Πιστοποιητικό 6.2

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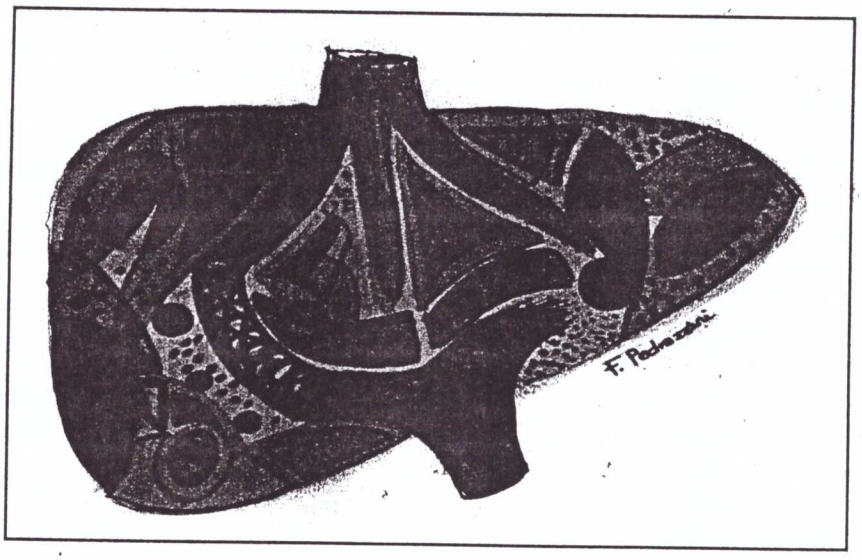
Transjugular Intrahepatic Portosystemic Shunt (TIPS)

indications, technique and results



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TIPS with Nitinol Strecker stent

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INTRODUCTION

In the management of cirrhotic patients with variceal bleeding, transjugular intrahepatic portosystemic shunt (TIPS) plays an important role in decompressing the portal system and preventing the danger of frequent rebleeding (1-3).

Technical inprovement of this procedure is related to the introduction of metallic stents, which confer a satisfactory patency of the shunt (4,5). At first, balloon expandable stents, such as Palmaz stents (Johnson-Johnson, Warren NJ), or Tantalum Strecker stents (Meditech, Boston Scientific, Watertown, MA) were employed in TIPS procedure, however, in time, many authors switched to self-expanding stents such as Wallstent (Schneider, Minneapolis MN), Nitinol Strecker stents (Boston Scientific International, Watertown, MA) Memotherm stents (Angiomed, BARD, Karlsruhe, Germany) or Gianturco/Rosch «Z» stents (Cook Inc., Bloomington, IN), which become more popular due to their easier deployment and variety of size available.

However, there are intrinsic differences among all self-expanding stents regarding elasticity, length, diameter, longitudinal flexibility hoop strength, mesh profile, and delivery system, which influence stent selection (6-8).

In a 5-year experience, from December 1991 to May 1996, we have performed 161/164 TIPS using Wallstent in 101, Nitinol Strecker stents in 49 cases, Memotherm stents in 2 patients, and Palmaz stents in 5 cases; however, we report here our experience with Nitinol Strecker stents only.

TECHNICAL CONSIDERATIONS

In our series, indications for TIPS included bleeding from gastroesophageal varices in 21 patients: 15 with recurrent bleeding not responding to sclerotherapy, 4 patients actively bleeding, and 5 patients included in a randomized study «TIPS vs sclerotherapy in prevention of variceal rebleeding» (9), refractory ascites in 9 patients and 21 candidates for liver transplantation.

Nitinol Strecker stent is a self-expanding stent made of a 0.13 mm thick nickel-titanium alloy wire (Ellastoy™) knitted into a cylindrically-shaped flexible mesh with a 10 mm diameter and looped ends (Fig. 14.1).

The 10F delivery system is made of an introducer shaft with three radiopaque markers and a cover sheath which releases the stent upon retraction.

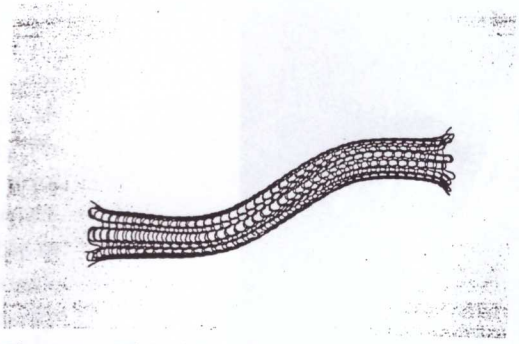

Fig. 14.1 - Nitinol Strecker stent.

The stent has low radiopacity and its identification is difficult especially in obese patients or when ascites is present. This may cause difficulties in positioning the stent because it is barely seen on fluoroscopy.

Therefore, during deployment it is mandatory to rely primarily on the three radiopaque markers present on the delivery system and, if necessary, to use spot films for better visualization of them and the stent.

At the beginning of our series, only 6 cm long stents were available, which were adequate for short intrahepatic tracts (2-3 cm). In long intrahepatic tracts, we were forced to place several stents in series, sometimes using other types of stents. At present, this problem has been solved because of the availability of 7 and 8 cm long stents.

When using self-expanding stents, incorrect placement of the device may occur due to shortening (10). Nitinol Strecker stent shortening is approximately 35% of the initial length and occurs predominantly at the proximal end of the stent because an anchoring system in the distal end, consisting of six prongs, holds the stent in place during release, and reduces the shortening of this end of the stent to 0.5-1.0 cm. Therefore, with this type of stent, shortening can be anticipated and complications avoided by advancing the introducer catheter with the distal radiopaque marker 1-1.5 cm inside the portal vein. Moreover, the anchoring system allows the advancement of the partially released stent within the portal system until the correct position for the stent is chosen.

Nitinol Strecker stent is quite flexible in its longitudinal axis, and this can be considered an advantage because the stent easily adapts to curved tracts. Moreover, thanks to their flexibility and looped ends, Nitinol Strecker stents can be easily and safely removed by a loop wire assembly or grasping forceps in case of incorrect placement.

In our experience with Nitinol Strecker stents, difficulties in correct placement of the stent were encountered in three cases (6%) due to an unpredictable shortening of the endoprosthesis in one patient and displacement of the stent in two cases. In all cases, removal of the stent was successfully performed and a new stent was placed. Late stent migration has never occurred.

Radial force is weak with Nitinol Strecker stent in comparison to Wallstent and full expansion of the stent within the intrahepatic tract is generally achieved in 24-48 hours. In case of incomplete expansion, it is advisable not to perform any balloon dilatations of the stent soon after its deployment because its flexibility in combination with its looped ends may lead to dislodgement of the stent. We prefer to postpone any stent dilations for at least 5 days. In the last patients, we took a greater advantage by dilating the intraparenchymal tract with a 12 mm balloon catheter before placing a 10 mm Nitinol Strecker stent.

A weak radial force, in some cases, could be considered an advantage because it allows calibration of the stent diameter as needed, especially in patients with high risk of encephalopathy.

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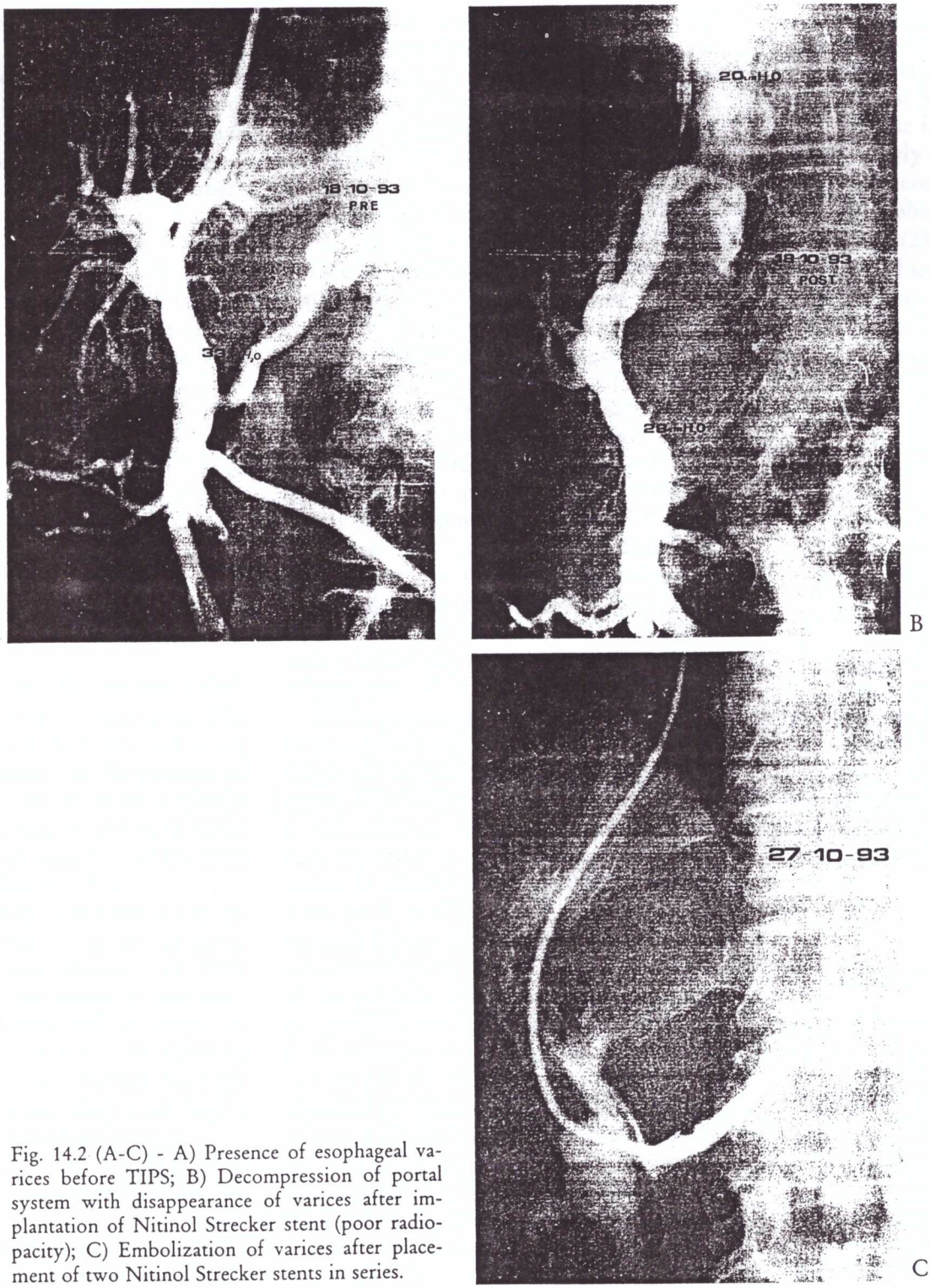

A B C

Fig. 14.2 (A-C) - A) Presence of esophageal varices before TIPS; B) Decompression of portal system with disappearance of varices after implantation of Nitinol Strecker stent (poor radiopacity); C) Embolization of varices after placement of two Nitinol Strecker stents in series.

It also reduces stent shortening after deployment, with a longer intrahepatic tract covered by the stent, when using 7 and 8 cm long stents. Lack of full expansion of the stent does not hinder dilatation during subsequent angiographic controls, especially when atrio-portal pressure gradient remains high.

In our experience, initial technical success in performing TIPS was achieved in all patients of the Nitinol trial (100%) with a decrease of the average portosystemic gradient from 22 mm Hg pre-TIPS to 11 mm Hg post-TIPS. Disappearance of varices was observed in all cases (Fig. 14.2A-B) except one, due to stent obstruction from shortening of the distal end of the stent in the intrahepatic tract. In this case an additional stent was placed and the varices were embolized (Fig. 14.2 C).

CLINICAL CONSIDERATIONS

Clinical success usually includes a clinical improvement of the patient soon after the procedure and during the follow-up. Of course, it is related to the patency of the stent, which has to be maintained with further reinterventions, if needed, in order to have an «assisted patency» of the stent at 1 or 2 years follow-up (11).

When considering improvement in ascites, incidence of rebleeding and encephalopathy de novo, our findings with Nitinol Strecker stents are similar to our experience with Wallstent and to those reported by other Authors with different stents (9,10,12,13), even though for optimal evaluation, randomized trials and a longer follow-up period are needed.

In our experience with Nitinol Strecker stents, clinical results can be listed as follows:

Bleeding: Variceal bleeding stopped in two of the four patients in whom the procedure was performed with Nitinol Strecker stent during active hemorrhage, in emergency as last resort. During the follow-up, rebleeding was observed in only 5 of 44 patients (11%).

Ascites: 4/7 patients had a complete resolution of the ascites (57%). Improvement was observed in another two cases (28%), as shown by a reduction of the dosage of diuretic agents and no change was observed in one other patient.

Encephalopathy: Transient episodes of mild portal-systemic encephalopathy (PSE) de novo were observed in 11 of 49 cases (22%), all controlled with medical therapy.

Mortality: Overall mortality was 15/36 (41%), not including 13 patients submitted to liver transplantation; 9/36 patients (25%) died within 30 days after TIPS procedure and 6/27 (22%) patients died after 2-6 months, due to hepatic failure in two cases and to rebleeding in the other four cases. Twenty-one patients are still alive, with a follow-up ranging from 1 week to 41 months.

When comparing our results obtained with implantation of 68 Nitinol Strecker stents in 49 TIPS procedures to those obtained with Wallstent which we have used in 101 patients, or like the Palmaz stent used by other Authors, no significant increase in shunt or hepatic vein complications, such as obstruction, thrombosis, or stenosis (5) can be observed. In fact, stent patency requires continuous surveillance of the patients due to the high frequency in pseudointimal hyperplasia producing stent stenosis, occurring during the follow-up period with any type of stent. As reported by other Authors (11), «assisted patency» of the stent is a reliable parameter to evaluate the efficacy of the shunt. In our opinion, a procedure does not have to be considered unsuccessful if the stent needs to be dilated once or twice during the follow-up.

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Our patients were submitted to short-term angiographic controls (5- day) in 31 cases and long-term (6/24-month) angiographic examinations in 34 cases. Angiographic findings were as follows:

Early stent thrombosis: Among short-term controlled patients, small thrombi were observed within the stent in 8/31 patients (25%) and complete obstruction occurred in 2/31 cases (6%). However, in all 10 cases recanalization of the shunt was obtained with balloon dilations.

Stenosis: During the follow-up, stent malfunction occurred in 14/34 patients (41%) in 12 due to stent stenosis caused by pseudointimal hyperplasia (35%).

Long-term obstruction: At a follow-up of 6-24 months, in 2/34 patients, shunt obstruction (5%) occurred. Of these 34 controlled patients, in 3 cases stent malfunction have occurred on previous angiographic controls.

In our experience, Nitinol Strecker stents offer similar results to other metallic stents currently available even though we are very confident in the ongoing research of new types of stents (14). By using these stents, we have obtained satisfactory overall clinical results, a limited occurrence of rebleeding or encephalopathy and a low stent-related complication rate.

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