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Interventional treatment with the Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure may offer a preferable alternative to systemic anticoagulation in patients with cirrhosis and portal vein thrombosis

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ABSTRACT A clinical decision report appraising:

Wang Z, Jiang MS, Zhang HL, et al. Is post-tips anticoagulation therapy necessary in patients with cirrhosis and portal vein thrombosis? A randomized controlled trial. *Radiology*. 2016;279(3):943-951. <https://doi.org/10.1148/radiol.2015150369>

for a patient with cryptogenic cirrhosis, gastroesophageal varices, pancreatic cancer, and portal vein thrombosis.

Keywords: *cirrhosis, cryptogenic cirrhosis, portal hypertension, portal vein thrombosis, PVT, transjugular intrahepatic portosystemic shunt, TIPS, anticoagulation, pancreatic cancer, varices, variceal bleeding, ascites, interventional radiology, radiology, hepatology*

Clinical-Social Context

Ms. Lisa Perez (pseudonym) is a 67-year-old Latina woman with past medical history of type II diabetes and hypertension. She is a retired factory worker who had heavy exposure to paints on the job. One month ago, Ms. Perez noticed her “belly started to bloat and fill with fluid.” First, she presented to an outside hospital, where abdominal ultrasound demonstrated liver cirrhosis with severe ascites. The patient denied any history of hepatitis or alcohol use, and a preliminary cirrhosis workup was inconclusive. After becoming febrile during admission, she was treated empirically for spontaneous bacterial peritonitis despite a negative paracentesis.

Weeks later, Ms. Perez presented to our hospital with watery diarrhea, ascites, and severe, crampy, postprandial epigastric pain. She was found to be *Clostridium difficile* (*C. diff*) positive and began oral vancomycin therapy. A CT abdomen found a mass in the pancreatic head, a large, partially obstructing clot in the extrahepatic portal vein, and large gastric and esophageal varices with ascites. She was taken for urgent endoscopy, where her varices were banded to prevent bleeding. The pancreatic mass was biopsied, and she was diagnosed with pancreatic adenocarcinoma. When her postprandial abdominal pain persisted after *C. diff* treatment, her care team believed portal vein thrombosis (PVT) could be the root cause.

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Given the paradoxical bleeding risk from the sequelae of her cirrhosis and the concomitant hypercoagulable state from the malignancy and low flow state in the portal vein, how best to treat her PVT was unclear. The patient was already on low-dose enoxaparin prophylaxis in the hospital, but this was insufficient to treat PVT. The primary team conferred with hepatology, who wondered whether it would be best to keep Ms. Perez for another week to monitor her, and whether it could possibly be safe to anticoagulate her further. Hepatology suggested that she might benefit from the transjugular intrahepatic portosystemic shunt (TIPS) procedure, and wondered whether it could be performed without subsequent anticoagulation given the size of her varices. TIPS is a procedure performed by the interventional radiologist under fluoroscopic guidance to connect the portal vein to a hepatic vein, creating a new channel that can decompress the portal system and reduce PVT clot burden in patients with severe disease, such as Ms. Perez.

In conversations with the patient about her wishes for treatment, Ms. Perez expressed that her top priority was to be home with family. Being newly diagnosed with pancreatic cancer during the ongoing COVID-19 pandemic, the patient had been unable to see family in two weeks, and the Thanksgiving holiday was fast-approaching. At the same time, she was “a little scared” of leaving the hospital with lingering symptoms. Despite having reliable transportation, she lived far from the hospital, and expressed concern if she were to have issues at home: “What would I do if I have bad pain again? What if I start bleeding at home?” She was wary of anticoagulation but interested in all treatment options that would ease her pain.

Clinical Question

Is the transjugular intrahepatic portosystemic shunt (TIPS) procedure able to safely and efficaciously treat portal vein thrombosis (PVT) without anticoagulation in a patient with cirrhosis and pancreatic adenocarcinoma who prioritizes safety, reduced symptom burden, and time spent home with family?

Research Article

Wang Z, Jiang MS, Zhang HL, et al. Is post-tips anticoagulation therapy necessary in patients with cirrhosis and portal vein thrombosis? A randomized controlled trial. *Radiology*. 2016;279(3):943-951. <https://doi.org/10.1148/radiol.2015150369>.

Description of Related Literature

A preliminary MEDLINE database search was performed via PubMed using the query (TIPS[Title/Abstract] OR transjugular intrahepatic portosystemic shunt[Title/Abstract]) AND portal vein thrombosis[Title/Abstract], retrieving 234 results. Results were limited to articles published within the last 10 years, resulting in 155 articles. 58 of these articles were review articles and were excluded. 97 articles remained, including three systematic reviews/meta analyses, each of which indicated TIPS was an efficacious and safe method for achieving portal vein recanalization in PVT.¹⁻³ These articles were reviewed for relevant citations before being set aside. On review of the remaining articles, an additional 32 were case reports and were discarded. Then, articles were removed that were clearly irrelevant to the clinical question, including TIPS studies on autoimmunity⁴, schistosomiasis⁵, splenectomy or trans-splenic shunts⁶⁻⁸, radiation exposure⁹, children¹⁰⁻¹³, and liver transplantation.¹⁴⁻¹⁹ Ultimately, the search was narrowed down to 16 viable articles for further review, of which 4 were randomized controlled trials.

Wan et al. performed an observational study with three post-TIPS treatment arms, to determine whether aspirin, clopidogrel, or warfarin offered superior post-TIPS anticoagulation.²⁰ Though useful, it is not pertinent to the clinical question of whether anticoagulation can be avoided. Yue-Meng et al. conducted a similar observational study on warfarin efficacy after TIPS, which was excluded for similar reasons.²¹ Merola et al. looked at post-TIPS survival in patients with PVT, which is useful for addressing the overall outlook for Ms. Perez post-TIPS, but cannot answer the clinical question about anticoagulation.²² Qi et al. conducted a prospective cohort study on TIPS efficacy and adverse outcome predictors in PVT, but all patients were anticoagulated.²³ Other articles, including one by Klinger et al. on ultrasound surveillance of stent patency, and another by Li et al. on bare vs. covered stents, were more focused on specific TIPS procedure techniques.²⁴⁻²⁵ Still others did not fit the clinical-social context: a Wang et al.



study focused on TIPS vs. banding ligation, which is not the comparison of interest, while articles by Roseqvist et al. and Senzolo et al. only had a small subset of patients who actually received TIPS.²⁶⁻²⁸

A long-term prospective article by Luca et al. followed 70 patients with PVT post-TIPS over 7 years to determine overall efficacy and long-term procedure outcomes.²⁹ Patients were not anticoagulated, and the study included patients with idiopathic cirrhosis, a fit for Ms. Perez. The article concluded that TIPS offers excellent long-term outcomes for patients with PVT, with complete recanalization of the portal vein in 57% of patients, and reduction in clot burden in an additional 30%. This article was set aside for further consideration.

Reviewing clinical studies next, a Habib et al. study focused on a novel transsplenic TIPS approach for liver transplantation patients, which did not relate to the clinical question, and another by Zhao et al. focused more on TIPS procedure techniques.³⁰⁻³¹ A randomized controlled trial by Lv et al. and another by Luo et al. compared TIPS to endoscopic banding, and another by Jiang et al. focused on superior mesenteric artery urokinase therapy; all are ultimately irrelevant to the clinical-social context.³²⁻³⁴

Finally, an article by Wang et al. was found, a randomized controlled trial on whether anticoagulation is necessary post-TIPS, which closely approximates the clinical question of interest.³⁵ The study had a sample size of 64, with two randomized arms to directly compare anticoagulation post-TIPS with no anticoagulation, providing a superior design to the Luca et al. prospective study. Wang et al.'s study also included patients with cryptogenic cirrhosis, similar to Ms. Perez, and was thus selected for critical appraisal. This area has Strength of Recommendation Taxonomy (SORT) strength of recommendation B for limited quality, patient-oriented evidence.³⁶

The Wang study was later located in Google Scholar and the "Related Articles" feature was used, which identified one more meta analysis and another observational study which did not change the decision about relevant clinical literature.³⁷⁻³⁸

Critical Appraisal

Wang et al.'s randomized controlled trial compared outcomes after TIPS in patients who either did or did not receive anticoagulation, with level of evidence 1B. Though funding information was not provided, all authors declared no conflicts of interest. To minimize selection bias, the trial considered all consecutive patients requiring TIPS at a major referral center in China from 2012 to 2014, comparing them against strict exclusion criteria for eligibility. Specified exclusion criteria for the study were many, and included technical failures of TIPS, a thrombus in intrahepatic portal branches, a diffuse PVT involving the entire portal venous system, contraindication to coagulation (other than severe cirrhosis/varices), and platelets of less than 20,000 or INR of greater than 2. Ms. Perez meets these criteria, yet patients with malignancy were also excluded from participation in the study, which would have disqualified her. This may significantly impact the applicability of the study to Ms. Perez, but unfortunately the other leading contender study by Luca et al. also excluded patients with malignancy, so there is no viable alternative in this regard. Because the study was entirely conducted in China, it is also notable that the patient population may not be a suitable match for a patient like Ms. Perez who is Latina and being treated in the United States. While the study collected and reported baseline patient factors in their patients, hypertension and type II diabetes, which were Ms. Perez's main comorbidities, were not mentioned by the authors.

Applying these exclusion criteria, the researchers ultimately selected a total of 64 patients with cirrhosis requiring TIPS from a pool of 76 patients. The authors clearly justified their sample size in the article, with statistical analysis to demonstrate sufficient size for a significance level of $\alpha = 0.05$. After pre-procedure planning and testing, the TIPS procedure was performed in all 64 patients by the same two interventional radiologists at their center, ensuring a more fair comparison between groups. Using a computerized random number generator, 33 patients were randomly allocated to the control group, TIPS with no anticoagulation, while 31 patients were allocated to the experimental group, TIPS with anticoagulation. Baseline factors were not statistically significant between the control and experimental group, indicating proper randomization. Low-dose warfarin was the long-term anticoagulant of choice in the study, while heparin or the newer direct oral anticoagulants were not assessed; it is unclear whether this decision may impact the applicability to Ms. Perez's case, as no potential anticoagulation regimen had been selected for her at the time of investigation. These groups were not blinded to patients or investigators, as patients in the warfarin group required continuous safety monitoring and INR checks. While this is a prudent and necessary design feature, it does introduce several potential sources of bias.



Anticoagulated patients were given 12 months of warfarin therapy, initially started at a uniform, low dose of 1.25 mg, and then titrated until a target international normalized ratio (INR) of 2 to 3 was reached. In contrast, patients in the control group received no anticoagulation therapy after they were discharged post-TIPS. Patients were assessed at 1, 3, 6, and 12-month follow-ups for portal vein patency and any shunt dysfunction. Thrombus size was tracked and categorized over time somewhat subjectively and imprecisely, by analyzing CT scans over time to determine which patients had greater than or less than 50% occlusion of the portal vein; thankfully, the reads were performed by a radiologist who was blinded to the patient allocations, preventing a biased interpretation. Overall survival and other adverse outcomes, including bleeding, and hepatic encephalopathy, which is an important adverse outcome associated with TIPS procedures specifically, were also tracked over time. Symptom burden experienced by patients was not tracked or quantified, which is unfortunate given its pertinence to Ms. Perez's own treatment priorities.

Over the 12-month period, no patients were lost to follow-up, but two patients died in the control group. One patient was included in analysis in an intention-to-treat fashion, while another was excluded from analysis as they were unable to obtain any clinical data on the patient, who had been treated before their death at another hospital. Results of the study were striking, and all clinical outcomes were clearly reported. At the one-year mark, PVT had improved on CT read in 96.8% of patients receiving the TIPS procedure, whether or not they had been anticoagulated, and had worsened in only one patient in the control group. The shunt patency was also not statistically significant between groups: 93.5% in the anticoagulation group remained patent vs. 93.8% in the control group ($p > 0.99$). Comparing PVT, at the 12-month follow up, 83.9% of patients had achieved full recanalization with anticoagulation, while 71.8% of patients had achieved this in the control group, and this difference was not statistically significant ($p = 0.252$). A statement on effect size, including number needed to treat (NNT) and number needed to harm (NNH) was not provided. Extrapolating from their study results directly, the absolute risk reduction for failed recanalization in PVT would be 12.1% in the experimental (anticoagulated) vs. control group, with a NNT of 8.3 patients needing anticoagulation for 1 additional patient to completely recanalize. Importantly, recanalization rates were lower at the start of treatment, indicating that it may take several months for recanalization in most patients. Depending on her symptom severity, this could impact treatment decisions for Ms. Perez. The only factor Wang et al. found to significantly contribute to recanalization failure after TIPS was SMV thrombosis, which Ms. Perez does not have.

When considering adverse effects, interestingly there was no difference in bleeding between groups, with only six patients total experiencing a bleeding episode in the 12 months post-procedure, three from the control and three from the anticoagulated group. As this suggests, the primary consideration against anticoagulation therapy after TIPS might not be safety, but rather insufficient evidence for efficacy. Hepatic encephalopathy was a more notable complication, with 13 patients (20.6%) developing an episode of hepatic encephalopathy during the first year, although there was no statistically significant difference between groups in this regard. Survival was only assessed up to 12 months after procedure, and while a total of two patients died in the control group, this was not statistically significant when compared to the anticoagulated group. After presenting the sum total of their findings, the authors concluded that in their population of interest, anticoagulation after TIPS may be unnecessary, with the caveat that their sample is not necessarily representative of the full spectrum of PVT; this conclusion offers internal validity and is in agreement with the study's findings. While it would certainly be feasible to perform the TIPS procedure without anticoagulation at the center where Ms. Perez is being treated, questions remain considering her considerable clinical complexity and multiple comorbidities that were not captured by the study.

Clinical Application

Despite its flaws, Wang et al.'s study makes a convincing case that certain patients with PVT could benefit from TIPS without systemic anticoagulation. While Ms. Perez's situation is not perfectly captured by the study, there is evidence that she could benefit from the TIPS procedure as an alternative to anticoagulation for treatment of her PVT, especially given the size of her varices and the severity of her symptoms. Of course, the role the patient's pancreatic malignancy could play in the outcome is less clear, and casts a degree of uncertainty on the clinical decision. Ms. Perez was mainly concerned with safely reducing her symptom burden while maximizing her time at home with family. Ultimately, it is difficult to quantify her needs based on the conclusions of the Wang et al. study, though it can be speculated that patients with recanalization of the portal vein after TIPS should have a reduction in symptoms, which would positively benefit Ms. Perez's overall quality of life. TIPS was well-tolerated in the study, with few safety concerns, and only a small number of cases of bleeding. Given Ms. Perez's lengthy drives to and from the hospital, there is perhaps still reason to avoid anticoagulation where possible to give her peace of mind.



Without anticoagulation, the patient's clinical monitoring could also be lessened somewhat, allowing her to prioritize family time. In contrast, hepatic encephalopathy was a more significant risk seen in the Wang et al. study, and Ms. Perez would have to be counseled about this possible side effect.

After careful consideration of the patient's wishes alongside available treatment options, and in light of possible TIPS complications, it was determined that the patient would be released from the hospital in advance of the Thanksgiving holiday without pursuing immediate treatment for PVT. Interventional radiology treatment with TIPS would be arranged at a later date, after the patient was presented at tumor board and established with outpatient oncology and hepatology care, with a plan to withhold additional anticoagulation measures if at all possible. In this case, treatment considerations were weighed heavily against the patient's need to be with family after being diagnosed with cancer with a poor prognosis, and her physical and emotional comfort was prioritized, with a new focus on pharmacological pain control after her cancer diagnosis. While Ms. Perez initially had some concerns about leaving the hospital, her fears were eased when follow up appointments were scheduled and a clear plan was put in place for treatment. She was instructed on warning signs and symptoms before her son picked her up from the hospital.

New Knowledge Related to Clinical Decision Science

As is demonstrated in this specific patient context, sometimes the technically safest or most efficacious treatment course is at odds with the best choice for a patient in full consideration of their unique social context. While this patient could have been kept an additional week or more for observation, and immediate treatment with TIPS could have been offered, these decisions must be balanced with an understanding of the patient's social support needs relative to the clinical urgency. If the patient had been treated over the Thanksgiving holiday, this would have robbed her of essential time spent with family after a devastating diagnosis. During the COVID-19 pandemic, decisions like this are being made on a daily basis, as health care teams have to advocate for their patients' physical and emotional health, in resource-strained systems where they are their patient's sole in-person support.

Conflict Of Interest Statement

The author declares no conflicts of interest.

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