Mid- to Long-term Results with the New Self-expanding, Large Caliber Allium Ureteral Stent (URS) - Multicentric Experience

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ABSTRACT

Introduction Chronic ureteral stenoses are currently managed by nephrostomy or by frequently exchanged double-J stents. To evaluate the long-term effectiveness of the new Allium ureteral stent (URS) in chronic ureteral stenosis in a multicentric setup.

Materials and Methods The Allium-URS is a self-expanding, fully covered large caliber stent. It was inserted either antegrade or retrograde after dilation of the stenoses. The Allium-URS were inserted into 37 patients (46 ureteral units) in 4 centers. The Allium-URS were 3-59 months (av. 17 months) during follow-up of up to 59 months. None of the stents occluded. Thirteen patients died from their primary malignancy. Stent migration occurred in 5 patients after 3-100 days. They were exchanged with a new one. In 3 patients the URS were removed endoscopically. Patients remained asymptomatic after URS removal.

Results Our mid- and long-term results indicate that the use of Allium URS in lower ureteral stenosis is feasible, safe and effective without secondary interventions to maintain ureteral patency for long periods. Larger number of patients and longer follow-up is needed to see the long-term efficacy of these new stents.

Conclusions

Background Currently chronic benign or malignant ureteral stenoses are managed by nephrostomy, or by polymer or metal made double-J stents. The polymeric double-J stents have to be changed every 2-6 months because of occlusion of their lumen within a few weeks and the risk of polymer disintegration. In occluded double-J stents double-J stents are used around the stent. The metal coil made Nasonic (Balt, France) has a 6F Coaxial ureteral guidewire with a capillary-flow around the coiled external surface of the stent. To evaluate its long-term effectiveness the new large caliber Allium URS stent was used in 37 patients (46 ureteral units) who were nephrostomised or had double-J stents because of benign or malignant ureteral occlusions. (Table 1)

Description of the Allium Self-expanding, Covered Ureteral Stent (URS)
The Allium Ureteral Stent (URS) is a fully covered self-expanding metal stent designed for use in the lower ureter. It is the first “covered metal stent” specifically designed for the ureter. The metal component of the URS is made of superelast steel-nickel-titanium (Nitinol). The entire stent is covered with a bio-compatible polymer to make it impermeable to liquids and tissues. The Allium URS comes in 2 calibers (24 and 32 Fr) and 2 lengths (10 and 12 cm). It has a main body with high radial force and specially designed softer end segments. The soft end segments are designed for reducing the friction between the ureteral wall and the ends of the stent, thus reducing the induction of reactive tissue proliferation seen with other metal stents. The stent is attached with a single wire passing through a ureteral vesicoureteral junction (UVJ) to an intravesical anchor. (Fig. 1) The Allium URS comes mounted on a 10 Fr antegrade or retrograde insertion device. Longitudinally the URS is very flexible. (Fig. 2 a) and has a strong enough radial force to keep the ureteral lumen open by opposing the ureteral wall to allow intraluminal flow. (Fig. 2 b) The stent also has a special unravelling feature to make its endoscopic removal easy, non-traumatic and secure. (Fig. 3) The URS does not shorten during or after its deployment, making its positioning accurate.

Table 1 - PATIENTS

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>No. PATIENTS</th>
<th>No. PATIENTAL UNITS</th>
<th>No. MIGRATION</th>
<th>No. MIGRATION (months)</th>
<th>URS STENT PATENCY</th>
<th>URS PATENCY AFTER URS REMOVAL</th>
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<tbody>
<tr>
<td>Surgery for gynecological Ca.</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>100%</td>
<td>1 patient 45 months</td>
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<tr>
<td>Surgery for gynecological Ca.</td>
<td>7</td>
<td>9</td>
<td>1-59</td>
<td>0</td>
<td>100%</td>
<td></td>
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<td>Radiation for gynecological Ca.</td>
<td>7</td>
<td>12</td>
<td>10-60</td>
<td>0</td>
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<td></td>
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<td>Radiation for gynecological Ca.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Bladder Ca.</td>
<td>5</td>
<td>5</td>
<td>10-13</td>
<td>1 at months</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>TMT nsy</td>
<td>3</td>
<td>3</td>
<td>12-12</td>
<td>0</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Post Hysterectomy Ureteral Leak</td>
<td>2</td>
<td>2</td>
<td>10-10</td>
<td>0</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Graft infection from skin</td>
<td>3</td>
<td>3</td>
<td>15-15</td>
<td>0</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Nephrolitholapaxy</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Ureteral stricture</td>
<td>3</td>
<td>3</td>
<td>15-15</td>
<td>0</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

Results

During the mean follow-up of 17 months (range 1-59 months) none of the stents occluded. In 9 patients the URS were early migrated a new stent was inserted. All 9 patients in whom the URS was removed are asymptomatic after 6-45 months.

Conclusions

Our mid- and long-term results indicate that the use of Allium URS in ureteral stenosis is a feasible, safe and effective procedure without secondary interventions to maintain ureteral patency up to 59 months. Larger number of patients and longer follow-up is needed to see the long-term efficacy of these new stents.

SAMPLE CASES

Bilateral URS Insertion After Pelvic Irradiation

Ischemic Stricture After Kidney Transplant

Post Hysterectomy Ureteral Leak

Stent infection from skin

Graft infection from skin

Nephrolitholapaxy

Ureteral stricture

Fig. 1

Fig. 2a

Fig. 2b

Fig. 3

Fig. 1

Fig. 2a

Fig. 2b

Fig. 3