Managing the expansion of TIPS stents supports optimal post-TIPS gradient and reduces post-TIPS HE

Schepis Filippo, MD

Hepatic Hemodynamic Laboratory
Gastroenterology Unit
University Hospital of Modena - Italy
Nitinol-based ePTFE covered stents (VIATORR©) represent the standard option for TIPS creation in cirrhotic patients. Unfortunately, development of hepatic encephalopathy (HE) makes hepatologists still cautious in indicating TIPS positioning. HE is related to post-TIPS portosystemic pressure gradient (PPG) drop. TIPS caliber (diameter) represents one of the hemodynamic factors determining post-TIPS PPG. No definitive data exist on the VIATORR© ability either to self-expand to nominal diameter or to maintain smaller calibers when under ballooned to avoid unwarranted PPG drop.

Background

![Graph showing Post-TIPS PPG and portal hypertension complications](image-url)

- Post-TIPS PPG
- EV Bleeding
- Ascites
- HE
- No Events

(Modified from Casado et al., 1998)
Aims

Primary Objectives

To define the "behavior" of VIATORR® in cirrhotic livers by answering the following questions:

1) Do VIATORR® endoprosthesis self-expand to their nominal diameter?

2) Do they keep undersized?

Secondary Objectives

To define the relationship between VIATORR® diameter and the achievement of clinically relevant endpoints by answering the following questions:

3) What’s the relationship between VIATORR® diameter and the post-TIPS PPG?

4) What’s the relationship between VIATORR® diameter and the post-TIPS incidence of portal hypertensive complications
226 patients

- Cohort retrospective study
- Centralized image analysis

198 → 10mm Ø
28 → 8mm Ø

56 from Modena
39 from Florence (Dr F. Vizzutti)
27 from Milan (Dr A. Rampoldi)
26 from Rome (Dr F. Fanelli)
25 from Bologna (Dr R. Golfieri)
20 from Bergamo (Dr R. Agazzi)
19 from Pavia (Dr P. Quaretti)
14 from Palermo (Dr A. Luca)
Methods

- Single operator
- Venous phase
- Double Oblique MPR
- Blooming artifact correction
- Larger diameter at each section
- Average diameter calculated
Results

1) Do VIATORR® endoprosthesis self-expand to their nominal diameter (ND)?
Results

1) Do VIATORR® endoprosthesis self-expand to their nominal diameter (ND)?

![Graph showing the average diameter of different sections of VIATORR® balloons to their ND. The graph compares diameters at different sections (PVW, IPT, SVW, SVT) with blue and red markers representing different diameters (10 mm, 8 mm) and sample sizes (N=34, N=11).]
2) Do they keep undersized?

Results
Results

2) Do they keep undersized?

Average diameter for the main groups of patients (10 mm)

N=198

Average diameter for each ballooning group (Ø 8 mm)

N=28
3) What’s the relationship between VIATORR® diameter and the post-TIPS HVPG?

**Results**

Ballooning and PPG targets

<table>
<thead>
<tr>
<th>Proportion (%)</th>
<th>≤ 6 mm</th>
<th>&gt; 6 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 12 mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 10 mmHg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

N=95 (25 vs 70)

ns 0.018
Results

4) What’s the relationship between VIATORR® diameter and the post-TIPS incidence of HE or portal hypertensive complications?
4) What’s the relationship between VIATORR® diameter and the post-TIPS incidence of HE or portal hypertensive complications?

**Results**

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Patients free of paracentesis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ballooning ≤ 6 mm</td>
</tr>
<tr>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>50</td>
<td>0.75</td>
</tr>
<tr>
<td>100</td>
<td>0.50</td>
</tr>
<tr>
<td>150</td>
<td>0.25</td>
</tr>
<tr>
<td>200</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Remaining cases:

- Ballooning ≤ 6 mm: 19, 16, 13, 10, 10, 10, 10, 10
- Ballooning > 6 mm: 39, 37, 32, 28, 27, 25, 24, 23

Log-Rank test, $p = 0.394$
Conclusions and **Take Home message**

- VIATORR® do not reach their nominal diameter both in the intraparenchymal and suprahepatic tract even though properly ballooned.

- When undersized, 10mm Ø VIATORR® quite reliably keep dilatation at 7, 8 (and 9mm), while 8mm Ø VIATORR® at 6 and 7mm.

- Overall, VIATORR® ballooning at 6mm ensures the achievement of the primary hemodynamic target (PPG <12mm Hg) in about 50% of patients with a 20% risk of exceeding the secondary (PPG <10mm Hg).

- *Pragmatic* ballooning at 6mm significantly reduces the risk of post-TIPS hepatic encephalopathy without decreasing the control of portal hypertensive complications (ascites).
Study design

Patient with indication to TIPS for refractory ascites

Minimization

Multi step strategy

10 mm Ø stent-graft dilated to 6 mm

6 wks FU

NR

Dilatation to 7 mm

6 wks FU

PR

12 mo FU

CR

PSPG guided strategy

10 mm Ø stent-graft dilated to 8-10 mm

12 mo FU

No Response (NR):
Ascites with need of large volume paracentesis (LVP) at similar intervals than before TIPS and no restoration of diuretics response and/or no improvement of kidney function

Partial Response (PR):
Stable grade 2-3 ascites in the last 2 wks and improvement of kidney function with or without diuretics

Complete Response (CR):
Grade 0-1 ascites with or without diuretics
# Acknowledgments

<table>
<thead>
<tr>
<th>Modena</th>
<th>Firenze Careggi</th>
<th>Milano Niguarda</th>
<th>Pavia San Matteo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guido Marzocchi</td>
<td>Francesco Vizzutti</td>
<td>Aldo Airoldi</td>
<td>Pietro Quaretti</td>
</tr>
<tr>
<td>Cristian Caporali</td>
<td>Umberto Arena</td>
<td>Antonio Rampoldi</td>
<td>Ilaria Fiorina</td>
</tr>
<tr>
<td>Stefano Colopi</td>
<td>Luigi Rega</td>
<td>Luca Belli</td>
<td>Lorenzo Moramarco</td>
</tr>
<tr>
<td>Mario De Santis</td>
<td></td>
<td></td>
<td>Raffaele Bruno</td>
</tr>
<tr>
<td>Tommaso Di Maira</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stefano Gitto</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erica Villa</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bologna Sant’Orsola</th>
<th>Bergamo HPG23</th>
<th>Palermo ISMETT</th>
<th>Roma La Sapienza</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rita Golfieri</td>
<td>Roberto Agazzi</td>
<td>Angelo Luca</td>
<td>Fabrizio Fanelli</td>
</tr>
<tr>
<td>Cristina Mosconi</td>
<td>Roberto Nani</td>
<td>Roberto Miraglia</td>
<td>Alessandro Cannavale</td>
</tr>
<tr>
<td>Matteo Renzulli</td>
<td>Stefano Fagiuoli</td>
<td></td>
<td>Oliviero Riggio</td>
</tr>
</tbody>
</table>
THANKS FOR THE ATTENTION
Methods

CT protocol test on VIATORR® phantom

CT maximum diameter (mm)

Ordered sections

Average diameter of VIATORR® phantom

8mm
10mm
4) What’s the relationship between VIATORR® diameter and the post-TIPS incidence of HE?

**Results**

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Patients free of HE</th>
<th>Remaining cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-50</td>
<td></td>
<td>95</td>
</tr>
<tr>
<td>51-100</td>
<td></td>
<td>67</td>
</tr>
<tr>
<td>101-150</td>
<td></td>
<td>59</td>
</tr>
<tr>
<td>151-200</td>
<td></td>
<td>53</td>
</tr>
<tr>
<td>201-250</td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>251-300</td>
<td></td>
<td>48</td>
</tr>
<tr>
<td>301-350</td>
<td></td>
<td>48</td>
</tr>
<tr>
<td>351-400</td>
<td></td>
<td>47</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Patients free of paracentesis</th>
<th>Remaining cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-50</td>
<td></td>
<td>58</td>
</tr>
<tr>
<td>51-100</td>
<td></td>
<td>63</td>
</tr>
<tr>
<td>101-150</td>
<td></td>
<td>46</td>
</tr>
<tr>
<td>151-200</td>
<td></td>
<td>38</td>
</tr>
<tr>
<td>201-250</td>
<td></td>
<td>17</td>
</tr>
<tr>
<td>251-300</td>
<td></td>
<td>26</td>
</tr>
<tr>
<td>301-350</td>
<td></td>
<td>34</td>
</tr>
<tr>
<td>351-400</td>
<td></td>
<td>33</td>
</tr>
</tbody>
</table>
Managing the expansion of TIPS stents supports optimal post
TIPS gradient and reduces post TIPS HE

Schepis Filippo, MD

Hepatic Hemodynamic Laboratory
Gastroenterology Unit
University Hospital of Modena - Italy