A new and improved transjugular intrahepatic portosystemic shunt (TIPS) stent graft: Controlled expansion

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Abstract

Initial underdilation of transjugular intrahepatic portosystemic shunt (TIPS) stents has been a widely proposed and commonly practiced technique to balance portal hypertension relief and the adverse effects associated with excess shunting, especially hepatic encephalopathy. However, this technique has been scrutinized by a number of studies which have shown that underdilated TIPS stents tend to passively expand with time. The recently launched GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion (VIATORR CX®) may address this problem with its novel diameter control capabilities. This article reviews literature concerning passive expansion of initially underdilated TIPS stents and explores preliminary data investigating the use and efficacy of the VIATORR CX® endoprosthesis.

Keywords: Hypertension, portal; Transjugular intrahepatic portosystemic shunt; Transjugular intrahepatic portosystemic shunt patency

Introduction

Transjugular intrahepatic portosystemic shunt (TIPS) has been used extensively to treat portal hypertension and its complications. However, TIPS placement causes a decrease in portosystemic pressure gradient (PSG), which has been associated with complications such as hepatic encephalopathy (HE) and deterioration of liver function. Initial underdilation of the TIPS stent is commonly practiced in order to balance portal hypertension relief and the adverse effects associated with excessive shunting. Despite this, multiple studies have shown that intentionally underdilated stents passively expand over time, raising questions about the effectiveness of this technique. The recently released GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion (VIATORR CX®) aims to address this issue by preventing self-expansion and allowing for constant TIPS diameter as intended.

In this review, we summarize the literature on passive expansion of underdilated TIPS stents. We then introduce the VIATORR CX® stent and explore preliminary data from a study and a case report investigating its use and efficacy.

Passive Expansion of TIPS Stents

Passive expansion of initially underdilated TIPS stents is a well-documented phenomenon with the first reports dating back to 1994. It is thought that passive expansion occurs when the expansive forces of the TIPS stent overcome the compressive forces of the cirrhotic liver. Haskal et al published a study in which 37 shunts were dilated using a 10-mm balloon. Immediately following shunt placement, 19 shunts measured 8.3 ± 1.2 mm (mean ± standard deviation) due to recoiling of stents. At follow-up in 3 to 6 months, 89% of stents had expanded to near 10 mm (9.8 ± 0.4 mm). Approximately ten years later, Gaba et al published a study in which 41 patients underwent TIPS creation with initial underdilation to 8.0 mm, while 20 patients had placement with initial expansion using a 10-mm balloon. Median stent diameter at follow-up in the underdilated group was 9.8 mm, which represented a significant increase from the 8.0 mm baseline diameter (P < 0.001). No significant difference in median stent diameter was observed at follow-up when comparing the underdilated and nominally dilated groups (9.8 mm vs 9.9 mm; P = 0.079).

The first of two studies published by Pieper et al retrospectively investigated passive stent expansion in 39 patients who
underwent TIPS creation using VIATORR and Wallstent™ endoprostheses. VIATORR stent grafts and Wallstent™ endoprostheses were initially underdilated to an average of 64.4% ± 2.3% and 65.63% ± 8.52% of nominal area, respectively. At the time of last follow-up, VIATORR and Wallstent™ endoprostheses had significantly expanded to a mean of 87.8% ± 7.9% and 82.34% ± 19.6% of nominal area in the TIPS tract, respectively (P < 0.05). Of note, significant expansion occurred within the first 30 days and between 30 and 180 days after TIPS creation in the VIATORR group. The authors also published the only prospective study to date investigating the expansion kinetics of underdilated TIPS stent grafts.11 In this study, 20 patients underwent TIPS creation using a 10-mm VIATORR stent graft with initial dilation to 8 mm. Stent diameter increased significantly at 1 and 6 weeks, measuring an average of 8.7 ± 0.27 mm and 9.4 ± 0.11 mm on three-dimensional ultrasound examination (P < 0.001).

Borghol et al10 examined endoluminal stent diameter in 16 patients who underwent TIPS creation using a 10-mm VIATORR stent graft, underdilated at the time of placement. Mean endoluminal stent diameter, measured via angiography, significantly increased from 8.96 ± 1.12 mm to 10.00 ± 1.45 mm after 6 months (P = 0.04). However, no significant enlargement was observed at time points beyond 12 months. Similarly, Mollaiyan et al13 investigated the behavior of self-expanding stents in 100 consecutive patients who received a TIPS revision. All stents were underdilated at implantation, reaching between 76% to 92% of their luminal diameter. At a mean follow-up time of 12.7 ± 17.8 months and prior to TIPS revision, the stents expanded by 0.5 to 1.6 mm depending on nominal stent size and degree of initial underdilation. The authors concluded that precise adjustment of the stent to achieve a desired PSG is not possible. Further, stents have a tendency to expand towards their nominal diameter and thus underdilation may not be useful. The authors noted that the new technologies such as VIATORR CX® endoprostheses may solve the dilemma of balancing sufficient clinical response while preventing the occurrence of HE.

VIATORR TIPS Endoprosthesis with Controlled Expansion

In March of 2017, W. L. Gore & Associates, Inc. announced the U.S. Food and Drug Administration approval and U.S. launch of its GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion [VIATORR CX®].13 According to the manufacturer, VIATORR CX® allows interventionalists to finely tune stent diameter until the desired PSG is reached and set the diameter to stay. Benchtop data showed a maximal diameter increase of no more than 0.25 mm over a simulation period of 10 years at physiological portal pressures. Controlled expansion is enabled by the addition of a controlled expansion sleeve on the outside of the device (Fig. 1). The ePTFE sleeve limits the diameter of the self-expanding nitinol stent within the range of 8 to 10 mm. The sleeve can then be stretched with balloon dilatation under an inflation pressure of at least 10 atm to achieve the desired device diameter based on chosen balloon diameter. Delivery and deployment are unchanged.

Preliminary data from a case-control study demonstrated a reduction in post-procedure complications in patients who underwent TIPS creation using the VIATORR CX® endoprostheses.14 The study compared 21 patients who underwent TIPS implantation using VIATORR CX® to 48 patients who received a regular covered VIATORR stent and 36 patients who received a bare metal stent (BMS). Patients were assessed at 7 days, 6 weeks, and 3 months following TIPS creation. MELD-Na score at 3 months was significantly improved in the VIATORR CX® group compared to the regular VIATORR and BMS groups (8 vs 11 vs 15; P = 0.019). In addition, blood flow velocity through the TIPS tract was significantly lower at 6 weeks in regular VIATORR and BMS recipients compared to VIATORR CX® recipients (P = 0.002). Patients who received BMS experienced splanchnic vein thrombosis significantly more frequently than both VIATORR CX® and regular VIATORR recipients (P < 0.001), while both VIATORR groups experienced fewer readmissions for sepsis compared to the BMS group (P = 0.034). Further, VIATORR CX® recipients had significantly fewer readmissions for ascites at 3 months compared to patients who received regular VIATORR or BMS (6% vs 14% vs 40%; P = 0.006).

Beyond its use in new TIPS creations, the VIATORR CX® endoprostheses may also be well-suited for TIPS reductions. In a recent letter to the editor, Srinivasa et al15 described two patients who developed medically refractory HE following TIPS creation. Both patients underwent TIPS reduction using the VIATORR CX® endoprostheses deployed to a diameter of 8 mm and experienced a 1-grade reduction in HE at follow-up. The authors point out that the VIATORR CX® is superior for TIPS reduction because it does
not require the use of multiple stents and balloons, resulting in a shorter procedure time. That being said, the VIATORR CX® endoprosthesis is not commercially available in diameters smaller than 8 mm and this could represent a disadvantage if shunt reduction to 8 mm is insufficient for certain patients suffering from TIPS-related complications.

Conclusion

In summary, initial underdilation of TIPS stents is commonly performed to relieve portal hypertension, while circumventing the complications associated with excess shunting. However, this approach is problematic due to the tendency of legacy stents to passively expand over time. The newly released VIATORR CX® endoprosthesis may address this issue with its novel diameter control capabilities. Preliminary results from a study comparing the VIATORR CX® stent to legacy VIATORR and BMS shows a reduction in post-TIPS complications in patients who receive the VIATORR CX®. Further, the new stent allows for simpler TIPS reductions with shorter procedure times. Further studies are necessary to fully understand the benefits of the new VIATORR CX® stent; however, the preliminary data appear promising.

Conflicts of Interest

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

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References