Restenosis and its management after metallic stents implantation in benign trachea and main bronchus stenosis

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Introduction
- Jul 1996 – Dec 2003
- Implanted stents for 30 tracheal stenosis and 35 main bronchial stenosis
- Observed occurrence of restenosis
- Gave interventional management under bronchoscope

Clinical data and methods

Objects
- Group A - benign tracheal stenosis
  - 30 cases, 12 males and 18 females
  - 19-72 (39.4 ± 14.9) years old
  - Primary diseases:
    - Tracheotomy 17
    - Tuberculosis 9
    - Airway burn 3
    - Relapsing polychondritis 1
  - 31 nickel-titanium memory alloy stents implanted
    - 14 Ultraflex stents (Boston Scientific company, USA)
    - 17 Chinese stents (Nonferrous Metal Research and Memory alloy New Material Ltd. Beijing)
  - The positions of stents:
    - Upper segment trachea 9
    - Middle-lower segment trachea 22

- Group B - bronchial stenosis caused by EBTB
  - 35 cases, 9 males and 26 females
  - 16 to 53 (31.4 ± 12.9) years old
  - Primary diseases:
    - Cicatricial stricture EBTB 19
      - Fibrotic period
    - Bronchial malacia EBTB 11
      - Inflammatory reactive period
    - Ulcerous necrosis EBTB 3
    - Granulation EBTB 2
  - 35 nickel-titanium memory alloy stents implanted
    - 22 Ultraflex stents (Boston Scientific company, USA)
  - 13 Chinese stents (Nonferrous Metal Research and Memory alloy New Material Ltd. Beijing)
  - The positions of stents:
    - Left main bronchus 30
    - Right main + bronchus intermedius 5


Management and follow up
- Instruments:
  - P240 electronic bronchoscope
  - T30 fiberoptic bronchoscope
  - High frequency electrocauterity machine (OLYMPUS)
  - High pressure balloon (Boston Scientific)
  - CO₂ cryotherapy machine (ERBE)
Management and follow-up

- The patients were followed from 6 months to 7 years after the stents were implanted.
  - Bronchoscopy was repeated twice the first week after stents were implanted.
  - Then it was repeated every 1 to 3 months.
  - Finally repeated every 6 months after the diseases were stable.

After restenosis was diagnosed:
- Group A: electrocautery first and then cryotherapy (one patient balloon dilation).
- Group B: balloon dilation or electrocautery first and then cryotherapy.

Management was repeated every 2-3 days.
Each course of treatment contained 3 times of management.
1 month interval between two courses of treatment.
Group A received 1-5 (3 ± 1) courses and group B 2-9 (5 ± 3) courses.

Evaluation of effectiveness

- Effective standards:
  - The restenotic lumen diameter increased to:
    - Group A: more than 1/2 of normal trachea (≥10 mm).
    - Group B: more than 1/2 of left main bronchus (≥7 mm).
  - Dyspnea disappeared.
  - The above conditions kept stable for more than 3 months.
- The dyspnea index (stage 0 to stage 4) and lung function were measured before management and after the conditions had already been stable.

Statistical analysis methods

- The data was expressed by mean ± SD.
- The significant difference of ratio (percentage) between 2 groups was done by X² test.
- The difference between relative data before and after management was compared by t test.

Results

Anesthesia

- Local
- General

Laryngeal mask

The occurrence of restenosis

- **Group A:**
  - Restenosis occurred in 6 of the 30 patients (20%)
  - 3 patients used Chinese stents (17.65%), 3 used Ultraflex stents (21.43%) - $P > 0.05$
  - Restenosis occurred in 4 patients with upper segment tracheal stents (44.44%) and two patients with middle-lower segment tracheal stents (9.09%) - $P < 0.05$

- **Group B:**
  - Restenosis occurred in 8 of the 35 patients (22.86%)
  - 3 patients used Chinese stents (23.08%), 5 patients used Ultraflex stents (22.73) - $P > 0.05$
  - The restenotic rates of the fibrotic period and the inflammatory reactive period were 16.67 (5/30) and 60% (3/5) respectively - $P < 0.05$

Under bronchoscopic presentations of restenosis after metallic stents implanted in benign tracheal stenosis

The occurrence of restenosis

- **Group B:**
  - Restenosis occurred in 8 of the 35 patients (22.86%)
  - 3 patients used Chinese stents (23.08%), 5 patients used Ultraflex stents (22.73) - $P > 0.05$
  - The restenotic rates of the fibrotic period and the inflammatory reactive period were 16.67 (5/30) and 60% (3/5) respectively - $P < 0.05$

The under bronchoscopic presentation of restenosis after metallic stent implanted in tuberculostuberculous main bronchial stenosis

Therapeutic effect and prognosis

- **Group A:**
  - 4 out 6 patients met the effective standards after management.
  - The effective rates were 2/4 and 2/2 in patients with upper segment stents and middle-lower segment stents respectively.
  - After management, the lumen diameter, dyspnea index, VC and FEV₁ improved significantly compared with pre-management

Therapeutic effect and prognosis

- **Group B:**
  - 7 out of 8 patients met the standards of effectiveness (87.5%)
  - After management the lumen diameter, dyspnea index, VC and FEV₁ improved significantly compared with pre-management
<table>
<thead>
<tr>
<th>Group</th>
<th>Diameter of bronchi (mm)</th>
<th>Dyspnea index</th>
<th>VC (L)</th>
<th>FEV₁ (L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before management</td>
<td>5.03 ± 1.76</td>
<td>1.63 ± 0.52</td>
<td>1.74 ± 0.16</td>
<td>1.41 ± 0.19</td>
</tr>
<tr>
<td>After management</td>
<td>7.38 ± 2.08**</td>
<td>0.89 ± 0.76*</td>
<td>2.74 ± 1.41**</td>
<td>2.36 ± 0.37**</td>
</tr>
<tr>
<td>t-value</td>
<td>8.22</td>
<td>4.96</td>
<td>6.25</td>
<td>6.73</td>
</tr>
</tbody>
</table>

*P<0.005 vs before management; **P<0.001 vs before management

**Discussion**

- Nowadays, there’s still controversy about stents implantation in benign central airway stenosis
- In the literatures*, the restenosis rates different from 6.8% to 40% in tracheal stenting and from 25% to 40% in bronchial stenting patients
- In our group the incidence was 20% and 22.86% respectively


**Chinese stent**

- Better flexibility and compressibility
- Cheaper
- Become longer when it is pressed by side forces
- Effects of attaching to the airway wall will be poor when it meet the irregular and unsmooth stenosis segments
Ultraflex stent

- Have better ability to attach to the wall of airway
- Indicated for the irregular and unsmooth airway stenosis
- The length will not change when meet side forces
- The release is worse when meet pressure and easier to cause mental fatigue even fracture

Fracture of Ultraflex stent

In literature*, silicon Dumon stent’s restenotic rate was lower than the metallic stent’s.

- Silicon Dumon stent might be a better choice when benign upper segment tracheal stenosis is not indicated for operation

The restenotic rate was 60% in the inflammatory stage EBTE patients and 16.67% in the fibrotic stage EBTB patients.

- It is important to restrict the indications of metallic stents implantation in tuberculous bronchial stenosis

The interventional therapies of restenosis after stents implanted include balloon dilation, airway melting technique (electrocautery, Nd-Yd laser and cryotherapy) and brachytherapy.

- Balloon dilation is appropriate for the lately restenosis, especially when the stenotic segment is longer
- High frequency electrocautery is appropriate for the obviously obstructed cases that need to be reopened immediately
- Cryotherapy is slower to take into effect, but the granuloma overgrowth is less than the other methods after management

In our group of data:

- The effectiveness of combined therapy was 4/6 in the tracheal and 7/8 in the bronchial restenosis
- The diameter of stenosis segment, the dyspnea index and the ventilation function (VC and FEV1) improved significantly


Conclusion

- Restenosis occurred in some benign tracheal and tuberculous bronchial stenosis patients after metallic stents being implanted.
- The restenotic rate was higher in the upper segment tracheal stenosis than that in the middle-lower segment stenosis. Caution should be taken to place metallic stents in this part of patients.
- The restenotic rate was higher in the inflammatory reaction stage EBTB than in the fibrostic stage. Effort should be taken to avoid placing metallic stents in this part of patients.
- Balloon dilatation, cryotherapy and electrosurgery are effective methods in management of restenosis after stents being implanted.

Case 1

(admission number: 430396)

Zhong Dong, male, 35 years old, repeated productive cough for 8 months.

Diagnosed as left main bronchus stenosis caused by EBTB and began anti-TB chemotherapy.

Bronchoscopy (2001.11.13)

Bronchoscopy (2001.11.16)

Bronchoscopy (2002.1.20)
Case 2

(admission number: 419980)

- Chen Bo, male, 25 years old, productive cough and dyspnea for 5 months
- Bronchoscopy and biopsy diagnosed(1998.11) : left main bronchus tuberculosis
- After 2 months anti-TB chemotherapy, mental stent was implanted Jan 1999

- The patient felt dyspnea again Since March 1999
- Bronchoscopy showed left main bronchus restenosis

- After two courses of management by balloon dilatation and cryotherapy the symptom disappeared and the lumen met the effective standards