New ideas - Congenital

Off-bypass implantation of a self-expandable valved stent between inferior vena cava and right atrium

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Abstract

A glutaraldehyde preserved valved bovine jugular xenograft mounted in a nitinol ‘Z’ stent, expandable from 7 to 28 mm of internal diameter, was evaluated in vitro (column of water developing a pressure of 45 mmHg and a mock loop including a pulsatile pump) and in vivo in five adult pigs with intra-vascular ultrasound to measure the inferior vena cava diameter via a retroperitoneal access. Through a stent-graft delivery system (24 French) the self-expandable valved stent was implanted off-bypass in the inferior vena cava, between hepatic veins and cavo-atrial junction, with flow and pressure gradient recording. The mean length of the valved stent was 22.80 ± 1.06 mm, the mean internal diameter 20.97 ± 0.5 mm and the mean external diameter 26.67 ± 0.9 mm. The valve leaking under pressure was 32.5 ± 12.3 ml/min. The mean pressure gradient recorded across the self-expandable valved stent implanted in the inferior vena cava was 1.0 ± 0.5 mmHg (range 0–2 mmHg). Intra-vascular ultrasound showed partial opening and closing of the valve (mean area reduction from 148.5 to 81.5 mm\textsuperscript{2}), with almost complete occlusion only during deep breaths. The in vitro and in vivo experiments confirmed the feasibility of potential application of the self-expandable valved stent implanted off-bypass in the inferior vena cava for late conversion of failing total cavo-pulmonary connection; intra-vascular ultrasound allows for adequate implantation and evaluation.

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1. Introduction

Despite the successful introduction of the extracardiac total cavo-pulmonary connection [1–3] in order to improve the surgical results in ‘functionally’ univentricular hearts [4], conversion of a failing conventional total cavo-pulmonary connection (modified Fontan procedure) can still be required either early or late because of different anatomical as well as functional reasons, all of them leading to systemic venous hypertension with or without supraventricular arrhythmias [5–8].

Life-saving treatments have been considered and utilized including conversion to an extra-cardiac total cavo-pulmonary connection, take down of the total cavo-pulmonary connection in favour of a partial cavo-pulmonary connection (end-to-side superior vena cava to right pulmonary artery bi-directional connection as described in modified Glenn procedure) with or without an additional source of pulmonary blood flow, conversion to one-and-half type of ventricular repair, and heart transplant.

One of the main reasons of the failure is the elevated venous pressure in the right atrium and coronary sinus, with the subsequent development of supra-ventricular arrhythmias and myocardial failure. We therefore speculated that the insertion of a valve in the inferior vena cava, by creating a pressure gradient across the valve, could reduce the right atrial hypertension and therefore might become an alternative option in case of failing total cavo-pulmonary connection.

After the reported experimental studies with percutaneous valve replacement in pulmonary [9] and aortic [10, 11] position, and the introduction in the clinical practice of percutaneous insertion of a biological valve in pulmonary position [12,13], this experimental study has been designed...
to evaluate the feasibility of the off-bypass implantation of a self-expandable valved stent in inferior vena cava.

2. Materials and methods

A glutaraldehyde preserved valved bovine jugular xenograft, with proved results for surgical repair of complex congenital heart defects [14,15], was mounted in two rings of non-thermosensitive nitinol ‘Z’ stents, expandable from 7 to 28 mm of internal diameter (Fig. 1). In vitro static performance was tested in five valved stents with a column of water, developing a pressure of 45 mmHg. Dynamic test evaluation of the valve regurgitation has been performed with a mock loop including a pulsatile pump (Video 1; http://www.icvts.org/elan/71/video1-2nd.mpg). Valve function was assessed with flow and pressure drop measurements as well as intra-vascular ultrasound (Boston Scientific Corporation, California, USA) with a 6 F, 12.5 MHz transducer in real time.

The self expandable valved stent was prepared with a teflon sheath stent-graft delivery system with overall diameter 8.0 mm = 24 F (Fig. 2).

Acute in vivo evaluation was performed in five adult pigs (mean body weight 80.5 ± 5.0 kg, range 74–85 kg).

After general anaesthesia, tracheal intubation and mechanical ventilation, with continuous monitoring of electrocardiogram, arterial pressure and oxygen saturation, heparin was administered i.v. (1 mg/kg).

The internal diameter and length of the inferior vena cava have been measured with intra-vascular ultrasound, with access via the right iliac vein through retro-peritoneal approach.

The self expandable valved stent was introduced off-bypass into the inferior vena cava by the same retro-peritoneal approach, positioned at the target level between hepatic veins and cavo-atrial junction and unloaded; mean duration of deployment was 8 min.

A high fidelity tip mounted Millar pressure transducer system was used to measure the pressure proximal and distal to the valve, and intra-vascular ultrasound was used to assess the valve function.

At the end of the study, after a mean period of observation of 4 h, the animals were electively sacrificed to check the adequate position of the self expandable valved stent, as well as its deployment and anchorage and the presence of any valve deformation.

All animals received human care in compliance with the ‘Principles of Laboratory Animals’ formulated by the National Society of Medical Research and the ‘Guide for the Care and Use of Laboratory Animals’ prepared by the Institute of Laboratory Animal Resources and published by the National Institutes of Health (NIH publication 85 – 23, revised 1985). The protocol was approved by the institutional Committee on Animal Research. All data were expressed as mean ± standard deviation.

3. Results

The mean length of the valved stent was 22.80 ± 1.06 mm, the mean internal diameter 20.97 ± 0.5 mm and the mean external diameter 26.67 ± 0.9 mm.

In vitro static performance testing of the valved stent

1 Intra-vascular ultrasound showing the complete opening and closing of the valve implanted in the self-expandable stent at the mock loop dynamic evaluation.
showed a mean leaking rate of 32.5 ± 12.3 ml/min for an after-load of 45 mmHg. The valve leaking under pressure was not statistically different from the results obtained with the original valved xenograft before mounting in a stent. The dynamic mock loop evaluation showed a peak-to-peak pressure gradient of 6.4 ± 2.7 mmHg through the valve at 4.30 ± 0.97 l/min of pulsatile flow.

Intra-vascular ultrasound showed a mean length of the inferior vena cava between heart and liver of 79 ± 2 mm (range 75–84 mm) and the internal diameter of the inferior vena cava was 20.4 ± 1.6 mm (range 18.71–22.56 mm). The mean pressure gradient recorded across the valved stent implanted in the inferior vena cava was 1.0 ± 0.5 mmHg (range 0–2 mmHg).

Intra-vascular ultrasound showed partial opening and closing of the valve, with a mean area reduction from 148.5 to 81.5 mm²; almost complete valve closure occurred only during deep breaths in these healthy animals (Video 2⁵; http://www.icvts.org/elan/71/video2-2nd.mpg).

In all animals autopsy confirmed the adequate position of the valved stent at about 2 cm proximal to the right atrial junction, without any deformation of the valved stent.

4. Discussion

Previous experimental studies demonstrated the feasibility of implantation of a valved stent in aortic position reached from the abdominal aorta via a retro-peritoneal access [16] or from the right common carotid artery surgically isolated [17,18], while another experimental study tested the deployment of a stented valved bovine jugular vein in the inferior vena cava or in the external iliac vein as a potential treatment for venous insufficiency [19].

The first goal of our study was to evaluate the feasibility of the implant of a biological valve within a self-expandable stent: both our in vitro test, with the mock loop including a pulsatile pump, and the in vivo acute animal study, demonstrated the adequacy of our home made self expandable valve stent. This device might represent an advantage on the currently available biological valves mounted on a platinum expandable, but not self expandable, stent [9,12,13], even if we have to acknowledge the recent introduction of another experimental model of self-expandable stent [20].

The most important goal of our study was to demonstrate the feasibility of the off-bypass implantation of the self expandable valved stent between inferior vena cava and right atrium. With regard to the mismatch between the size of the vena cava and the self expandable valved stent, our study demonstrated that the internal diameter and the length of the inferior vena cava are suitable for implantation of the valved stent. Our measurements of inferior vena cava, performed with the intra-vascular ultrasound, provided results in agreement with the values reported with computerized tomographic (CT) scans on human beings between 2 and 19 years of age, where the mean diameter of the inferior vena cava varied from 13.8 mm (range 6.1–21.6 mm) at 2 years of age to a mean diameter of 28.4 mm (range 20.5–36.4 mm) at 19 years of age, while the length of the inferior vena cava (measured from the confluence of the iliac veins to the diaphragm) varied from 116 mm (range 71–162 mm) at 2 years of age to a mean length of 225 mm (range 179–272 mm) at 19 years of age [21].

In our acute experimental observations, in absence of right heart failure and systemic venous hypertension, the retro-peritoneal approach allowed for an easy and reproducible introduction via the right iliac vein of the self expandable valved stent, as well as its positioning between the inferior vena cava and the right atrium. Our home made valved stent presents the advantages of allowing the off-bypass introduction of a biological valve up to 22 mm internal diameter. This size has been demonstrated in our clinical practice to be adequate for the entire systemic venous return, not only for the inferior vena cava, when implanted in pulmonary position in patients of very large size and body weight, up to 91 kg [14]. Of course this should represent a potential clinical advantage over the currently available off-bypass systems, where the introduction from the femoral vein limit the size up to a biological valve with internal diameter of 18 mm [13].

Evaluation of the potential application of our protocol for patients with failure of a total cavo-pulmonary connection

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⁵ Intra-vascular ultrasound showing opening and partial closing of the valve, with almost complete valve closure during deep breaths (final sequence of the video).
was the last goal of our project which has not been completely fulfilled. We demonstrated the complete opening of the valve but only a partial closure, which became almost complete closure only during deep breaths, with minimal hemodynamic pressure gradients across the valve. Therefore our speculation regarding the potential clinical application remains still open, requiring probably for additional experimental chronic studies on animals with induced right heart failure.

The last advantage proved by our experimental study was the possibility of performing both the implantation and the evaluation of the self-expandable valved stent with intravascular ultrasound as diagnostic tool. As already demonstrated for the treatment of acquired diseases of the aorta [22], the off-bypass implantation of valved stent does not require the angiography nor the utilization of any contrast medium.

5. Conclusions

(a) The in vitro and in vivo experiments confirmed the feasibility of potential application of the self-expandable valved stent implanted off-bypass in the inferior vena cava for late conversion of failing total cavo-pulmonary connection; and (b) intra-vascular ultrasound allows for adequate implantation and evaluation.

References


Appendix A. Disclaimer

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