

## W. L. GORE & ASSOCIATES MARKS 20 YEARS OF IMPROVING AND EXTENDING LIFE FOR PATIENTS WITH LIVER CIRRHOSIS COMPLICATIONS

As liver disease prevalence grows worldwide, earlier TIPS intervention with the GORE® VIATORR® TIPS Endoprosthesis has proven to increase survival and to reduce complications of liver cirrhosis over conventional therapies.¹

**FLAGSTAFF, Ariz. (August 25, 2020)** — W. L. Gore & Associates is marking the 20th anniversary of the only covered stent indicated for transjugular intrahepatic portosystemic shunt procedures (TIPS). The GORE® VIATORR® TIPS Endoprosthesis, marketed since 2000, and GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion, introduced in 2016, have helped physicians in more than 60 countries to increase survival and improve quality of life in high-risk bleeding and refractory ascites patients.

"Patients who need repeated paracentesis treatments should be considered for TIPS. Paracentesis improves symptoms short-term but may have a negative impact on the systemic hemodynamics and renal function in many patients. This can be overcome by TIPS treatment; still, careful evaluation of the patients is needed," said Jonel Trebicka, M.D., Hepatologist, Frankfurt, Germany, who consults for Gore. "Cirrhosis patients with ascites and, thereby, diuretic-induced renal dysfunction, as well as those unlikely to respond to diuretics, should also be considered for TIPS."

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Brett Fortune, M.D., New York, New York

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Now, as the prevalence of liver disease and related metabolic disorders increases worldwide, and pharmaceutical innovations remain delayed, these Gore devices are emerging in more than their formerly designated roles as tools of last resort. They are becoming known as interventions to be deployed earlier in the care protocol to deliver better value, sooner, to patients who still have the chance to recapture quality life years.

"Our practice is seeing more and more patients with advanced liver disease, particularly fatty liver disease, and it's clear that earlier TIPS intervention benefits patients and disrupts the progression of their morbid condition. We can extend lives and improve quality of life sooner, compared to doing multiple interventions for ascites or variceal bleeding, by treating someone once with TIPS," said Brett Fortune, M.D., Transplant Hepatologist, New York, New York, who consults for Gore.

According to a recent article in the Journal of Hepatology, worldwide, mortality and advanced liver disease are predicted to more than double during 2016 to 2030. Fatty liver disease, including non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH), is an increasing cause of cirrhosis. NAFLD prevalence has been estimated at 24 percent in the general population and NASH prevalence has been estimated at 3 percent to 5 percent in adults. By 2030, the prevalence of NAFLD is predicted to reach over 28 percent in the United States, 29 percent in Italy and 23 percent in France. From 2016 to 2030, NASH cases are projected to increase by 48 percent in China, 43 percent in Germany, 49 percent in Spain and 56 percent in the United States. In the latter, the number of cases is expected to rise from 17 million to 27 million.<sup>2</sup>

"Over the 20 years the Gore device has been used in TIPS, we've seen physicians collaborating in new ways to treat patients earlier in their liver disease diagnoses. Collaboration across gastroenterologists, hepatologists and interventional radiologists has found that earlier referral for TIPS shows significant outcomes improvements for patients," said Eric Zacharias, Gore Medical Products Divisional Leader.

In patients with recurrent ascites, the one-year, transplant-free survival rate for those treated with TIPS was 93 percent, compared to 52 percent for those treated with large-volume paracenteses and albumin infusion (LVP+A). Patients treated with TIPS averaged 17 days of hospitalization compared to 35 for those treated with LVP+A.¹ For Child-Pugh C patients with acute variceal bleeding, the one-year survival rate for TIPS was 78 percent, compared to 53 percent for pharmacotherapy combined with endoscopic therapy.³

"We are seeing treatment with TIPS providing better patient quality of life and value in managing refractory ascites and complications of portal hypertension prior to liver transplant," Dr. Brett Fortune said. "In the world of liver transplant, we are not growing more organs. We need to develop better strategies that effectively manage the complications of cirrhosis and implement them on a global scale. TIPS can support this."

For more information on GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion and the treatment of portal hypertension, visit www.goremedical.com/products/viatorr.

- \*For complete indications and other important safety information for Gore commercial products referenced herein, refer to the applicable *Instructions for Use* (IFU).
- 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. Estes C, Anstee QM, Arias-Loste MT, et al. Modeling NAFLD disease burden in China, France, Germany, Italy, Japan, Spain, United Kingdom, and United States for the period 2016-2030. *Journal of Hepatology* 2018;69(4):896-904.
- 3. Hernández-Gea V, Procopet B, Giráldez Á, et al; International Variceal Bleeding Observational Study Group and Baveno Cooperation. Preemptive-TIPS improves outcome in highrisk variceal bleeding: an observational study. *Hepatology* 2019;69(1):282–293.

Gore engineers medical devices that treat a range of cardiovascular and other health conditions. With more than 45 million medical devices implanted over the course of more than 40 years, Gore builds on its legacy of improving patient outcomes through research, education and quality initiatives. Product performance, ease of use and quality of service provide sustainable cost savings for physicians, hospitals and insurers. Gore is joined in service with clinicians and through this collaboration, we are improving lives, goremedical.com

## **About Gore**

W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Since 1958, Gore has solved complex technical challenges in demanding environments — from outer space to the world's highest peaks to the inner workings of the human body. With more than 10,500 Associates and a strong, team-oriented culture, Gore generates annual revenues of \$3.7 billion. gore.com