Long-term Patency of Nitinol Stent Placement in Dysfunctional Hemodialysis

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**Purpose:** To evaluate the long-term patency of stents placement on dysfunctional hemodialysis shunt after failed balloon angioplasty and analysis the factors affecting the patency of nitinol stent.

**Materials and methods:** Eighty-three patients with dysfunctional dialysis shunts underwent bail-out stenting to restore vascular access. The indications included 1) residual stenosis more than 50% after percutaneous transluminal angioplasty (PTA) 2) venous rupture or dissection 3) early restenosis less than 3 months after PTA. Overall cumulative primary rates at 3 months, 6 months, 1-, 2-, 3-, and 4-year and secondary patency rates at 3 months, 6 months, 1-, 2-, 3-, 4-, 5-, and 6-year were calculated by Kaplan-Meier survival analysis. The primary and secondary patency rates according to age and gender of the patient, history of diabetes mellitus and hypertension, diameter and length of the stent, location of the stent (central, upper arm, cubital, forearm), type of the hemodialysis shunt (native arteriovenous fistula [AVF] or arteriovenous graft [AVG]), and presence of stent fracture, were compared by Kaplan-Meier log-rank test.

**Results:** The stents were placed in 26 central veins (31.3%), 40 upper arm veins (48.2%), 11 cubital veins (13.3%), and 6 forearm veins (7.2%) with 100% technical and clinical success rates. The 3 months, 6 months, 1-, 2-, 3-, and 4-year primary patency rates were 81%, 66.7%, 43.1%, 28.8%, 25.2%, and 25.2%, respectively. The 3 months, 6 months, 1-, 2-, 3-, 4-, 5-, and 6-year secondary patency rates were 91.6%, 88%, 82.9%, 73.9%, 62.6%, 59.1%, 59.1%, and 29.6%, respectively. During follow up, 12 stent fractures (14.5%) were occurred in 11 peripheral veins (4 cubital veins, 7 forearm veins) and 1 central vein. There was a one case of stent migration, which located in central vein. The primary patency rates did not statistically differ according to age and gender of the patient, history of diabetes mellitus and hypertension, diameter and length of the stent, location of the stent, and type of the hemodialysis shunt. However, stent fracture group showed significantly decreased primary patency rates.
patency rate in comparison with non-fracture group (p=0.0004), but there was no statistical
difference in secondary patency rates between two groups (p=0.58). The secondary patency
rates did not statistically differ according to gender of the patient, history of diabetes mellitus
and hypertension, diameter and length of the stent, location of the stent, type of the
hemodialysis shunt, and stent fracture. Only older age group (≥ 65 years) showed
significantly decreased secondary patency rate in comparison with younger age group
(p=0.045).

**Conclusion**: In conclusion, nitinol stent placement is effective method to prolong dialysis
access not only the central veins but also the peripheral veins including cubital veins. Stent
fracture may shorten the primary patency, but not secondary patency.

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Keywords: nitinol stent, patency, cubital vein, stent fracture, stent migration
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I. INTRODUCTION

Vascular access stenosis is a common complication that may lead to significant morbidity and dysfunction of hemodialysis and increased cost of medical care. Recent studies show feasibility of endovascular stents which could be used in treatment of central as well as peripheral stenotic lesions (Beathard, 1993; Quinn et al., 1995; Hoffer et al., 1997; Chen et al., 2003; Maskova et al., 2003; Sprouse et al., 2004; Vogel and Parise, 2004; Rajan et al., 2007; Chan et al., 2008; Vesely, 2008). With recent technological advances, nitinol stents has become available and Vogel et al. reported that nitinol stent is safe and effective for treating dialysis-access venous stenoses that are resistant to standard angioplasty (Vogel and Parise, 2004, 2005). However, long-term patency of nitinol stent in large study population has not been reported and there are only few reports of complications associated with nitinol stent including fracture or migration in hemodialysis access (Maleux et al., 1998; Vogel and Parise, 2004; Brewster et al., 2006; Wada et al., 2007).

The aim of this study was to evaluate the long-term patency of stents placement on dysfunctional hemodialysis shunt after failed balloon angioplasty and analysis the factors affecting the patency of nitinol stents.
II. MATERIALS AND METHODS

A. Patients

From January 2005 to March 2011, 86 consecutive patients with dysfunctional dialysis shunts who underwent bail-out stenting to restore vascular access were retrospectively reviewed. After excluding three patients with follow up loss, ultimately 83 patients (47 men, 36 women; mean age, 63.24 ± 12.55 years) were enrolled in this study. All patients underwent hemodialysis access surgery at same institution (Ajou university hospital) by 15 year experienced vascular surgeon. Patients underwent hemodialysis at our dialysis center or our dialysis branches connected on the medical network. Consecutive medical records and radiographic images of all patients were reviewed.

B. Indications for stent placement

According to DOQI guidelines (1997), all angioplasties were performed on patients exhibiting >50% stenosis and clinical/physiologic abnormalities. The indications of stent placement included 1) residual stenosis more than 50% after percutaneous transluminal angioplasty (PTA), 2) venous rupture or dissection, 3) early restenosis less than 3months after PTA.

C. Balloon angioplasty procedures

All procedures were accomplished on outpatient basis at our hospital. Patients were monitored using pulse oximetry, blood pressure measurements, and electrocardiography. Fistulography was performed immediately before balloon angioplasty to measure vessel diameter. Thereafter, if a lesion was identified as requiring dilatation (>50% stenosis in diameter), a 6-8 Fr sheath introducer was positioned and balloon angioplasty proceeded. PTA balloon diameters ranged from 6-16mm with burst pressures ranged from 16 to 30 atm. The following balloons were used : Ultra Thin diamond, Blue Max20, XXL (Boston Scientific, MA, USA), and Conquest (Bard Peripheral vascular, Inc. AZ, USA). The required balloon diameters were 1-2mm larger than the diameter of the adjacent normal vein as measured on fistulography. After 2003, cutting balloons (Boston Scientific, Natick, MA, USA) with
larger-diameter conventional balloons were used in PTA-resistant lesions when they were available. We determined whether or not a continuous palpable thrill was converted immediately after balloon angioplasty. Fistulography was performed after balloon angioplasty to confirm whether sufficient restoration of access flow could be obtained. The entire access circuit from the arterial anastomosis to the superior vena cava was evaluated by digital subtraction angiography during the procedure. All procedures were performed in the angiography room by two interventional radiologists (10 year- and 15 year experienced).

D. Sedation, analgesia, and patient monitoring

Intravenous remifentanil was used for procedural sedation and analgesia (Ultiva; GlaxoSmithKline, Zeist, Netherlands). Remifentanil was prepared as a 0.01mg/mL solution (1mg remifentanil mixed with 100mL normal saline) and was administered via an infusion pump at a rate of 0.1 g/kg/minute as the loading dose, 0.05 g/kg/minute as the maintenance dose, and 0.15 g/kg/minute as the maximal dose, through exclusive intravenous access made on the back of the contralateral hand (Wilhelm and Kreuer, 2008). Infusion was started with the loading dose, approximately 5 minutes before the balloon angioplasty, and the infusion rate was adjusted according to development of pain during the procedure. Patients were monitored by a designated nurse, who used non-invasive measurement of blood pressure and arterial oxygen saturation, checked venous lines, reactions and emotional status, and provided support. Following the procedure, patients were transferred to the recovery room and were monitored at 5-minute intervals by a nurse for at least 30 minutes, until they had fully recovered from the sedation. No anesthesiologist was present during the procedures.

E. Stent placement

All stents were bare metallic nitinol stents (S.M.A.R.T Control stent; Cordis, Miami, USA) ranging from 6-14 mm in diameter and 40-150mm in length. On follow-up, we also used PTA as the choice of treatment of restenosis or obstruction within the stents. Additional stenting was reserved for PTA-resistant lesions such as elastic recoil, dissection or rupture. After stent insertion, fistulography was performed to evaluate the access flow. All patients
who had stent placement received 100 mg Aspirin (Astrix cap, Boryung pharmaceutical co., Seoul, Korea) and 75mg Clopidogrel (Plavix tab, Handok, Seoul, Korea) once a day for 1 month.

F. Study Definitions and Statistics

Technical success of the procedure was defined as restoration of flow combined with a maximal residual diameter stenosis of less than 30%. Clinical success was defined as the resumption of normal hemodialysis via the treated shunts for at least one session after the procedure. Patency estimates were calculated using the Kaplan-Meier life-table analysis and patency rates were measured from the time of percutaneous intervention. Primary patency was defined as the interval following intervention until the next access thrombosis or repeated intervention, and secondary patency as the interval after interventions until the access was surgically revised or abandoned due to various factors. Kidney transplantation and death with patent fistula were regarded as the end of the study. Complications were investigated and classified into major and minor complications according to definitions established by the Society of Interventional Radiology (Sacks et al., 1997; Gray et al., 2003). Primary and secondary patency rates were calculated using the Kaplan-Meier method. Patency rates were calculated according to age and gender of the patient, history of diabetes mellitus and hypertension, diameter and length of the stent, location of the stent (central, upper arm, cubital, forearm), type of the hemodialysis shunts (native arteriovenous fistula [AVF] or arteriovenous graft [AVG]), and stent fracture during follow up by Kaplan-Meier log-rank test to compare the probability of patency among these groups. Cox’s proportional hazard regression model was used separately in each sub groups to identify the factors affecting stent patency and to evaluate the relative risk rates. A p-value of 0.05 or less was considered significant. Statistical analyses were performed using SPSS 15.0 software (Statistical Package for the Social Sciences SPSS Inc., Chicago, IL, USA).

G. Follow-up

Follow-up was performed by review of patients’ records. Fistulography was performed for assessment of patency when restenosis or occlusion of the fistula was suspected during
physical examination or hemodialysis. In addition, some of the patients were also contacted by telephone and interviewed on the last date of follow up.
III. RESULTS

Eighty-three patients with dysfunctional dialysis shunts underwent bail-out stenting to restore vascular access. The stents were placed in 26 central veins (31.3%), 40 upper arm veins (48.2%), 11 cubital veins (13.3%), and 6 forearm veins (7.2%). There were 43 native arteriovenous fistulas (51.8%) and 40 arteriovenous grafts (48.2%). Patient characteristics are summarized in Table 2.

Technical success was achieved in 100% of procedures and clinical success was achieved in 100% of procedures. The mean duration of follow-up (±standard deviation) was 23.8 months ± 16.2 (range; 2 days to 6.3 year) and the mean number of reintervention to maintain secondary patency after stent placement was 1.79 ± 2.5 (range; 0-17). The mean primary patency time (±standard deviation) was 19.88 months ± 2.691 (95% CI; 14.607 to 25.154) and the mean secondary patency time was 49.53 months ± 4.859 (95% CI; 40.001 to 59.049). The median primary and secondary patency times were 9.5 months and 63.9 months, respectively. The 3 months, 6 months, 1-, 2-, 3-, and 4-year primary patency rates were 81%, 66.7%, 43.1%, 28.8%, 25.2%, and 25.2%, respectively (Fig. 1A). The 3 months, 6 months, 1-, 2-, 3-, 4-, 5-, and 6-year secondary patency rates were 91.6%, 88%, 82.9%, 73.9%, 62.6%, 59.1%, 59.1%, and 29.6%, respectively (Fig. 1B).

The primary and secondary patency rates did not statistically differ between stent location of four subgroups (central, upper arm, cubital, and forearm) by Kaplan-Meier log-rank test (p=0.99, 0.54, respectively, Fig. 2).

The mean primary patency times (±standard deviation) were 19.63 months ± 3.808 (95% CI; 12.170 to 27.097) in stents located at central veins and 20.35 months ± 3.288 (95% CI; 13.904 to 26.793) in stents located at peripheral veins, including upper arm, cubital, and forearm veins (p=0.87). The mean secondary patency times were 40.5 months ± 4.458 (95% CI; 31.767 to 49.242) in stents located at central veins and 50.04 months ± 5.349 (95% CI; 39.558 to 60.525) in stents located at peripheral veins (p=0.83). The median primary patency times were 9.5 months in stents located at central veins and 9.23 months in stents located at peripheral veins. The median secondary patency time in stents located at central veins cannot be computed in Kaplan-Meiere analysis due to survival curve does not fall to 50% (Fig. 3B). The median secondary patency time in stents located at peripheral
veins was 63.9 months.

For the central stents, the 3-months, 6-months, 1-, 2-, 3-, and 4-year primary patency rates were 92.1%, 68.1%, 36.1%, 36.1%, 32.1%, and 32.1%, respectively. For the peripheral stents including upper arm, cubital and forearm, the 3-months, 6-months, 1-, 2-, 3-, and 4-year primary patency rates were 75.9%, 66.2%, 47.4%, 29.8%, 25.6%, and 25.6%, respectively (Fig. 3A). There was no significant difference in primary patency between two subgroups (p=0.87) and relative risk for survival failure in peripheral stents, compared with central stents was 0.954 (95% CI; 0.530 to 1.715).

For the central stents, the 3-months, 6-months, 1-, 2-, 3-, 4-, 5-, and 6-year secondary patency rates were 92.3%, 88.5%, 88.5%, 65.5%, 65.5%, 65.5%, 65.5%, and 65.5%, respectively. For the peripheral stents including upper arm, cubital, and forearm, the 3-months, 6-months, 1-, 2-, 3-, 4-, 5-, and 6-year secondary patency rates were 91.2%, 87.7%, 80.3%, 78.2%, 63.6%, 59.1%, 59.1%, and 29.5, respectively (Fig. 3B). There was no significant difference in secondary patency between two subgroups (p=0.83) and relative risk for survival failure in peripheral stents, compared with central stents was 0.914 (95% CI; 0.391 to 2.135).

During follow up period, 12 stent fractures (12/83, 14.5%) were occurred. A total of 11 (91.7%) occurred in the peripheral veins (cubital vein 4, forearm vein 7), compared to 1 (8.3%) in the central vein. According to the Cardiovascular Institute of South (CIS) nitinol stent fracture classification system (David, 2004) (Table 1), there were 1/12 (8.3%) type I, 5/12 (41.7%) type II, 2/12 (16.7%) type III, and 4/12 (33.3%) type IV fractures.

Table 1. Nitinol stent fracture classification

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>A single strut fracture only</td>
</tr>
<tr>
<td>Type 2</td>
<td>Multiple single nitinol stent fractures that can occur at different sites</td>
</tr>
<tr>
<td>Type 3</td>
<td>Multiple nitinol stent fractures resulting in complete transverse linear fracture but without stent displacement</td>
</tr>
<tr>
<td>Type 4</td>
<td>A complete transverse linear type III fracture with stent displacement</td>
</tr>
<tr>
<td>Table 2. Clinical characteristics of 83 study patients</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>47</td>
</tr>
<tr>
<td>Female</td>
<td>36</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>63.24 ± 12.55 years</td>
</tr>
<tr>
<td><strong>Hemodialysis shunts type</strong></td>
<td></td>
</tr>
<tr>
<td>Native AVF</td>
<td>43 (51.8%)</td>
</tr>
<tr>
<td>AVG</td>
<td>40 (48.2%)</td>
</tr>
<tr>
<td><strong>Stent location</strong></td>
<td></td>
</tr>
<tr>
<td>Central vein</td>
<td>26 (31.3%)</td>
</tr>
<tr>
<td>Upper arm vein</td>
<td>40 (48.2%)</td>
</tr>
<tr>
<td>Cubital vein</td>
<td>11 (13.3%)</td>
</tr>
<tr>
<td>Forearm vein</td>
<td>6 (7.2%)</td>
</tr>
<tr>
<td><strong>Stent diameter</strong></td>
<td></td>
</tr>
<tr>
<td>6mm</td>
<td>12 (14.5%)</td>
</tr>
<tr>
<td>7mm</td>
<td>28 (33.7%)</td>
</tr>
<tr>
<td>8mm</td>
<td>13 (15.7%)</td>
</tr>
<tr>
<td>9mm</td>
<td>1 (1.2%)</td>
</tr>
<tr>
<td>10mm</td>
<td>5 (6.0%)</td>
</tr>
<tr>
<td>12mm</td>
<td>6 (7.2%)</td>
</tr>
<tr>
<td>14mm</td>
<td>18 (21.7%)</td>
</tr>
<tr>
<td><strong>Stent length</strong></td>
<td></td>
</tr>
<tr>
<td>40mm</td>
<td>11 (13.3%)</td>
</tr>
<tr>
<td>60mm</td>
<td>31 (37.3%)</td>
</tr>
<tr>
<td>70mm</td>
<td>3 (3.6%)</td>
</tr>
<tr>
<td>80mm</td>
<td>20 (24.1%)</td>
</tr>
<tr>
<td>100mm</td>
<td>8 (9.6%)</td>
</tr>
<tr>
<td>120mm</td>
<td>7 (8.4%)</td>
</tr>
<tr>
<td>140mm</td>
<td>1 (1.2%)</td>
</tr>
<tr>
<td>150mm</td>
<td>2 (2.4%)</td>
</tr>
</tbody>
</table>
Fig. 1. Kaplan-Meier analysis of primary patency (a) and secondary patency rates (b) after nitinol stent placement (n=83).

Fig. 2. Primary and secondary patency rates did not statistically differ between the stent location of four subgroups by Kaplan Meier log rank test and p-values were 0.99 (a) and 0.54 (b), respectively.
Fig. 3. Primary and secondary patency rates did not statistically differ between the stent location of two subgroups by Kaplan Meier log rank test and p-values were 0.87 (a) and 0.83 (b), respectively.

Fig. 4. Primary and secondary patency rates did not statistically differ between the type of hemodialysis shunts by Kaplan Meier log rank test and p-values were 0.37 (a) and 0.81 (b), respectively.

The type of hemodialysis shunts did not significantly affect the primary patency (p=0.37) and relative risk for survival failure in AVG, compared with AVF was 1.278 (95% CI ; 0.737 to 2.214). There was also no significant difference in secondary patency between
two groups (p=0.81) and relative risk for survival failure in AVG, compared with AVF was 1.097 (95% CI; 0.509 to 2.368) (Fig. 4).

Presence of comorbidity of diabetes mellitus did not significantly affect the primary and secondary patency (p=0.31, 0.92, respectively) and relative risk ratios for survival failure were 1.321 (95% CI; 0.762 to 2.292) and 0.964 (95% CI; 0.447 to 2.080), respectively (Fig. 5).

**Fig. 5.** Presence of diabetes mellitus did not significantly affect the primary and secondary patency rates by Kaplan Meier log rank test and p-values were 0.31 (a) and 0.92 (b), respectively.

However, stent fracture group showed significantly decreased primary patency rate in comparison with non-fracture group (p=0.0004) and relative risk for survival failure was 2.998 (95% CI; 1.166 to 7.709), but there was no statistical difference in secondary patency between two groups (p=0.58) and relative risk was 0.715 (95% CI; 0.247 to 2.073) (Fig.6, Fig.8).

In patients with same or more than 65 years old, the primary patency rate did not statistically differ comparison with less than 65 years old group (p=0.163, relative risk=0.682 with 95% CI; 0.392 to 1.186), however, there was significant difference between two groups in secondary patency (p=0.045) and relative risk of survival failure in older age group was 2.247 (95% CI : 1.042 to 4.846), compared with younger age group (Fig. 7).
Fig. 6. The stent fracture group showed significantly decreased primary patency rate (p=0.0004) in comparison with non-fracture group (a), but there was no statistical difference in secondary patency (p=0.58) between two groups (b).

Fig. 7. Primary patency rate did not statistically differ between two groups (p=0.163) (a), but older age group of same or more than 65 years old showed significantly decreased secondary patency rate (p=0.045) in comparison with younger age group by Kaplan Meier log rank test (b).
Only stent fracture significantly affect the primary patency and the other factors including age and gender of the patient, history of diabetes mellitus and hypertension, diameter and length of the stent, location of the stent, and type of the hemodialysis shunt did not significantly affect the primary patency by Kaplan Meier log rank test. P-values and hazard ratios are summarized in table 3.

Only patient’s age significantly affect the secondary patency and the other factors including gender of the patient, history of diabetes mellitus and hypertension, diameter and length of the stent, location of the stent, type of the hemodialysis shunt, and stent fracture did not significantly affect the secondary patency by Kaplan Meier log rank test. P-values and hazard ratios are summarized in table 4.
<table>
<thead>
<tr>
<th></th>
<th>P-value $^*$</th>
<th>Hazard ratio</th>
<th>95% CI lower level</th>
<th>95% CI upper level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age $^a$</td>
<td>0.163</td>
<td>0.682</td>
<td>0.392</td>
<td>1.186</td>
</tr>
<tr>
<td>Sex $^b$</td>
<td>0.443</td>
<td>0.810</td>
<td>0.464</td>
<td>1.413</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.312</td>
<td>1.321</td>
<td>0.762</td>
<td>2.292</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.790</td>
<td>1.077</td>
<td>0.619</td>
<td>1.876</td>
</tr>
<tr>
<td>Stent diameter $^c$</td>
<td>0.714</td>
<td>0.901</td>
<td>0.514</td>
<td>1.579</td>
</tr>
<tr>
<td>Stent length $^d$</td>
<td>0.845</td>
<td>1.055</td>
<td>0.609</td>
<td>1.828</td>
</tr>
<tr>
<td>Stent location $^e$</td>
<td>0.872</td>
<td>0.954</td>
<td>0.530</td>
<td>1.715</td>
</tr>
<tr>
<td>Shunt type $^f$</td>
<td>0.374</td>
<td>1.278</td>
<td>0.737</td>
<td>2.214</td>
</tr>
<tr>
<td>Stent fracture</td>
<td>0.0004</td>
<td>2.998</td>
<td>1.166</td>
<td>7.709</td>
</tr>
</tbody>
</table>

$^a$ Classified into two subgroups of ≥65 years old and <65 years old. Hazard ratio means the relative risk of older age group compared with younger age group.

$^b$ Hazard ratio means the relative risk of male group compared with female group.

$^c$ Classified into two subgroups according to the median value of 8 mm, >8mm and ≤8mm. Hazard ratio means the relative risk of larger stent diameter group compared with smaller diameter group.

$^d$ Classified into two subgroups according to the median value of 60 mm, >60mm and ≤60mm. Hazard ratio means the relative risk of longer stent length group compared with shorter length group.

$^e$ Classified into two subgroups of central and peripheral location and Hazard ratio means the relative risk of peripheral stent group compared with central stent group.

$^f$ Hazard ratio means the relative risk of AVG group compared with AVF group.

$^*$ Cox model was used separately in each parameter and p-values were same as log-rank test.
<table>
<thead>
<tr>
<th></th>
<th>P-value $^*$</th>
<th>Hazard ratio</th>
<th>95% CI lower level</th>
<th>95% CI upper level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong> $^a$</td>
<td>0.045</td>
<td>2.247</td>
<td>1.042</td>
<td>4.846</td>
</tr>
<tr>
<td><strong>Sex</strong> $^b$</td>
<td>0.502</td>
<td>1.292</td>
<td>0.599</td>
<td>2.788</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.924</td>
<td>0.964</td>
<td>0.447</td>
<td>2.080</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.885</td>
<td>0.944</td>
<td>0.432</td>
<td>2.063</td>
</tr>
<tr>
<td>Stent diameter $^c$</td>
<td>0.847</td>
<td>0.924</td>
<td>0.416</td>
<td>2.054</td>
</tr>
<tr>
<td>Stent length $^d$</td>
<td>0.722</td>
<td>0.873</td>
<td>0.405</td>
<td>1.883</td>
</tr>
<tr>
<td>Stent location $^e$</td>
<td>0.830</td>
<td>0.914</td>
<td>0.391</td>
<td>2.135</td>
</tr>
<tr>
<td>Shunt type $^f$</td>
<td>0.811</td>
<td>1.097</td>
<td>0.509</td>
<td>2.368</td>
</tr>
<tr>
<td>Stent fracture</td>
<td>0.581</td>
<td>0.715</td>
<td>0.247</td>
<td>2.073</td>
</tr>
</tbody>
</table>

$^a$ Classified into two subgroups of ≥65 years old and <65 years old. Hazard ratio means the relative risk of older age group compared with younger age group.

$^b$ Hazard ratio means the relative risk of male group compared with female group.

$^c$ Classified into two subgroups according to the median value of 8 mm, >8mm and ≤8mm. Hazard ratio means the relative risk of larger stent diameter group compared with smaller diameter group.

$^d$ Classified into two subgroups according to the median value of 60 mm, >60mm and ≤60mm. Hazard ratio means the relative risk of longer stent length group compared with shorter length group.

$^e$ Classified into two subgroups of central and peripheral location and Hazard ratio means the relative risk of peripheral stent group compared with central stent group.

$^f$ Hazard ratio means the relative risk of AVG group compared with AVF group.

* Cox model was used separately in each parameter and p-values were same as log-rank test.
The complication rate was 7.2% (6/83) with four major complications and two minor complications. Three cases of major complications were wound infection at the surgical site. Another major complication was a case of stent migration, located in the central vein. After 17 days after the procedure, the patient had a progressive right arm swelling. The follow up venography showed that stent migrated to the SVC, so the graft abandoned (Fig. 9). Minor complications included one case of local infection which did not require hospitalization and one case of stent insertion site discomfort which located in cubital vein.
Fig. 8. 78-year old female with right brachio-brachial AVG. There was residual stenosis more than 50% after balloon angioplasty at venous limb. The stent inserted and the patient achieved technical and clinical success (a). 26 days after stent insertion, the patient had follow up venography due to insufficient flow. There was type 4 nitinol stent fracture and significant in-stent restenosis. After balloon angioplasty, blood flow restored (b). The secondary patency was 3 year 7 months and four sessions of reintervention were performed to maintain secondary patency. Last venography which performed due to insufficient shunt flow shows significant stenosis at upper arm vein, but intact stent patency in spite of fracture (c).
Fig. 9. 75-year old male with right brachiocephalic AVF. Initial fistulography showed near total occlusion of right brachiocephalic vein. There was residual stenosis more than 50% after balloon angioplasty. The stent inserted and the patient achieved technical and clinical
success (a). After 17 days, the patient had follow up venography due to progressive right arm swelling. There was a migration of stent (arrow) to the SVC, so the graft abandoned.
IV. DISCUSSION

Most of previous study reported experience of endovascular treatment with the Wallstent (Boston Sicentific, Natick, MA, USA). However, recently Vogel et al. (Vogel and Parise, 2004) used nitinol stent for hemodialysis access in 64 patients and the mean patency durations were 14.9 months in stents located at central veins and 8.9 months in stents located at peripheral veins. In study of Vogel et al. (Vogel and Parise, 2004), the 3-, 6-, 12- months primary patency rates were 81%, 74, and 67% for central stents and 77%, 51%, and 20% for peripheral stents. The same author followed prospective study (Vogel and Parise, 2005) of comparing nitinol stent placement with PTA in 60 patients and all patients were followed for 1-year. The mean primary patency durations were 5.6 months after PTA and 8.2 months after stent treatment and the 3-, 6-, 12-months primary patency rates of nitinol stents were 88%, 67%, and 41%.

The mean primary and secondary patency durations of nitinol stents in our center were 19.88 months and 49.53 months, respectively. The mean primary patency durations were 19.63 months in stents located at central veins and 20.35 months in stents located at peripheral veins and there was no significant difference in patency between central and peripheral located stents. In our study, the overall 3-, 6-, 12-months primary patency rates were 81%, 66.7%, 43.1% for overall, 92.1%, 68.1%, 36.1% for central stents and 75.9%, 66.2%, 47.4% for peripheral stents.

We subclassified peripheral veins to upper arm vein, cubital vein across the elbow joint, and lower arm vein. Side with previous study of Vogel et al. (Vogel and Parise, 2004, 2005), 11 of 83 (13.3%) stents located in cubital vein and there was no significant difference in patency between these patients and those who had stents placed at other peripheral veins. Consequently, our study shows that nitinol stent across the elbow joint could be feasible treatment and provide similar patency compared with stents placed at other peripheral veins.

In study of Vogel et al. (Vogel and Parise, 2004), there was only one stent-related complication, which was venous dissection in a patient with a stent across the elbow joint, and none of patients had stent fracture or migration. In another prospective study of Vogel et al. (Vogel and Parise, 2005), all patients were followed for 1-year and there was only one venous rupture and a single stent fracture, which was located across the level of the elbow.
joint on follow-up. However, our study showed more frequent stent fractures (12/83, 14.5%), and among 11 patients with stents placed in cubital vein, there were 4 (36.4%) stent fractures during follow up. This result may be due to longer follow up period of our study, compared with two studies of Vogel et al. (Vogel and Parise, 2004, 2005). By Kaplan-Meier log-rank test, stent fracture significantly shortens the primary patency, but not secondary patency.

There are several reports of nitinol stent fractures at lower extremity angioplasty, especially superficial femoral veins (Duda et al., 2002; David, 2004; Schlager et al., 2005), but only few reports exists at hemodialysis access. Tsuji et al. (Wada et al., 2007) described self-expanding stent fracture in the left brachiocephalic vein and a Brewster et al. (Brewster et al., 2006) described fracture of two overlapping stents, but long-term follow up data with large study population is not reported. Our study shows that the true incidence of nitinol stent fracture in hemodialysis access is more prevalent than suspected (14.5%) and may imply that stents fracture may lead to in-stent restenosis and shortens the primary patency. However, no significant difference was identified in secondary patency between fracture and non-fracture group. The etiology of stent fracture is not evaluated in this study, but more frequent fracture was identified at peripheral veins (91.7%, 4 cubital veins, 7 forearm veins) compared to 1 (8.3%) in the central vein. This finding could be explained by more biomechanical forces exerted on peripheral vein than central vein, but further investigations are needed.

Covered stent as they are known, lead to occasionally stent shortening and migration (Verstandig et al., 2003). However, to our knowledge, nitinol stent migration has not been reported in the literature. During follow up, one case of stent migration was occurred, which was located in the cephalic vein and migrated to the SVC. Verstandig et al. (Verstandig et al., 2003) explained the Wallstent (Schneider, Bulach, Switzerland) migration in central veins by shortening-lengthening-shortening mechanism. The normal expansion and contraction of the central vein during respiration, which when combined with the geometry of the stent, can lead to a sequence of shortening-lengthening-shortening of the stent, and this sequence can lead to stent movement and migration. However, unlike covered stent, bare-metal nitinol stent may provide more deployment in lumen and until now no report of nitinol stent shortening or migration exists. So not only the “shortening-lengthening-shortening” of the stent in central vein, but also the repeated extrinsic biomechanical forces (i.e. arm abduction and adduction) on the stents at thoracic outlet level, could be the possible mechanism of
nitinol stent migration.

We evaluated factors affecting stent patency, and except stent fracture, no other factors significantly affect the primary patency of stent. Also only the age of patients significantly affects the secondary patency of stent. Kolakowski et al. (Kolakowski et al., 2003) performed prospective, nonrandomized study on 61 subjects comparing the use of stents in forearm versus the upper arm, and primary patency was significantly decreased in forearm, but no significant difference was noted in secondary patency. Unlike Kolakowski et al. (Kolakowski et al., 2003), our study shows no significant difference in primary and secondary patency according to stent location between central, upper arm, forearm, and even more cubital veins. Other investigators (Rajan et al., 2007) have endeavored to determine the difference in access patency between AVF and AVG in central vein stenosis, and intervention primary patency remained significantly longer for fistulas than grafts. However, there was no significant difference in stent patency between and AVF and AVG group in our study.

The age of the patients was the only variable affecting the secondary patency. The end point of this study includes the death with patent access, and that may lead to shortening of secondary patency in old age.

The limitations of our study include the restrospective study design and the absence of comparative control of angioplasty group. We defined the end of the primary patency to repeated intervention anywhere within the access circuit, like Vogel et al. (Vogel and Parise, 2004). However in one study (Vesely, 2008), patency of the access circuit was shorter than the patency of the stent per se (target lesion). Other areas of stenoses are the likely culprits in ultimate demise of patency of the access circuit. Vogel et al. (Vogel and Parise, 2004) also observed non-significant, but higher patency rate among patients with isolated central lesions compared with patients with other peripheral stenoses in addition to central stenosis. The additive effects of stenoses anywhere along the hemodialysis circuit will confer an additional risk to loss of patency. That will be the limitation of our study, since we did not retrospectively analysis the other additive stenoses anywhere along the access circuit. Finally, we cannot use the recent spotlighted expanded polytetrafluoroethylene self-expanding stent graft. Recently, Haskal et al. (Haskal et al., 2010) performed prospective randomized study of comparing expanded polytetrafluoroethylene self-expanding stent graft placement with PTA in 190 patients and showed that the stent graft provide longer-term and superior patency.
than standard balloon angioplasty. However, expanded polytetrafluoroethylene self-expanding stent graft is not yet available in our country and expensiveness of graft could be the problem.
V. CONCLUSION

In conclusion, nitinol SMART stent can be effectively used to salvage suboptimal angioplasty results in hemodialysis access venous stenosis not only the central veins but also the peripheral veins including cubital veins. Long-term incidence of nitinol stent fractures in hemodialysis access was more prevalent than suspected (14.5%), especially which were located in peripheral veins. Stent fracture may lead to in-stent restenosis and shorten the primary patency, but not secondary patency.
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기능부전 혈액투석 동정맥루 치료법으로서 Nitinol 스텐트 설치술의 장기 개통률 평가

연구목적: 기능부전 혈액투석동정맥루 치료로서의 Nitinol 스텐트 설치술의 장기 개통률과 이에 영향을 미치는 요소를 알아보고자 하였다.

재료 및 방법: 기능부전 혈액투석동정맥루를 가진 83명의 환자가 스텐트 설치술을 시행받았고, 적응증으로는 첫째 경피경관혈관성형술 이후에도 50% 이상의 잔여협착이 남았을 경우, 둘째 정맥의 파열 혹은 박리, 셋째 경피경관혈관성형술을 시행받은 3개월 이내에 조기 재협착이 생긴 경우로 하였다. 일차, 이차 개통률은 Kaplan-Meier 생존분석을 하였고, 환자의 성별과 나이, 당뇨와 고혈압의 유무, 스텐트의 직경 및 길이, 스텐트가 설치된 위치 (중앙정맥, 위팔, 팔꿈치, 아래팔), 혈액투석동정맥루의 종류 (자가정맥, 이식정맥), 스텐트 골절의 유무에 따른 개통률 차이를 Kaplan-Meier log-rank test로 분석하였다.

결과: 스텐트는 26개의 중심정맥(31.3%), 40개의 위팔정맥 (48.2%), 11개의 팔꿈치정맥 (13.3%), 6개의 아래팔정맥 (7.2%)에 설치되었고, 기술적 그리고 임상적 성공률은 모두 100%였다. 3개월, 6개월, 1년, 2년, 3년, 4년 일차 개통률은 각각 81%, 66.7%, 43.1%, 28.8%, 25.2%, 25.2%였다. 3개월, 6개월, 1년, 2년, 3년, 4년, 5년, 6년 이차 개통률은 각각 91.6%, 88%, 82.9%, 73.9%, 62.6%, 59.1%, 59.1%, 29.6%였다. 추적 관찰 기간 중에 12개의 스텐트 골절 (14.5%)가 발생하였고 11개는 말초정맥에 (팔꿈치정맥 4, 아래팔정맥 7), 1개는 중심정맥에 발생하였다. 중심정맥에 위치했던 한 개의 스텐트 이동이 있었다. Kaplan-Meier log-rank test로 분석하였을 때, 일차...
개통률은 환자의 성별과 나이, 당뇨와 고혈압의 유무, 스텀트의 직경 및 길이, 스텀트가 설치된 위치, 혈액투석동정맥부의 종류에 따른 차이가 없었다. 하지만 스텀트 골절이 있는 집단은 통계학적으로 유의하게 스텀트 골절이 없는 집단보다 일차 개통률이 감소하였다 (p=0.0004). 하지만 이차 개통률은 두 그룹간에 차이가 없었다 (p=0.58). 이차 개통률은 환자의 성별, 당뇨와 고혈압의 유무, 스텀트의 직경 및 길이, 스텀트가 설치된 위치, 혈액투석동정맥부의 종류, 스텀트 골절에 따른 차이가 없었다. 하지만 유일하게 65세 이상의 환자 집단이 65세 미만보다 이차 개통률이 감소하였다 (p=0.045).

결론: Nitinol 스텀트는 동정맥부 협착이 동반된 혈액투석 환자에서 중심정맥뿐만 아니라 말초정맥에도 효과적인 치료법이며 팔꿈치 정맥에서도 다른 위치의 스텀트와 비교하여 개통률의 유의한 차이가 없었다. 장기 추적 관찰 시에 스텀트 골절은 알려진 보고들 보다 많이 발생하였고 (14.5%), 한 개의 스텀트 이동이 있었다. 하지만 스텀트 골절은 일차 개통률을 유의하게 감소시켰으나, 이차 개통률에는 유의한 영향을 주지 않았다.

핵심어: Nitinol 스텀트, 개통률, 팔꿈치정맥, 스텀트 골절, 스텀트 이동