

# NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of stent placement for vena cava obstruction

#### **Introduction**

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

#### **Date prepared**

This overview was prepared by Bazian Ltd in April 2003.

#### **Procedure name**

Stent placement for vena caval vein obstruction

#### **Specialty societies**

*British Paediatric Cardiac Association*

*British Society of Interventional Radiologists*

#### **Description**

Vena cava obstruction is the narrowing or occlusion of the caval veins (the inferior vena cava or the superior vena cava), which return blood from the body to the heart. Caval vein obstruction is most commonly due to cancer, especially lung cancer. When caused by cancer, the condition is known as malignant caval vein obstruction. Non-malignant causes of caval vein obstruction are rare, and include scarring, fibrosis or thrombosis, for example, following pacemaker insertion or liver transplant. Rarely, caval vein stenosis is congenital, or occurs following surgical treatment for congenital heart disease.

Malignant superior vena cava obstruction has a poor prognosis.

In malignant caval vein obstruction, balloon angioplasty or stenting may replace or supplement traditional treatments including radiotherapy and chemotherapy. Both radiotherapy and chemotherapy may cause severe adverse effects, and response to treatment may take several weeks.

Balloon angioplasty for caval vein obstruction is a minimally invasive procedure which involves inserting a catheter into a large vein, usually in the groin, and passing it into the narrowed area under X ray control. A balloon is then inflated to relieve the narrowing. Stenting involves placing a tube inside the vein. The claimed advantages of balloon angioplasty with or without stenting are a more rapid response to treatment

and a lower incidence of adverse effects compared with chemotherapy or radiotherapy.

### **Efficacy**

According to the literature, stenting for vena cava obstruction relieves symptoms quickly in most cases.

According to the Specialist Advisor, stenting for vena cava obstruction is efficacious.

### **Safety**

According to the literature, the incidence of complications of stenting for vena cava obstruction is relatively low. Complications include transient chest pain, stent migration or embolisation, and thrombosis.

According to the Specialist Advisors, potential risks include caval vein rupture requiring emergency surgery, perforation of the vein, stent migration and embolisation.

## **Literature review**

### **Appraisal criteria**

Studies examining balloon angioplasty or stenting of inferior or superior vena cava obstruction of any cause were included.

### **List of studies found**

One systematic review was found (search date 2001) examining treatments for superior vena cava obstruction in lung cancer.<sup>1</sup>

No randomised controlled trials were found.

Two non-randomised controlled studies were found.<sup>2,3</sup> Eleven case series were found. The table gives details of the controlled studies and the three largest case series.<sup>4,5,6</sup> References to the smaller studies are given in the Appendix.

## Summary of key efficacy and safety findings (1)

Study details	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
<p>Rowell, 2001<sup>1</sup> Systematic review</p> <p>Studies of treatments of superior vena cava obstruction in lung cancer n=23 non-randomised studies (study design not described; assumed case series) including 159 people</p>	<p>Relief of obstruction: 151/159 people</p> <p>Relapse up to 8 months: 17/159 people</p> <p>Median survival after stenting: 1.5 to 6.5 months</p>	<p>Transient chest discomfort: 'some' people</p> <p>Deaths related to stent insertion: none</p>	<p>Good quality systematic review</p> <p>Included case series only</p> <p>Examined superior vena cava obstruction in lung cancer</p>
<p>Tanigawa, 1998<sup>2</sup> Controlled study Japan</p> <p>n=33 with malignant superior vena cava obstruction</p> <ul style="list-style-type: none"> <li>• 23 received stent (age range 35 to 79 years; 19 had lung cancer, 1 had mesothelioma, 1 had thyroid cancer, 1 oesophageal cancer, one thymic cancer)</li> <li>• 10 received radiotherapy or chemotherapy (age range 40 to 77 years; all had lung cancer)</li> </ul> <p>Follow up: to death</p>	<p>Symptoms relieved completely:</p> <ul style="list-style-type: none"> <li>• Stent: 78%</li> <li>• Radio/chemotherapy: 80%</li> </ul> <p>Time to effect:</p> <ul style="list-style-type: none"> <li>• Stent: within 1 day</li> <li>• Radio/chemotherapy: after 5 days</li> </ul> <p>Mean survival:</p> <ul style="list-style-type: none"> <li>• Stent: 145 days</li> <li>• Radio/chemotherapy: 146 days</li> </ul>	<p>Complications:</p> <ul style="list-style-type: none"> <li>• Stent: 1 person (phlebitis in lower limb)</li> <li>• Radio/chemotherapy: not stated</li> </ul> <p>Recurrence of obstruction:</p> <ul style="list-style-type: none"> <li>• Stent: 1 person</li> <li>• Radio/chemotherapy: 1 person</li> </ul>	<p>Allocation method not described</p> <p>'Patient groups did not differ significantly in age, gender, length of stenosis'</p> <p>Complications of radio or chemotherapy not described</p> <p>Follow up complete</p> <p>Examined superior vena cava obstruction</p>
<p>Nicholson, 1997<sup>3</sup> Historical controlled study UK</p> <p>n=101 people with malignant superior vena cava obstruction</p> <ul style="list-style-type: none"> <li>• 76 received stents between 1991 and 1996 (age range 41 to 82 years) studied prospectively</li> <li>• 25 received radiotherapy between 1987 and 1993 (age range 45 to 78 years)</li> </ul> <p>Follow up until recurrence of symptoms or death</p>	<p>Relief of symptoms:</p> <ul style="list-style-type: none"> <li>• Stents: 100%</li> <li>• Radiotherapy: 64%</li> </ul> <p>Mean symptom score:</p> <ul style="list-style-type: none"> <li>• Stents: 7.5/10 reduced to 1.3/10</li> <li>• Radiotherapy: 7.0/10 reduced to 5.6/10</li> </ul> <p>p&lt;0.001</p> <p>Time to effect:</p> <ul style="list-style-type: none"> <li>• Stents: Immediate to 48 hours</li> <li>• Radiotherapy: No change before 2 weeks, maximum change at 3 weeks</li> </ul> <p>Mean asymptomatic survival:</p> <ul style="list-style-type: none"> <li>• Stents: 22 weeks</li> <li>• Radiotherapy: 12 weeks</li> </ul>	<p>Stents:</p> <ul style="list-style-type: none"> <li>• transfusion: 1 person</li> <li>• anticoagulation required: 1 person</li> <li>• transient chest pain: 1 person</li> <li>• misplaced stents: 2 people</li> </ul> <p>Radiotherapy:</p> <ul style="list-style-type: none"> <li>• malaise and nausea: all</li> <li>• radiation burns: 3 people</li> <li>• initial worsening of symptoms: 6 people</li> <li>• required further radiotherapy: 9 people</li> </ul> <p>Recurrence after first 48 hours:</p> <ul style="list-style-type: none"> <li>• Stents: 9%</li> <li>• Radiotherapy: 88%</li> </ul> <p>p=0.0005</p>	<p>Historical controlled study</p> <p>Characteristics of group were similar</p> <p>Examined superior vena cava obstruction</p>

## Summary of key efficacy and safety findings (2)

Study details	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
<p>Mathias, 1998<sup>4</sup> Case series Germany</p> <p>n=204 received stents</p> <ul style="list-style-type: none"> <li>• 76 with superior vena cava obstruction</li> <li>• 28 with inferior vena cava obstruction</li> </ul> <p>Cause not clear – assumed to be malignant</p>	<p>'Success': 198/204</p> <p>Relief of symptoms: 'most'</p>	<p>'No major complications'</p>	<p>Published in German; data extracted from abstract</p> <p>Uncontrolled case series</p> <p>Examined both superior and inferior vena cava obstruction</p>
<p>Chunqing, 1999<sup>5</sup> Case series China</p> <p>n=83 received stent for inferior vena cava occlusion or stenosis; all unknown cause except one with tuberculosis</p> <p>Follow up 1 to 46 months</p>	<p>Successful placement of stent: 79/83</p> <p>Symptoms disappeared or markedly improved: all</p> <p>Blockage of hepatic outflow relieved: 67/83</p>	<ul style="list-style-type: none"> <li>• pericardial effusion: 1 person</li> <li>• complete heart block: 1 person</li> <li>• stent migration into right atrium: 1 person</li> <li>• restenosis: 1 person</li> </ul>	<p>Uncontrolled case series</p> <p>Examined inferior vena cava obstruction</p>
<p>Lanciego, 2001<sup>6</sup> Case series Spain</p> <p>n=52 with malignant superior vena cava obstruction (age range 44 to 78 years)</p>	<p>Successful placement of stent: All</p> <p>Symptoms disappeared completely within 72 hours: all</p> <p>Mean symptom-free survival: 6 months</p>	<p>Stent obstruction: 6 people</p> <p>Stent migration: 1 person</p>	<p>Uncontrolled case series</p> <p>Examined superior vena cava obstruction</p>

### **Validity and generalisability of the studies**

All the studies found examined stenting, rather than balloon angioplasty alone, for caval vein obstruction.

One high quality systematic review was found.<sup>1</sup> It found only case series. It examined only stenting for superior vena cava obstruction in lung cancer.

Two non-randomised controlled studies were found comparing stenting with chemotherapy or radiotherapy for malignant superior vena cava syndrome.<sup>2,3</sup>

The other studies found were case series. One was large<sup>4</sup> and included people with superior and inferior vena cava obstruction. One case series, set in China, examined only people with inferior vena cava obstruction.

### **Specialist advisor's opinion / advisors' opinions**

*Specialist advice was sought from consultants who have been nominated or ratified by their Specialist society or Royal College.*

Operators should be trained in interventional paediatric cardiology or adult cardiology. Procedures should be carried out in a specialised unit with biphase fluoroscopy and surgical cover.

## References

1. Rowell NP, Gleeson FV, Steroids, radiotherapy, chemotherapy and stents for superior vena caval obstruction in carcinoma of the bronchus (Cochrane Review). In: *The Cochrane Library*, Issue 1, 2003. Oxford: Update Software.
2. Tanigawa N, Sawada S, Mishima K, Okuda Y, et al. Clinical outcome of stenting in superior vena cava syndrome associated with malignant tumors. Comparison with conventional treatment. *Acta Radiologica* 1998; 39: 669-74.
3. Nicholson AA, Ettles DF, Arnold A, Greenstone M, et al. Treatment of malignant superior vena cava obstruction: metal stents or radiation therapy. *Journal of Vascular & Interventional Radiology* 1997; 8: 781-8.
4. Mathias K, Jager H, Willaschek J, and Theophil B. Interventional radiology in central venous obstructions. Dilatation--stent implantation--thrombolysis [German]. *Radiologe* 1998; 38: 606-13.
5. Chunqing Z, Lina F, Guoquan Z, Lin X, et al. Ultrasonically guided inferior vena cava stent placement: Experience in 83 cases *Journal of Vascular & Interventional Radiology* 1999; 10: 85-91.
6. Lanciego C, Chacon JL, Julian A, Andrade J, et al. Stenting as first option for endovascular treatment of malignant superior vena cava syndrome. *American Journal of Roentgenology* 2001; 177: 585-93.

## Appendix: References to studies not described in the table

Reference	Number of participants
Kishi, K. and Sato, M. Rationale and clinical effects of stent therapy and radiotherapy to superior vena cava syndrome, tracheobronchial stenosis, and esophageal stenosis or fistula due to malignant tumor Japanese Journal of Clinical Radiology 1998; 43: 657-665.	152 but a variety of interventions
Kee, S. T., Kinoshita, L., Razavi, M. K., Nyman, U. R., Semba, C. P., and Dake, M. D. Superior vena cava syndrome: treatment with catheter-directed thrombolysis and endovascular stent placement. Radiology 1998; 206: 187-193.	51
Yang, X. L., Cheng, T. O., and Chen, C. R. Successful treatment by percutaneous balloon angioplasty of Budd-Chiari syndrome caused by membranous obstruction of inferior vena cava: 8-year follow-up study. Journal of the American College of Cardiology 1996; 28: 1720-1724.	42
Mathias, K., Willaschek, J., and Kempkes, U. Interventional radiology in the superior vena cava syndrome. Radiologia Diagnostica 1993; 34: 332-343.	42
Marcy, P. Y., Magne, N., Bentolila, F., Drouillard, J., Bruneton, J. N., and Descamps, B. Superior vena cava obstruction: is stenting necessary? Supportive Care in Cancer 2001; 9: 103-107.	40
De, B. K., Biswas, P. K., Sen, S., Das, D., De, K. K., Das, U., Mandal, S. K., and Majumdar, D. Management of the Budd-Chiari syndrome by balloon cavoplasty. Indian Journal of Gastroenterology 2001; 20: 151-154.	40
Furui, S., Sawada, S., Kuramoto, K., Inoue, Y., Irie, T., Makita, K., Yamauchi, T., Tsuchiya, K., and Kusano, S. Gianturco stent placement in malignant caval obstruction: analysis of factors for predicting the outcome. Radiology 1995; 195: 147-152.	39
Xu, K., He, F. X., Zhang, H. G., Zhang, X. T., Han, M. J., Wang, C. R., Kaneko, M., Takahashi, M., and Okawada, T. Budd-Chiari syndrome caused by obstruction of the hepatic inferior vena cava: immediate and 2-year treatment results of transluminal angioplasty and metallic stent placement. Cardiovascular & Interventional Radiology 1996; 19: 32-36.	32