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Editorial

Rethinking TIPS: From clinical insight to device innovation

The mind, like a parachute, performs best when is open.
James Dewar

The aphorism captures an enduring truth about scientific progress: innovation rarely advances through rigid adherence to established clinical frameworks that have progressively crystallized into dogma. Rather, it flourishes when clinicians and researchers remain open to challenging assumptions that have long guided medical practice. In Hepatology, a compelling example is the development of the under-dilated transjugular intrahepatic portosystemic shunt (U-TIPS) strategy, conceived within the scientific community of the Italian Association for the Study of the Liver.

Clinician-driven innovation begins with dissatisfaction. When experienced practitioners recognize that conventional protocols do not consistently produce the desired outcomes, new questions arise. Why do some patients deteriorate despite technically successful procedures? Could a different strategy yield a better balance between benefits and risks? What if the underlying assumptions guiding our interventions are not entirely correct? Such questions, when pursued systematically, can reshape entire fields.

TIPS is widely regarded as the most effective therapy for severe complications of portal hypertension, supported by decades of evidence and a central role in current guidelines [1–6]; accordingly, its application deserves critical appraisal. Before addressing technical aspects, the discussion should be anchored to the goals of TIPS: controlling variceal bleeding and recurrent/refractory ascites, preventing further decompensation, preserving hepatic, neurocognitive, and cardiac function, and improving quality of life. These patient-centered outcomes, not procedural metrics, should guide decision-making.

The practice of targeting a post-TIPS portocaval pressure gradient (PCPG) <12 mm Hg is grounded in a robust pathophysiological rationale, as early studies associated this threshold with reduced recurrence and improved control of portal hypertension-driven complications. Relative reductions (50% and 60% for bleeding and ascites indications, respectively) were subsequently proposed [1–3]. Over time, however, this pragmatic surrogate has hardened into dogma: a population-derived heuristic increasingly dictates procedural choices, rather than informing individualized decision-making at the time of TIPS placement.

This drift is further compounded by methodological limitations in PCPG determination that are fundamental yet often overlooked, including variability in measurement technique, type of anesthesia, hemodynamic conditions, concomitant pharmacological treatments, and patient comorbidities. For these reasons, the PCPG obtained immediately at the end of the TIPS cannot be regarded as a stable or reliable biological parameter. Accordingly, attainment of recommended hemodynamic targets at the end of TIPS does not necessarily translate into improved clinical outcomes [7], and the prognostic value of the PCPG is better captured when measured under more stable conditions: at 24 hours after TIPS placement in the prophylaxis of variceal rebleeding or later (e.g., at one month), in patients treated for ascites without an adequate clinical response. Furthermore, in ascites setting, the lack of adequately validated hemodynamic targets is well recognized [1–3]. Building a procedural paradigm on a physiologically unstable measurement that is insufficiently validated across indications therefore represents an extreme simplification that does not necessarily translate into a benefit for the patient.

Beyond measurement limitations, a more fundamental problem emerges: the PCPG, even when meticulously measured, is an inherently reductive surrogate that cannot capture the biological complexity it purports to represent. Portal hemodynamics, cardiopulmonary and systemic circulations, hepatic function, and neurocognitive vulnerability are not discrete domains, but tightly interwoven components of a single pathophysiological continuum.

Reducing portal pressure below 10 mm Hg, or even normalizing it (<6 mm Hg), does not reliably predict clinical benefit, and excessive decompression/shunting may carry serious consequences. Among these, hepatic encephalopathy (HE) remains the most clinically relevant, which impairs quality of life, burdens caregivers, drives healthcare costs, reduces work capacity, and, in severe cases, affects survival [8–9]. Importantly, shunt magnitude is an independent predictor of post-TIPS HE [10]. Moreover, beyond a reduced portal venous inflow to the liver, over-shunting may further aggravate hepatic insufficiency through cardiac dysfunction and reduced overall hepatic perfusion in advanced cirrhosis. Given the heterogeneity of TIPS candidates in hepatic, cardiac, and neurological reserve, and the unpredictable evolving hemodynamic impact of the shunt over time, reliance on a single intra-procedural PCPG value as a “one-size-fits-all” approach is inherently inadequate as a universal guide Fig. 1.

The principle underlying U-TIPS is deceptively simple, yet its implications are substantial. Rather than immediately deploying a fully expanded endoprosthesis that produces a large and abrupt hemodynamic change, a deliberately under-dilated endoprosthesis (5–6 mm) is inserted, achieving a milder initial reduction in PCPG that minimizes the risks associated with over-shunting. This approach significantly reduces the incidence of HE [10–11] while maintaining comparable efficacy in controlling ascites and preventing recurrent variceal bleeding [11–12], regardless of whether immediate post-TIPS hemodynamic targets are achieved. Importantly,

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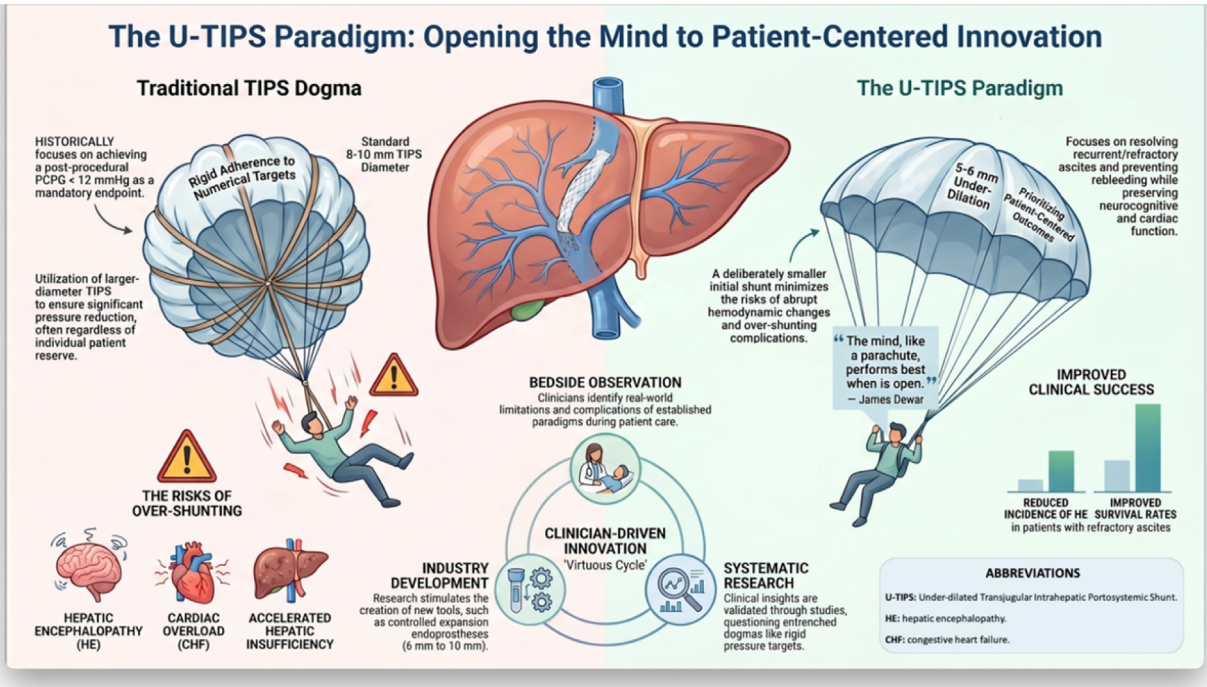

Fig. 1. The U-TIPS paradigm: from clinician-driven insight to patient-centered therapeutic advancement. The U-TIPS strategy challenges the traditional reliance on unreliable post-TIPS pressure targets and a one-size-fits-all approach, reframing procedural decision-making toward a more integrated, patient-centered assessment of clinical outcomes. Such paradigm shifts originate at the bedside — in clinics, wards, and procedure rooms — where the complexity of real-world patients drives innovation.

U-TIPS also prevents further PH-related complications beyond the primary indication [13] and, in patients with refractory ascites, is associated with improved survival [7,14]. Furthermore, like TIPS implanted at nominal diameter, U-TIPS enables selected patients to regain eligibility for curative-intent surgery for extrahepatic malignancies [15].

An important dimension of the U-TIPS story is its origin. Rather than emerging from industry-led research and development, the concept arose from clinicians who, confronted with the complexities of real-world care, recognized the limitations of existing strategies in everyday practice. Bedside observation, systematic and rigorous reflection, and the willingness to challenge entrenched paradigms remain among the most potent drivers of medical innovation. This should not be framed as a tension between clinical insight and industrial development; rather, they are complementary forces that advance progress most effectively in concert. Indeed, the U-TIPS concept has prompted the development of dedicated controlled-expansion endoprostheses, featuring an initial deployment diameter of 6 mm and the possibility of subsequent stepwise dilation up to 10 mm. This exemplifies a virtuous cycle in which bedside experience drives procedural and technological innovation, and industry, in turn, equips clinicians. Crucially, the U-TIPS approach is still evolving and new devices, however promising, should be regarded as derivatives of the U-TIPS strategy rather than its equivalent. The outcomes observed with U-TIPS reflect a specific procedural approach, patient selection, and accumulated expertise; controlled-expansion devices must demonstrate their ability to reproduce these results independently.

Declaration of generative AI and AI-assisted technologies in the manuscript preparation process

During the preparation of this work, the authors used Google NotebookLM to generate, according to the instructions provided to the application, the figure associated with the manuscript. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

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Potential competing interests

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Authors' contributions

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