIPS vs. 52% LVP+A (p = .003)

Higher survival in Child-Pugh C patients with acute variceal bleeding (AVB) at one year^{†,2}

78% TIPS vs. 53% pharmacotherapy+ endoscopic band ligation (EBL) (p = .002)

See additional evidence of improved outcomes for early TIPS in ascites and variceal bleeding patients.



93%

TIPS vs. 52% LVP+A

Higher transplant-free survival
for recurrent ascites at one year^{*,1}

(p = .003)

TIPS with covered stents improved one year transplant-free survival in selected patients with recurrent ascites and should therefore be preferred to LVP with volume expansion.

– Bureau, *et al.*

Earlier TIPS for ascites

Earlier TIPS shows significant improvement in outcomes compared to large-volume paracenteses and albumin infusion (LVP+A) at one year.¹



Higher transplant-free survival at one year
93% TIPS vs. 52% LVP+A (p = .003)



Less recurrence of ascites
32 TIPS vs. 320 LVP+A (p < .001) total number of paracenteses (TIPS n = 29, LVP+A n = 33)



Fewer complications
0% TIPS vs. 18% LVP+A (p = .01) portal hypertension-related bleeding and hernia-related complications



No difference in hepatic encephalopathy (HE)
65% TIPS vs. 65% LVP+A (p = .868) probability of remaining free of hepatic encephalopathy

Earlier TIPS for variceal bleeding

Evidence shows that early TIPS[†] can significantly improve outcomes in liver disease patients, compared to pharmacotherapy and EBL in Child-Pugh B with active bleeding (AB) and Child-Pugh C patients with acute variceal bleeding at one year.²

	Higher survival in Child-Pugh C patients at one year 78% TIPS vs. 53% pharmacotherapy+EBL (p = .002)
	Greater freedom from rebleeding and treatment failure 92% TIPS vs. 74% pharmacotherapy+EBL (p = .017) freedom from failure to control bleeding or prevent rebleeding in Child-Pugh B+AB and C patients
	Less frequent de novo ascites or worsening of previous ascites 9.1% TIPS vs. 47.6% pharmacotherapy+EBL (p < .001) in Child-Pugh B+AB and C patients
	No difference in hepatic encephalopathy 42.4% TIPS vs. 37.7% pharmacotherapy+EBL (p = .863) experienced hepatic encephalopathy

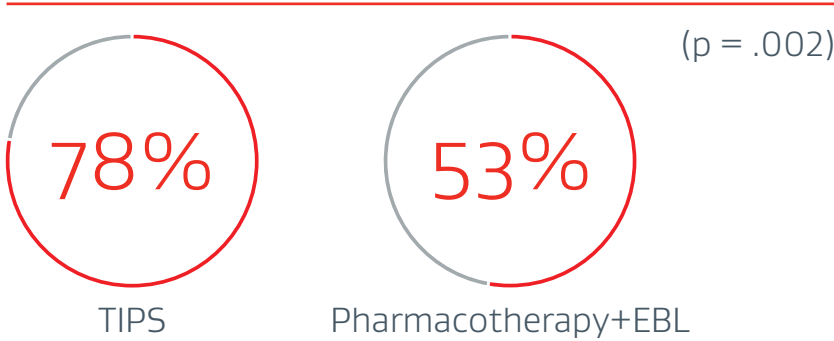
Our study, which included a large number of patients with high-risk criteria admitted for AVB, clearly confirms that the use of p-TIPS[†] reduces failure to control bleeding and rebleeding, reduces de novo or worsening of ascites, did not increase HE, and improved survival.

– Hernández-Gea, *et al.*



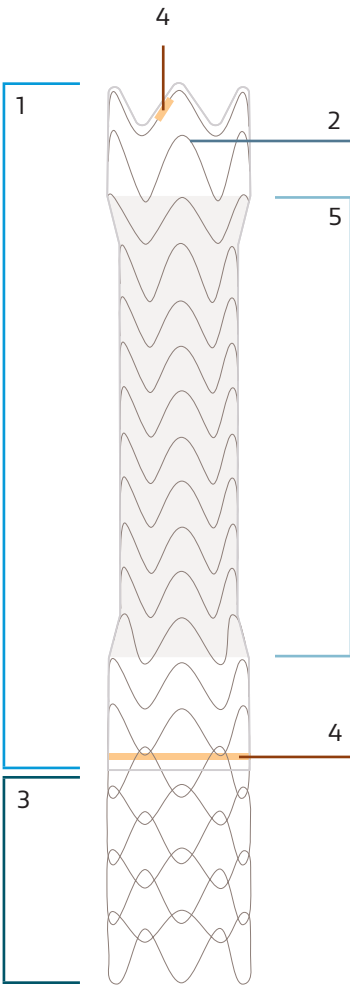
Higher survival

in Child-Pugh C patients with acute variceal bleeding (AVB) at one year^{†,2}



Early TIPS with Controlled Expansion endoprosthesis

GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion combines the legacy of proven patency³ with diameter control to reach a targeted portal pressure gradient.



Continued innovation

- Control the diameter —**
 - Designed to reach a targeted portal pressure gradient
- Lasting diameter control⁵ —**
 - Size and set the diameter to stay
- Engineered for flexibility —**
 - Conformability to tortuous anatomy

Device specifications:

	Feature	Benefit
1	ePTFE graft-lining	Sustained patency due to reduced in-stent stenosis
2	Nitinol frame	Self-expanding, radial force and flexibility
3	Unlined portal region	For portal perfusion and shunt perfusion
4	Radiopaque gold markers	Easy visualization
5	Controlled expansion sleeve	Size and set the diameter during implantation

Review the data. Rethink TIPS.

Consider the evidence for early TIPS

Ascites: Prospective study of patients with cirrhosis and at least two LVPs within a minimum of three weeks. ¹	TIPS (n = 29)	LVP+A (n = 33)
Survival without a liver transplant for one year after the procedure	93%	52% (p = .003)
Total number of paracenteses during one-year follow-up	32	320 (p < .001)
Portal hypertension-related bleeding	0%	18% (p = .01)
Hernia-related complications	0%	18% (p = .01)
Hospitalization	17 days	35 days (p = .04)
One-year probability of freedom from hepatic encephalopathy	65%	65% (p = .868)

All results above were reported at one year.

Variceal Bleeding: Multicenter, international observational study of patients admitted for AVB and at high-risk of treatment failure. ^{†,2}	TIPS (n = 66)	Pharmacotherapy +EBL (n = 605)
One-year probability of survival (in CP-C group)	78%	53% (p = .002)
One-year probability of survival (CP-B with active bleeding group)	75%	77% (p = .935)
De novo or worsening of previous ascites	9.1%	47.6% (p < .001)
Failure to control bleeding and prevent rebleeding	4.5%	23.3% (p = .002)
Hepatic encephalopathy	42.4%	37.7% (p = .863)

All results above were reported at one year.

Ask about the latest published evidence for earlier TIPS with the GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion.

Footnotes and references

* Early TIPS (n = 29) compared to large-volume paracenteses and albumin infusion (LVP+A) (n = 33)

† Early TIPS (n = 66) compared to pharmacotherapy+endoscopic band ligation (EBL) (n = 605). Child-Pugh C patients with scores < 14.

‡ Early TIPS or preemptive TIPS (p-TIPS) for variceal bleeding is defined as treatment within 72 hours of admission, before uncontrolled bleeding or rebleeding occurs.

§ Based on benchtop data on file. Less than 0.25 mm increase in diameter (diameter expansion) demonstrated by a simulated 10 year period at physiologic portal pressures.

1. Bureau C, Thabut D, Oberti F, *et al.* Transjugular intrahepatic portosystemic shunts with covered stents increase transplant-free survival of patients with cirrhosis and recurrent ascites. *Gastroenterology* 2017;152(1):157–163.

2. Hernández-Gea V, Procopet B, Giraldez Á, *et al*; International Variceal Bleeding Observational Study Group and Baveno Cooperation. Preemptive-TIPS improves outcome in high-risk variceal bleeding: an observational study. *Hepatology* 2019;69(1):282–293.

3. Based on GORE® VIATORR® TIPS Endoprosthesis: Bureau C, Pagan JCG, Layrargues GP, *et al.* Patency of stents covered with polytetrafluoroethylene in patients treated by transjugular intrahepatic portosystemic shunts: long term results of a randomized multicentre study. *Liver International* 2007;27(6):742–747.

 Consult Instructions for Use

Refer to *Instructions for Use* for a complete description of all warnings, precautions, and contraindications. ^{Rx Only}

Products listed may not be available in all markets.

GORE, *Together, improving life*, VIATORR and designs are trademarks of W. L. Gore & Associates, Inc.

© 2019 W. L. Gore & Associates, Inc. JULY 2019

W. L. Gore & Associates, Inc.

Flagstaff, AZ 86004

Asia Pacific +65 67332882 **Europe** 00800 6334 4673
United States 800 437 8181 928 779 2771 goremedical.com



AY0645-EN2