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#### **Position Paper**

# Consensus conference on TIPS management: Techniques, indications, contraindications



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#### ABSTRACT

The trans jugular intrahepatic Porto systemic shunt (TIPS) is no longer viewed as a salvage therapy or a bridge to liver transplantation and is currently indicated for a number of conditions related to portal hypertension with positive results in survival. Moreover, the availability of self-expandable polytetrafluoroethylene (PTFE)-covered endoprostheses has dramatically improved the long-term patency of TIPS. However, since the last updated International guidelines have been published (year 2009) new evidence have come, which have open the field to new indications and solved areas of uncertainty. On this basis, the Italian Association of the Study of the Liver (AISF), the Italian College of Interventional Radiology—Italian Society of Medical Radiology (ICIR-SIRM), and the Italian Society of Anesthesia, Analgesia and Intensive Care (SIAARTI) promoted a Consensus Conference on TIPS. Under the auspices of the three scientific societies, the consensus process started with the review of the literature by a scientific board of experts and ended with a formal consensus meeting in Bergamo on June 4th and 5th, 2015. The final statements presented here were graded according to quality of evidence and strength of recommendations and were approved by an independent jury. By highlighting strengths and weaknesses of current indications to TIPS, the recommendations of AISF-ICIR-SIRM-SIAARTI may represent the starting point for further studies.

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Introduction

Portal hypertension (PH) is one of the major complications of cirrhosis. The trans jugular intrahepatic porto systemic shunt (TIPS) has been an established procedure in the treatment of the complications of portal hypertension, including bleeding oesophageal

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varices, refractory ascites, hepatic hydrothorax, type-2 hepatorenal syndrome, and more recently, Budd-Chiari syndrome and veno-occlusive disease. However, despite these broad applications, many clinical aspects remain controversial. The multispecialistic contribute to patient selection and TIPS management have led the Italian hepatologic community to produce a consensus statements aimed to the reassessment of the technical and clinical aspects.

#### Methods

The goal of this document was to provide clinical guidelines for the proper management of TIPS. Promoter of this "Consensus Guidelines" was the Italian association for the Study of Liver (AISF). The Consensus was endorsed by: ICIR (Italian College of Interventional Radiology), SIRM (Italian Society of Medical Radiology) and SIAARTI (Italian Society of Anesthesia, Analgesia and Intensive Care)

According to the PNLG (National Plan for GuideLines), the promoter identified a Scientific Board of Experts. The Scientific Board defined methodology, goals and acted as developer and reviewer.

The methodology chosen involved the following steps:

- 1. The Promoters and the Scientific Board selected the main topics of interest: 1. Technique, contraindications, and untoward effects of TIPS, 2. G.I bleeding, 3. Ascites, 4. Vascular disorders, 5. Liver transplantation, 6. Rare indications.
- 2. For each topic a working party was identified by both the Promoters and the Scientific Board, and was composed by a group of at least four experts guided by a chairman. The chairman, together with the promoters and the Scientific Board, selected the relevant clinical questions aiming at focusing on the clinical practice and controversial areas. The questions were circulated within the working groups to refine the topics and to avoid duplications. The members of the working parties were identified on the basis of competence, role, expertise and publication/research in the field of end stage liver diseases and liver transplantation.
- 3. Each working group independently carried out a systematic literature search and review, between October 2014 and May 2015, using Medline/Pub Med to support definitions and statements. Each recommendation was graded according with the Oxford grading system (Appendix 1 in Supplementary material).
- 4. The working groups elaborated the proposed statements, graded according with the selected grading system. They prepared the statements together with the presentation of the literature review for each topic during phone conferences, group meetings and mailing exchange before the Consensus Conference (between February and May 2015).
- 5. The jury members were nowhere involved in the selection, preparation and discussion of the topics and statements prior to the Consensus Conference.
- 6. All the promoters, members of the Scientific board, working groups, and Jury invited to participate to the Consensus conference were asked to declare any potential conflict of interests.
- 7. On June 4th and 5th, 2015 a Consensus Meeting was held in Bergamo. The consensus group consisted of a total of 102 participants (promoters, Scientific Board, Working Groups, and Jury). The jury was selected among Hepatologists, Radiologists, Surgeons, Methodologists, Intensive care physicians, epidemiologists, patient representatives and ethicists. During the first sessions the chairman of each group presented the selected topics and the proposed statements. A general discussion was held in order to refine the. At the end of the general session each group met independently to re-elaborate the final statements to be presented in the voting session according to the advices received by the jury. The final general session consisted in the

- presentation of the statement by the chairman of each working group, followed by a public vote from the jury. The agreement was reached if over 73% of the voters agreed upon a two-levels score (Agree, Disagree).
- 8. The format of this document, drafted by the writing committee, includes the questions, the statements, the quality comments by the working group chairmen, the percentage of agreement of the jury and the selected references.

#### SESSION 1—TIPS placement technique

Although no clear definition of technical skills and relative learning curve exists, only a physician with elevated knowledge in both hepatic and cardiopulmonary hemodynamic, should perform TIPS placement [1–7].

#### Steps required for proper TIPS placement

- 1. Creation of a vascular access by the puncture of the internal jugular vein, which must be performed under US guidance [2].
- 2. Catheterization of one of the hepatic veins, which can be also punctured percutaneously under real time US guidance when its ostium is not easily accessible [3]. When hepatic veins are occluded (Budd-Chiari syndrome), portal vein branches can be reached by direct puncture from the inferior vena cava [4–11].
- 3. Puncture through the liver parenchyma of one of the main branches of portal vein with or without real time ultrasound guidance [12].
- 4. Measurement of the porto-systemic pressure gradient (PPG) by a digital recording system properly set-up for venous pressure [13,14]. Inferior vena cava and not right atrium blood pressure should be subtracted to portal vein pressure to calculate the gradient [15].
- Balloon dilatation of the parenchymal tract between the hepatic (or inferior vena cava) and portal veins.
- 6. Deployment of the stent within the parenchymal tract.
- 7. Hemodynamic assessment of the resultant PPG reduction followed by further balloon dilatation of the lumen to reach the desired target of pressure gradient [14,16]. PPG measurement upon recovery from deep sedation should be considered at least in patients with variceal bleeding as an indication [14,17].

The use of bare metal stents to perform TIPS has been associated with high rates of dysfunction and recurrence of portal hypertension complications [14]. Stents covered with polytetrafluoroethylene (PTFE—endoprostheses), have proven to warrant long-term patency [18]. Dysfunctions occurring with the use of new generation TIPS sets (early thrombosis, later stenosis) appear to be highly dependent upon the operative skills and the accuracy of placement technique [19–21]. Clinical and technical indications, success rates (>90%) and complications (<5%) of TIPS should be monitored periodically in each Center [22,23].

#### Statements: technical coinsideration and patients selection

1.1. Where should a TIPS procedure be performed and who should

#### Statement 1.1

- 1.1a. TIPS should only be performed in tertiary care Centres by interventional radiologists or specially trained physicians experienced in: (a) portal vein catheterization either through a hepatic vein or the inferior vena cava; (b) assessment and interpretation of invasive hepatic and cardiopulmonary hemodynamic; (c) trans catheter embolization, and (d) management of procedural complications (5, D) [15,24–26].
- 1.1b. The decision to perform a TIPS should be reached by an expert team made of one hepatologist (clinical indication) and an interventional radiologist (technical feasibility); in high risk patients, the decision to place a TIPS should be based on liver transplantation candidacy and a transplant surgeon should also be involved in the evaluation period (5, D) [24,27].
- 1.1c. Clinical and technical indications, success rates (>90%) and complications (<5%) of TIPS should be monitored periodically in each Center (5, D) [22,23].</p>

Votation 1.1: Votes in Favour: 96%.

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