Development of the Baylor Gyro permanently implantable centrifugal blood pump as a biventricular assist device


Abstract
The Baylor Gyro permanently implantable centrifugal blood pump (Gyro PI pump) has been under development since 1995 at Baylor College of Medicine. Excellent results were achieved as a left ventricular assist device (LVAD) with survival up to 284 days. Based on these results, we are now focusing on the development of a biventricular assist device (BVAD) system, which requires 2 pumps to be implanted simultaneously in the preperitoneal space. Our hypothesis was that the Gyro PI pump would be an appropriate device for an implantable BVAD system. The Gyro PI 700 pump is fabricated from titanium alloy and has a 25 ml priming volume, pump weight of 204 g, height of 45 mm, and pump diameter of 65 mm. This pump can provide 5 L/min against 100 mm Hg at 2,000 rpm. In this study, 6 half-Dexter healthy calves have been used as the experimental model. The right pump was applied between the infundibular of the right ventricle and the main pulmonary artery. The left pump was applied between the apex of the left ventricle and the thoracic descending aorta. As for anticoagulation, heparin was administered at the first postoperative week and then converted to warfarin sodium from the second week after surgery. Both pump flow rates were controlled maintaining a pulmonary arterial flow of less than 160 ml/kg/min for the sake of avoidance of pulmonary congestion. Blood sampling was done to assess visceral organ function, and the data regarding pump performance were collected. After encountering the endpoint, which the study could not keep for any reasons, necropsy and histopathological examinations were performed. The first 2 cases were terminated within 1 week. Deterioration of the pump flow due to suction phenomenon was recognized in both cases. To avoid the suction phenomenon, a flexible conduit attached on the inlet conduit was designed and implanted. After using the flexible inflow conduit, the required power and the rotational speed were reduced. Furthermore, the suction phenomenon was not observed except for 1 case. There was no deterioration regarding visceral organ function, and pulmonary function was maintained within normal range except for 1 case. Even though the experimental animal survived up to 45 days with the flexible inflow conduit, an increase in power consumption due to thrombus formation behind the impeller became a problem. Lower rotational speed, which was probably produced by the effectiveness of the flexible inflow conduit, was speculated to be one of the reasons. And the minimum range of rotational speed was 1,950 rpm in these 6 BVAD cases and the previous 3 cases of LVAD. In conclusion, 6 cases of BVAD implantation were performed as in vivo animal studies and were observed up to 45 days. The flexible inflow conduit was applied in 4 of 6 cases, and it was effective in avoiding a suction phenomenon. The proper rotational speed of the Gyro PI 700 pump was detected from the viewpoint of antithrombogenicity, which is more than 1,950 rpm.

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