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The underdilation of nitinol stents at TIPS implantation: Solution or illusion?

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ABSTRACT

Purpose: This study investigates the behaviour of self-expanding nitinol stents at the time of TIPS-implantation and thereafter.
Methods: Hundred consecutive patients with cirrhosis receiving a TIPS revision were included. The smallest stent diameter was measured radiologically immediately after implantation and before shunt revision. Accuracy of the measurement was assessed by comparing the nominal stent diameter with the largest stent diameter measured at the time of revision.
Results: Pearson correlation between largest measured and nominal diameters was excellent ($r = 0.952$, $p < 0.001$) showing that measurements are accurate. At TIPS implantation all stents were markedly underdilated reaching only 76–92% of their nominal diameter. Smallest measured diameters were similar (8 mm) irrespective of the nominal diameter (8, 9, 10 mm) of the stent. In addition, smallest diameters of 10 mm stents were similar irrespective whether 8, 9 or 10 mm balloons were used.

During a mean follow-up of 12.7 ± 17.8 months (median 3 months, range 1–81) stents expanded by 0.5–1.6 mm dependent on the nominal stent size (8, 9, 10 mm) and the grade of primary underdilation. No significant difference was found between Viatorr and bare stents.
Conclusions: At TIPS-implantation, the compliance of the surrounding tissue predominantly determines the stent diameter. The nominal size of the stent or the dilatation balloon has little influence. Accurate adjustment of a desired pressure gradient is, therefore, not possible. During follow-up, stents expand towards their nominal diameter questioning the usefulness of underdilation.

1. Introduction

Hepatic encephalopathy (HE) is the major and most frequent complication of the transjugular intrahepatic portosystemic shunt (TIPS) [1–3]. In addition to the shunt, several host dependent risk factors of HE have been identified such as older age, advanced cirrhosis, presence of HE before TIPS implantation, and a decreased mean arterial blood pressure [4–13]. Both, the shunt and the host factors are responsible for increasing the post-TIPS incidence of HE by about a factor of 2 [1].

The diameter of the stent determines the degree of shunting and the portosystemic pressure gradient. To reduce the risk of shunt related complications the Quality Improvement Guidelines of the American Society of Interventional Radiology recommend that the portosystemic pressure gradient after TIPS should not be <5 mmHg [14]. This recommendation is, however, not based on respective study results. In contrary, a recent study could not find a difference in HE in patients with post-TIPS gradients above or below 5 or even 8 mmHg [15]. However, taking a higher threshold of 12 mmHg [16] clearly separated patients with a high or low risk of HE or rebleeding. With few exceptions patients with worsening or de novo HE after TIPS had fully patent shunts with gradients of <12 mmHg, while those with rebleeding had TIPS insufficiency with gradients of >12 mmHg. Accordingly, a gradient of 12 mmHg may be the ideal therapeutic "window" for HE and rebleeding as well. This is why shunt reduction or occlusion, aiming at a gradient of >12 mmHg, is effective to improve severe or debilitating HE [17,18]. In patients with low pre-TIPS gradients (e.g. 15 mmHG) a reduction to 12 mmHg may not be sufficient. These patients may benefit from a relative reduction of the gradient by 25–50% [19].

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A specific post TIPS gradient may be approximated by the use of nitinol stents with different nominal diameters or by balloon expandable stents with variable diameters. Only one study evaluated the effect of 8 and 10 mm nitinol stents on outcome variables including HE [20]. Unfortunately, the study was closed preterm and its small sample size did not allow meaningful analysis with respect to HE. However, if one compares the results of previous studies using 10 mm stents with those of a recent study using 8 mm stents, post-TIPS HE decreased from about 36% [1,13] to 18% [21]. According to the law of Hagen-Poiseuille, the shunt flow is proportional to the fourth potency of the radius. This underlines the impact of small variations of the stent diameter on shunt flow and, eventually, shunt-related complications such as HE.

On the other hand, smaller shunts may increase the risk of treatment failure [20]. To overcome the dilemma between wider shunts with a higher risk of HE and smaller shunts with a higher risk of insufficient response, interventionalists often implant 10 mm stents but dilate them to only 7 or 8 mm. In case of insufficient response a further dilatation of the stent is intended [1,22,23].

In the beginning of the TIPS technique in the late 1980th and early 1990th balloon expandable stainless steel stents such as the Palmaz-stent, were frequently used. They allowed stepwise dilatation with the aim to optimize the reduction of the portosystemic pressure gradient. Later in the 1990th nitinol stents were used almost exclusively probably because of their better flexibility and easier placement. Nitinol, an alloy out of titanium and nickel, is known for its shape-memory that seeks to unfold the stent untill its nominal diameter. Therefore, the commonly practiced attitude to underdilate the stent may have an only temporary benefit and may not sufficiently decrease the risk of shunt-related complications.

The purpose of this study was to investigate the behaviour of nitinol stents at implantation and their potential expansion during follow-up by radiological measurement of stent diameters. Since design and covering of stents may influence their radial forces, a comparison between the covered Viatorr stent and various types of bare stents was performed.

2. Materials and methods

The monocentric and retrospective study includes 100 consecutive patients who received a TIPS revision between 2006 and 2014. Clinical data were collected from records and radiological data were obtained from our interventional radiology division TIPS-registry. Approval from an ethic commission was granted for the analysis of data from patients that are included in the TIPS-registry. All patients had given written consent for the electronical recording and analysis of data.

47 patients received a PTFE-covered nitinol Stent (Viatorr, W.L.Gore, Flagstaff, Arizona, USA) while 53 patients received a bare nitinol stent among the following stent types: Resistant (Eucatech, Weil am Rhein, Germany), Luminexx (Bard-Angiomed, Karlsruhe, Germany), Sinusflexx (Optimed, Ettlingen, Germany) and Protegé (Covidien ev3 Europe, Paris, France). Stents were selected according to clinical and morphological conditions. In case of a significant curvature of the intrahepatic shunt tract a very flexible stent (for example Resistant stent) was employed. The Viatorr stent was used in particular in patients with a good prognosis and in case of variceal bleeding indication. Narrow Viatorr stents (8 mm) were employed exclusively in cases of variceal bleeding, since it was believed that a lower pressure reduction was enough to prevent a recurrence.

The TIPS implantation was performed by or under supervision of the same interventionalist (M,R,) as described previously [1,24]. After sonographically guided puncture of the right or left portal branch, the needle tract was dilated using balloon catheters of 8–10 mm. The same balloon was then used to dilate the stent after its introduction, placement and release. Dilatation was always performed using a pressure device and pressures between 12 and 15 atm were applied for 20 s. A final angiography was performed which was used to measure the stent diameters in patients with a need for revision.

The measurement of the stent-diameter was performed on angiographic images using Siemens Axiom Artis dTA and Siemens Polytron-Top. Measurements were performed with the software of the IMPACS system (AGFA IMPAX EE R20 XV SU3, Agfa HealthCare NV – Mortsel, Belgien) used in our institution. Measurements were performed on last images at TIPS placement and first images at TIPS revision before any intervention was performed. The smallest diameter of the stent was measured in the angiographic image after TIPS placement. At revision, measurement was performed at the same location. In addition, the largest diameter was measured at the proximal end of the stent.

2.1. Statistics

Continuous variables are expressed as mean with standard deviationas well as median with the corresponding range whereas categorial variables are reported as frequencies and percentages. For continuous variables, differences were determined using Wilcoxon-Mann-Whitney and Kruskal-Wallis tests as there was no Gaussian distribution of the data confirmed by the Kolmogorov-Smirnov test. χ^2 tests or Fisher's Exact tests were used for categorial variables. The relation between the measured diameter and the nominal diameter was assessed by the Pearsons correlation as well as by the interclass correlation coefficient (ICC) for absolute agreement, and the ICC for consistency. The ICC for absolute agreement is influenced by any differences between the observed values while the ICC for consistency is not influenced by systematic differences. Values of the ICC can range from 0.00 indicating no agreement to 1.00 indicating perfect agreement. A good agreement is shown by ICC values >0.80 and a perfect agreement is indicated by values >0.90. P values of 0.05 or lower were considered statistically significant. Statistical analysis was performed using SPSS (Version 20.0, IBM, New York, USA) and GraphPad Prism (Version 5, GraphPad Software, San Diego, CA, USA).

3. Results

The characteristics of the patients are summarized in Table 1. Most of the patients had alcoholic cirrhosis of Child-Pugh stage B and received the TIPS intervention for treatment of refractory ascites. Relevant additional complications of portal hypertension such as hepatorenal syndrome, hepatic hydrothorax, and HE were seen in 19, 2, and 15% of patients, respectively. TIPS implantation resulted in a significant reduction of the porto-systemic pressure gradient, the gradient between the portal vein and the right atrium.

3.1. Measurement of diameters and validation

The radiological measurement of the smallest and largest stent diameters are shown in Fig. 1. In general, the smallest diameter was at the entrance of the stent into the portal vein which may be due to a higher resistance of the wall of the portal vein. The largest diameter was measured at the proximal end of the stent where Nitinol expansion is not influenced by surrounding tissue. The method is validated by comparing the largest measured with the nominal diameter of the stent. The largest measured diameters of stents with a nominal diameter of 8, 9, and 10 mm are 8.1 ± 0.1 (8.1; 7.9–8.3) mm, 8.9 ± 0.1 (8.9; 8.8–9.0) mm, and 10.0 ± 0.2 (10.0; 9.4–10.7) mm, respectively. Pearson correlation between measured and nominal values is excellent ($r = 0.952$, $p < 0.001$) with interclass correlation coefficiencies of 0.976 [95% CI: 0.964–0.984] and