CLINICAL STUDY

Long-Term Patency and Clinical Analysis of Expanded Polytetrafluoroethylene–Covered Transjugular Intrahepatic Portosystemic Shunt Stent Grafts

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ABSTRACT

Purpose: To evaluate long-term patency and symptomatic recurrence rates following transjugular intrahepatic portosystemic shunt (TIPS) creation with expanded polytetrafluoroethylene (ePTFE)–covered stent grafts and to determine the necessity of extended clinical follow-up beyond 2 years after TIPS creation.

Materials and Methods: A retrospective review including 262 TIPSs created with ePTFE-covered stent grafts between July 2002 and October 2012 was performed. Primary, primary assisted, and secondary patency rates were calculated. Assessment of clinical data included technical, hemodynamic, and clinical success rates, as well as mortality after TIPS creation.

Results: Primary patency rates at 2, 4, and 6 years were 74%, 62%, and 50%, respectively. Primary assisted patency rates at 2, 4, and 6 years were 93%, 85%, and 78%, respectively. Secondary patency rates at 2, 4, and 6 years were 99%, 91%, and 84%, respectively. Technical and hemodynamic success rates were 99% and 93%, respectively. Clinical success rates for refractory ascites were 66% (complete response) and 90% (partial response); clinical success rate for bleeding/varices was 90%. Mortality rates at 2, 4, and 6 years after TIPS creation were 27%, 38%, and 46%, respectively. At the median wait time until transplantation, patients had an 84% chance of being alive. TIPS dysfunction developed in 21% of patients; 30% of revisions occurred later than 2 years during follow-up.

Conclusions: Beyond 2 years after TIPS creation, patency rates gradually decrease, mortality rates continue to increase, and the chance of recurrent ascites or bleeding remains present. Together, these findings suggest that continued clinical follow-up beyond 2 years is necessary in patients with a TIPS created with an ePTFE-covered stent graft.

ABBREVIATIONS

ePTFE = expanded polytetrafluoroethylene, HE = hepatic encephalopathy, LVP = large-volume paracentesis, PSG = portosystemic gradient, SEM = standard error of the mean, TIPS = transjugular intrahepatic portosystemic shunt

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Transjugular intrahepatic portosystemic shunts (TIPSs) were initially created by using bare metal stents to create a shunt tract from the portal venous system to the hepatic venous system for treatment of symptomatic portal hypertension. However, these stents have unacceptably low patency rates at short-term follow-up—often less than 50% at 1 year—leading to frequent clinical relapse and stent revision, which carry additional procedural risks and expense (1). With the development of expanded polytetrafluoroethylene (ePTFE)–covered stent grafts, short-term TIPS patency has improved. Numerous studies have demonstrated superiority of ePTFE stent grafts for TIPS creation (2–4), prompting the American Association for the Study of Liver Diseases to recommend the use of ePTFE stent grafts over bare metal stents (5).

The majority of studies assessing patency of TIPSs created with ePTFE-covered stent grafts evaluate short to intermediate follow-up (1–2 y; **Table 1**) (2–4,6–21). The literature contains few data evaluating long-term patency of TIPSs created with ePTFE-covered stent grafts or the need for close clinical follow-up beyond 2 years. The present study presents a single health system experience with ePTFE-covered stent-graft TIPSs created during the past decade, specifically addressing the long-term patency of these shunts and rates of symptomatic recurrence, thereby examining the necessity for extended clinical follow-up beyond 2 years after TIPS creation.

MATERIALS AND METHODS

Study Design and Definitions

With approval from the institutional review board and in compliance with the Health Insurance Portability and Accountability Act, the interventional radiology database (HI-IQ; ConexSys, Lincoln, Rhode Island) was used to identify all TIPSs created with an ePTFE-covered stent graft between July 2002 and October 2012 at two hospitals within a single health system. By using the electronic medical record, long-term follow-up data were retrospectively analyzed to determine primary, primary assisted, and secondary patency rates. Primary patency was defined as the time from TIPS creation until the need for revision. Primary assisted patency was defined as the time from TIPS creation until shunt occlusion requiring recanalization. Secondary patency was defined as the time from TIPS creation until permanent shunt occlusion, ie, the shunt could not be recanalized or no recanalization was attempted. Dysfunctional TIPSs were those that required revision based on venographic findings including stenosis, occlusion, portosystemic gradient (PSG) > 12 mm Hg, and variceal or portal venous branch opacification in symptomatic patients without other obvious TIPS abnormality.

For the purpose of the present study, severe refractory hepatic encephalopathy (HE) was defined as encephal-

Table 1. Reported ePTFE-Covered TIPS Patency Rates (2–4,6–21)

			Primary Patency (%)			
Study, Year	No. of TIPSs*	Follow-up (y)	1 Year	2 Years	3 Years	Study Design
Angeloni et al (14), 2004	32	1	76	–	–	ePTFE vs BMS
Bureau et al (15), 2004	39	2	86	80	–	ePTFE vs BMS
Charon et al (6), 2004	100	1	84	–	–	ePTFE only
Hausegger et al (13), 2004	71	1	81	–	–	ePTFE only
Maleux et al (10), 2004	56	1	89	–	–	ePTFE only
Rossi et al (11), 2004	53	1	84	–	–	ePTFE only
Barrio et al (2), 2005	20	1	100	–	–	ePTFE vs BMS
Vignali et al (7), 2005	114	2	80	76	–	ePTFE only
Rössle et al (12), 2006	100	3	90	84	74	ePTFE only
Tripathi et al (16), 2006	157	2	92	89	–	ePTFE vs BMS
Jung et al (17), 2009	40	1	38	–	–	ePTFE vs BMS
Saad et al (9), 2010	126	2	87	62	–	ePTFE only (VIATORR vs Fluency)
Luca et al (8), 2011	57	2	79	71	–	ePTFE vs BMS
Gaba et al (3), 2012	70	2	90	78	–	ePTFE vs BMS
Sommer et al (4), 2012	58	1	62	–	–	ePTFE vs BMS
Chen et al (18), 2013	103	3	81	76	76	ePTFE only†
Luo et al (19), 2013	33	2	91	85	–	ePTFE vs Wallgraft
Sajja et al (20), 2013	59	2	–	80	–	ePTFE only
Wu et al (21), 2013	114	2	87	75	–	ePTFE only (Fluency)

BMS = bare metal stent, ePTFE = expanded polytetrafluoroethylene, TIPS = transjugular intrahepatic portosystemic shunt.
*Created with VIATORR stent graft unless otherwise specified.
†Patency rates for TIPS-only group (no variceal embolization).