

Reporting Standards for Transjugular Intrahepatic Portosystemic Shunts

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IN the last 5 years, the transjugular intrahepatic portosystemic shunt (TIPS) procedure has become widely disseminated. The number of interventional radiologists who are creating shunts has steadily increased as the procedure has become an accepted method of reducing portal vein pressure (1–28).

Although the optimal technique for shunt creation continues to evolve, shunts can routinely be created in more than 93% of patients (5,8,13,14,18,29). Accordingly, significant attention is now directed to the collection and reporting of prospective, standardized controlled data regarding the safety, efficacy, and patency of TIPS. The purpose of this document is to aid this process by recommending standards for reporting of TIPS data.

At present, the most accepted indication for TIPS is for the treatment of recurrent variceal hemorrhage that is refractory or not amenable to endoscopic therapy. Other indications are being evaluated, such as refractory ascites. It is too early to reach a consensus on reporting standards addressing all uses of TIPS. Future addenda to

this document will discuss other uses of TIPS as they become more established.

STUDY POPULATION AND STRATIFICATION

It is well documented in both medical and surgical literature that both early and long-term morbidity and mortality after an episode of variceal hemorrhage are closely related to the etiology and severity of the underlying hepatocellular disease (6,30–33). For example, patients with advanced alcohol-related cirrhosis often fare poorly when compared to patients with nonalcoholic cirrhosis, particularly those patients who continue to actively abuse alcohol (34,35). Accordingly, the etiology of liver disease should be reported in patients undergoing TIPS placement (Table 1). In patients with alcoholic cirrhosis, the presence of continuing alcohol abuse at the time of TIPS creation and at subsequent follow-up intervals should be noted.

The Child-Pugh score is a modification of the Child-Turcotte classification, which allows stratification of patients beyond the categorical classes of the Child-Turcotte classification (36) (Tables 2 and 3). This easily calculated score is a continuous variable that better describes the range of severity of liver disease. Its predictive value has been well documented. It is recommended that Child-Pugh scores be reported for patients undergoing TIPS. Child classes can be documented as well (36–39); however, there are discrepancies among different versions of the Child classification. In some cases,

a score of 10 points or more defines a patient as Child class C, while in other cases a score of 12 or higher defines class C. This apparently small difference can have a large impact on stratifying patient outcomes (7,24,34,35). To standardize Child class nomenclature among investigators, it is recommended that the point system outlined in Table 3 (modified Child-Pugh system) be used both for calculating the Child-Pugh score and Child classes.

The degree of physiologic derangement and comorbidities at the time of shunt surgery or TIPS can have marked effects on early outcome. Such differences, in part, account for the disparity in survival and outcome reported in clinical series of TIPS patients. To better describe the treated population, the presence or absence of the following conditions should be noted in a patient undergoing TIPS: (a) continuing red blood cell transfusion requirement within 24 hours prior to TIPS; (b) pharmacologic therapies to reduce portal pressure, including intravenous vasopressin, somatostatin, and nitrate infusions; (c) endotracheal intubation; (d) balloon tamponade; (e) preexisting sepsis; (f) bacteremia; (g) pneumonia; (h) adult respiratory distress syndrome (ARDS); (i) bacterial peritonitis; (j) ascites; (k) pulmonary edema or heart failure; and (l) hepatic or renal failure. For “actively bleeding” patients, the interval between patient referral and time of shunt creation (eg, hours vs days) should be noted. The type and location of variceal bleeding must be reported (eg, esophageal, gastric, or intestinal varices, or portal gastropathy). Con-

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Table 1
Patient Descriptors

- Etiology of liver disease (for patients with alcoholic cirrhosis, note continuing alcohol abuse/abstinence)
- Number of prior episodes of bleeding/prior treatment (eg, surgical portosystemic shunt/endoscopic therapy)
- Child-Pugh score/class
- Continuing pharmacologic requirements: blood transfusion, vasopressin, somatostatin analogues
- Endotracheal intubation
- Balloon tamponade
- Preexisting sepsis
- Bacteremia
- Pneumonia
- Adult respiratory distress syndrome (ARDS)
- Hepatic or renal failure
- Pre-shunt laboratory parameters: hemoglobin, prothrombin time, bilirubin, albumin, alanine aminotransferase (ALT/SGPT), aspartate aminotransferase (AST/SGOT), alkaline phosphatase, white blood cell count (WBC), platelet count, creatinine, serum venous ammonia
- APACHE II score
- Anatomic abnormalities, including portal, mesenteric, splenic and hepatic vein thromboses, and malignancies
- Quality of life assessment
- Inclusion/exclusion criteria specific to the reported study.

comitant nonvariceal gastrointestinal bleeding should be recorded, such as that due to peptic disease or sclerotherapy ulcers. Suggested pertinent serum laboratory parameters include hemoglobin, prothrombin time, albumin, bilirubin, alanine aminotransferase (ALT/SGPT), aspartate aminotransferase (AST/SGOT), alkaline phosphatase, white blood cell count, platelet count, serum venous ammonia, and creatinine. In all cases, if possible, the number of previous episodes of variceal bleeding, endoscopic sclerotherapy or banding sessions, surgeries, and/or other therapies should be reported.

The APACHE II (Acute Physiology and Chronic Health Evaluation) score provides a validated method of stratifying outcome of patients admitted to intensive care units for a large variety of illnesses (40). As a measure of acute

Table 2
Child-Turcotte Classification (Not Recommended) (39)

Variable	Class		
	A	B	C
Bilirubin (mg/dL)	<2.0	2.0–3.0	>3.0
Albumin (mg/dL)	>3.5	3.0–3.5	<3.0
Ascites	None	Easily controlled	Refractory
Encephalopathy	None	Minimal	Advanced
Nutritional status	Excellent	Fair	Poor

physiologic derangement, it appears similarly effective at stratifying and predicting the degree of 30-day morbidity and mortality of patients referred for TIPS (5,32,41). If APACHE II data are reported, the scores should be calculated from physiologic data from the 24 hours preceding shunt placement.

The presence of unusual anatomic abnormalities, such as hepatic, portal, splenic, or mesenteric venous thromboses or stenoses should be noted, particularly if patients were excluded because of these conditions. Intrahepatic or pancreatic malignancies should be described.

The prevalence of patients with truly refractory and intractable ascites—that is, patients who do not respond to high-dose diuretics, bedrest, and low-sodium diets, and/or do not tolerate effective diuretic regimens because of serious side effects (eg, renal failure, hepatic encephalopathy, electrolyte imbalance, and drug allergy)—is approximately 5% of all cirrhotic patients with ascites (42–44). These patients may carry a much poorer prognosis than patients with ascites that may be difficult but not impossible to control because they have commonly associated severe underlying liver disease. Many patients undergoing TIPS for treatment of ascites may, in fact, be undergoing TIPS for poorly controlled or difficult to manage ascites rather than truly refractory or intractable ascites. Because outcomes may vary widely among these two groups, it is important that investigations of TIPS for treatment of ascites describe in depth the population of patients being treated. Therefore, centers must clearly state their definition of the term “refractory.” Inclusion and exclusion criteria, and the specific diuretic and paracentesis reg-

imens used prior to TIPS must be reported. The application of a standardized diuretic and/or paracentesis regimen for a predefined period prior to TIPS is recommended for those centers reporting comparisons of TIPS with other treatments for ascites. Sonographic methods for quantifying the amount of ascites remain controversial. Therefore, no specific sonographic ascites grading method is currently recommended. At a minimum, the severity of ascites can be classified as absent, minimal, moderate, and severe. Minimal ascites is defined as that which is only detectable with sonography; moderate ascites is ascites that is clinically apparent; severe ascites is defined as ascites that results in a tense abdomen. This grading system is recommended for all studies that discuss the primary or secondary effects of TIPS on ascites.

All patients must be reported on an “intention-to-treat” basis. The definition of intention to treat must be clearly defined in terms that are most relevant to the group that is reported. For example, intention to treat can be defined as the time of initial referral for TIPS or the point at which the procedure is actually initiated. The use of the first definition may avoid the exclusion bias related to patient death prior to the TIPS procedure.

Study inclusion and exclusion criteria must be clearly stated. For example, exclusion of patients with biliary ductal dilation or malignancies should be noted.

Prospective evaluation of quality of life is important because TIPS placement can significantly alter the functional status of the patient (18,45). For example, quality of life and nutritional status may improve with the resolution of ascites. Alternatively, quality of life may worsen from portosystemic

Table 3
Child-Pugh Score (28) and Point Scheme for Child's Classes (Recommended)

Variable	Points Accorded		
	1	2	3
Bilirubin (mg/dL)	<2.0	2.0–3.0	>3.0
Albumin (mg/dL)	>3.5	2.8–3.5	<2.8
Ascites (clinical evaluation)	None*	Easily controlled	Poorly controlled
Neurologic disorder	None†	Minimal	Advanced
Prothrombin (sec > control)	<4.0	4–6	>6

Note.—Point modification for bilirubin values in patients with primary biliary cirrhosis: Bilirubin (mg/dL): 1–4: 1 point, >4–10: 2 points, >10: 3 points.
 * Physical examination.
 † Clinical evaluation.
 Class A: 5, 6 points.
 Class B: 7–9 points.
 Class C: 10–15 points.

encephalopathy (PSE). These effects can be quantified and graded with use of one of several validated schemata, including the sickness impact profile (SIP) or the Karnofsky scale (46–49). The scales vary significantly in their complexity and length. The choice of an appropriate scale should be based on the specific questions posed in the study.

TREATMENT DESCRIPTION

In order to describe their level of experience in creating shunts, centers should report the approximate number of TIPS created at that center prior to instituting the described study.

The technique and needle system used to create the shunt should be described or referenced. The venous access site and anatomic location of the shunt should be recorded. The type of stents placed, and, in the case of self-expanding stents such as the Wallstent or Strecker stent, the nominal size of that stent should be reported. The diameter of the largest balloon catheter used to dilate the shunt should be noted. If embolization is performed, the site of embolization and the agents used must be noted.

All forms of portosystemic diversion, by necessity, deprive the liver of a fraction of blood flow. Several investigators have correlated the direction of portal blood flow before and after shunt placement with encephalopathy and liver function. Complete deprivation of nutrient hepatic perfusion, as occurs with total portocaval shunts,

leads to accelerated liver failure and higher rates of encephalopathy. This effect is much less pronounced in small-diameter surgical shunts or TIPS (50–52). To allow investigators to better clarify the role of direction of portal flow and hepatic function, it is necessary to standardize the use of the terms hepatofugal and hepatopetal.

If changes in the direction of portal venous flow are reported after TIPS, the following terminology should be used. Hepatofugal and hepatopetal refer to the direction of blood flow with respect to the hepatic sinusoids. In the absence of portal hypertension, the direction of main portal vein flow is well correlated with the direction of intrahepatic portal flow. On the other hand, patients with liver disease often have segmental differences in the direction of intrahepatic portal flow (53). For example, prior to TIPS, blood in the main and right portal veins may flow in the hepatopetal direction, whereas left portal flow may be hepatofugal, flowing away from the sinusoids into a recanalized umbilical vein. Once a TIPS is created, the direction of main portal vein flow is further dissociated from intrahepatic portal flow because the intrahepatic portal flow often reverses, and flows toward the shunt. A patient with total hepatofugal portal flow prior to TIPS may have hepatopetal main portal flow yet continued hepatofugal intrahepatic portal flow after TIPS. Newly hepatopetal main portal flow in the latter example does not imply improvement of nutrient portal perfusion because intrahe-

patic portal flow remains fugal, now simply traveling into the TIPS instead of the main portal vein. Therefore, use of the terms hepatopetal and hepatofugal must be accompanied by the name of the specific vein to which they are applied. These definitions apply to all invasive and noninvasive methods of shunt and portal venous imaging.

Measures of Success

Success should be classified as technical, hemodynamic, and clinical success.

Technical Success—Technical success describes the successful creation of a shunt between the hepatic vein and intrahepatic branch of the portal vein. In the case of parallel shunt placement, technical success is reported for individual shunts.

Hemodynamic Success—Hemodynamic success refers to the successful post-TIPS reduction of the portosystemic gradient below a threshold chosen for that study. Some authors have reported that, in patients with bleeding varices, cessation of variceal filling during hand-injected splenic (or, in the case of intestinal varices, mesenteric) venography is a useful marker of successful decompression. This sign can be more difficult to standardize because different injection rates can lead to differences in the appearance of variceal flow. While it can be argued that endoscopic confirmation of variceal decompression may be the gold standard for confirming hemodynamic success, this is impractical and probably unnecessary. Hemodynamic success can also be reported at follow-up shunt revisions. Absolute portal and right atrial pressures and the calculated portosystemic gradient, in millimeters of mercury, should be recorded at the start and completion of the procedure. The data should be reported as mean \pm standard deviation. This committee does not currently recommend a particular threshold value for portosystemic gradient for reasons that are discussed in greater detail in the section discussing follow-up shunt function.

Clinical Success—Numerous prospective and retrospective uncontrolled studies have documented the efficacy and complications of TIPS

for treatment of variceal bleeding and refractory ascites. These “feasibility” studies must be followed with prospective multicenter randomized trials, which compare the clinical success of TIPS with that of endoscopic, medical, and surgical therapies. Although much has been written about the unpredictable initial patency of TIPS, the long-term management of patients after their first episode of variceal bleeding will depend on the actual outcomes of differing treatments, not on the absolute patency of a TIPS. Therefore, clinical success is perhaps the most important parameter in longitudinal studies of TIPS patients.

In the case of actively bleeding patients, early clinical success is determined by prompt arrest of acute variceal hemorrhage. This is indicated by cessation of demonstrable gastrointestinal bleeding, transfusion requirements, pharmacologic support, balloon tamponade, and return of hemodynamic stability. Because nonvariceal bleeding can coexist in upward of one-third of patients with varices, it is essential to verify endoscopically the causes of continued or recurrent bleeding after shunt placement or revision (54,55). The results of repeated shunt venography, when performed in these cases, must be reported.

Clinical success is also reflected in the interval of time during which the patient remains free of the symptoms alleviated by the TIPS. For patients treated for variceal hemorrhage, this is the period after TIPS until a bleeding episode recurs. For patients with ascites, this is the period between improvement or resolution of ascites and recurrence of ascites. This is best described in terms of “event free survival” intervals after TIPS placement. For variceal bleeding, it is recognized that this measure will greatly underestimate shunt stenosis or occlusion because TIPS patients may remain asymptomatic for prolonged periods despite highly stenotic or occluded shunts. Data should be analyzed with use of the Kaplan-Meier or life-table method (56,57). Cases at risk at each time interval and standard error should be included in the graphical analysis unless included in an accompanying life table. The causes for case attrition at each interval must be

Table 4
Complications of TIPS

- Transient or permanent contrast-induced renal failure
- Pulmonary edema
- Hepatic infarction
- Hepatic arterial injury
- Gallbladder puncture
- Stent malpositions
- Hemobilia
- Hemolysis
- Fever
- Sepsis
- Hemoperitoneum
- Radiation injury
- Entry site hematoma
- Subcapsular hematoma
- Encephalopathy
- Liver failure

reported (eg, death, transplantation, lost to follow-up, and so forth).

Complications

All morbidity and mortality that occurs within 30 days of shunt creation must be reported. As a subset of this list, it is important to note those complications that are specific to the nature of the TIPS procedure. These include transient or permanent contrast-induced renal failure (within 48 hours), pulmonary edema, hepatic infarction, entry site hematoma, hepatic arterial injury, hemobilia, hemolysis, fever, sepsis, subcapsular hematoma, hemoperitoneum, gallbladder puncture, stent malpositions, and radiation injury (Table 4). The following complications are common to all portosystemic shunts and should be reported if they occur at any time after shunt placement: liver failure and encephalopathy (discussed later).

Complications that occur at the time of follow-up shunt interventions should be reported separately.

FOLLOW-UP SHUNT STUDIES

Definitions

Intervention refers to all procedures that change the status of an existing shunt.

Revision refers to all interventions performed in patent, preexisting shunts, including balloon dilation, mechanical or pharmacologic treatment

of stenoses, placement of additional stents, or procedures to limit or reduce the degree of shunting.

Recanalization refers to all interventions to treat complete shunt occlusions. It includes “revisions” performed as part of recanalization.

Creation of a new shunt refers to the creation of a separate shunt within an entirely new intrahepatic tract.

Shunt Function During Follow-up

At present, shunt efficacy is primarily limited by the development of shunt stenosis or occlusion. Approximately 20%–50% of shunts will develop flow-limiting stenoses or occlusions within 1 year of shunt creation (7,8,58–64). With surveillance and revision, however, flow through the shunt can be maintained or restored in nearly all cases. In the majority of cases, recurrent variceal hemorrhage or ascites is clearly correlated with flow-limiting shunt stenoses or increasing portal system pressures due to worsening liver disease. Accordingly, much effort has been directed to describing sonographic and venographic follow-up regimens designed to detect and maintain shunt patency. The widely varying rates of shunt “patency” are mostly due to different reporting methods and definitions of patency. In the past, this term has been used to reflect investigator-defined degrees of shunt stenosis or portal hypertension above which shunt revision was believed to be warranted. A more appropriate use of the term patency is in the binary fashion applied to all vascular grafts. Thus, patency of a TIPS is defined as a lack of shunt thrombosis/occlusion.

At present, thresholds for shunt revision cannot be standardized for TIPS because the relationships between clinical effect and threshold values for loss of shunt function remain ill-defined. While it is clear that shunt stenosis will place patients at increased risk of recurrent symptoms, the specific thresholds that define and quantify this relative risk are unknown. The event(s) that triggers the onset of new or recurrent variceal hemorrhage in patients with long-standing portal hypertension is unknown. Many patients with stenotic or occluded surgical portosystemic shunts or TIPS may remain asymptomatic for long periods. Sim-

Table 5
Grading of Mental State

Grade	Mental State
0	No abnormality
1	Trivial lack of awareness Euphoria or anxiety Shortened attention span Impaired performance of addition
2	Lethargy or apathy Minimal disorientation for time or place Subtle personality change Inappropriate behavior Impaired performance of subtraction
3	Somnolence to semi-stupor, but responsive to verbal stimuli Confusion
4	Coma (unresponsive to verbal or noxious stimuli)

Table 6
Grading of Asterixis

Grade	Asterixis
0	No flapping motions
1+	Rare flapping motion (1–2 per 30 sec)
2+	Occasional, irregular flaps (3–4 per 30 sec)
3+	Frequent flaps (5–30 per 30 sec)
4+	Almost continuous flapping motions

Table 7
Number Connection Test

Grade	Duration of Test
0	20–40 sec
1	41–60 sec
2	61–90 sec
3	91–120 sec
4>	120 sec, unable to perform test

Table 8
Ammonia Concentration

Grade	Ammonia Concentration
0	Within normal limits
1+	1–1.33 × the upper limit of normal
2+	1.33–1.67 × the upper limit of normal
3+	1.67–2.0 × the upper limit of normal
4+	>2 × the upper limit of normal

ple elevation of the portosystemic gradient above 12 mm Hg alone does not cause variceal bleeding, whereas reduction of the portosystemic gradient to below 12 mm Hg will not eradicate bleeding in all patients (65–68). Several authors have suggested that non-filling of varices during shunt venography is an alternative index for shunt adequacy because portal and systemic pressures fluctuate markedly during the procedure and in the postprocedure period. In nonbleeding patients, it is harder still to define uniform endpoints for shunt placement. For example, an elective patient with portal gastropathy and a very high portal pressure might be effectively treated with a percentage reduction of the portosystemic gradient rather than reduction below an absolute pressure value. Finally, threshold pressure gradients for treatment of refractory ascites are presently indeterminate, as this body of relevant experience continues to grow.

Some authors have used a 50% stenosis as a loss of shunt patency. Although this standard has proved useful in the arterial system (69), it is not directly transferable to the portal venous system because partial portal decompression can be achieved and maintained with different diameter shunts in different patients. Furthermore, the severity of portal hypertension varies in individual patients over

time as the severity of their liver disease changes. For example, a patient requiring a 10-mm-diameter shunt during a massive bleeding episode may, at follow-up, maintain a low portosystemic gradient and remain symptom-free despite having only a 4-mm shunt. With use of a 50% stenosis threshold, this patient would be defined as having a stenotic yet effective shunt. In contrast, in a patient with severe portal hypertension, effective decompression can be achieved with a 12-mm shunt, but recurrent symptoms may develop when the shunt narrows to a 10-mm diameter. This 10-mm TIPS would be classified as “patent,” although actually ineffective and revision or parallel shunt placement is warranted. Furthermore, accurate measurement of limiting shunt diameter (especially the outflow hepatic vein) is difficult without multiple projection venography and radiographic rulers (8,70). Intravascular ultrasound is the most accurate measure of shunt luminal diameter.

Until further clinical studies clarify these issues, consensus cannot be reached on standard definitions for shunt function. Longitudinal clinical studies of TIPS patients should describe follow-up methods and protocols used, as well as patient compliance returning for follow-up at each interval. The latter is particularly important because incomplete follow-up or long follow-up intervals can overestimate shunt function, as stenoses may develop early within the study interval. Given that stenoses frequently occur within the first 6 months after TIPS, reports of shunt stenosis should have sufficient data points within the first 6 months to create valid life tables and avoid underesti-

imating the rate of shunt stenosis. The number and type of interventions performed, percentage of shunt stenosis, portal and systemic pressures, and portosystemic gradients recorded at each interval should be described. The frequency and method of shunt follow-up and imaging should be relevant to the phenomenon being studied.

Finally, one setting in which percentage shunt stenosis becomes an important parameter is within trials comparing techniques or devices designed to minimize shunt stenosis and occlusion. For example, core laboratory measurement of luminal stenosis would be necessary to compare the durability of a TIPS stent-graft with a bare mesh stent.

ENCEPHALOPATHY

Assessing the presence and severity of PSE is an essential component of patient care and clinical research in TIPS. The lack of agreement on a common standard for assessment of PSE makes it difficult to compare encephalopathy data for patients undergoing creation of TIPS or surgical shunts. For example, at some centers, all patients received prophylactic lactulose after TIPS, whereas at others, lactulose and

Table 9
Sample Calculation of PSE Index: Tracking the Improvement of Encephalopathy from Immediately after TIPS to 6 Months Later

Component	Immediately after TIPS			6 Months + Lactulose	
	Factor	Grade	Score	Grade	Score
Mental state	3	2	6	0	0
Number connection	1	4	4	1	1
Asterixis	1	2	2	0	0
Ammonia	1	3	3	2	2
PSE Sum			15		3
PSE Index	15/24 = .625 = 62.5%			3/24 = .125 = 12.5%	

Note.—Where 24 is the worst possible score, $3 \times 4 + 4 + 4 + 4 = 24$. Reproduced with permission from reference 74.

dietary therapy were instituted only when PSE became apparent. These differences, as well as different grading scales, in part, account for reported PSE rates ranging from 9% to 30% (7,13,19,71–73).

The most logical approach to standardize PSE data after portosystemic shunt placement is to recommend a validated, semiquantitative method of assessing PSE that can be calculated in nearly all patients. The PSE index serves this function (74). It is a reproducible grading system that incorporates both physical signs and symptoms of the disorder and has been validated in over 25 clinical trials that have involved over 1,000 patients (74).

The original PSE index consisted of five components: mental status assessment, number connection test, asterixis evaluation, venous ammonia levels, and electroencephalography (EEG) (Tables 5–8). For practical purposes, the EEG can be deleted from the index without greatly affecting its overall reliability (74). The mental state is considered the most important of the five components and is, therefore, arbitrarily weighted by a factor of 3. The remaining components are not weighted. The individual grades are summed and then divided by the worst possible score. This index reflects the percentage of maximally severe encephalopathy. It can be used for both longitudinal assessment of PSE in individual patients, and comparison of groups of patients at different times or institutions. A sample calculation is illustrated in Table 9.

Encephalopathy should be classified as acute (potentially associated with either identifiable precipitating

factors such as gastrointestinal bleeding, sepsis, medications, or electrolyte abnormalities) or chronic (stable at baseline without identifiable precipitating factors). It should be assessed at every follow-up visit. A description of any PSE therapy performed, including oral lactulose, dietary changes, shunt size reduction, hospitalization, or intentional shunt occlusion, must be provided.

CONCLUSIONS

TIPS remains a procedure in evolution. It is hoped that the next series of advances in TIPS will include both technique and device improvements, as well as large-scale comparative studies that strive to define the permanent role of TIPS in the treatment of portal hypertension. This document attempts to guide future studies toward a consistency of reporting that will allow comparisons and meta-analyses among studies from different sites. Future updates to this document will expand TIPS reporting standards as our knowledge about TIPS increases.

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