NICE National Institute for Health and Care Excellence

NICE guidance

Artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure

HealthTech guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG602.

1 Recommendations

1.1 Current evidence on the safety and efficacy of total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure is limited in quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure (see NICE's interventional procedure outcomes audit tool).

1.3 Clinicians should enter details about all patients having total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure onto an appropriate registry and review local clinical outcomes.

1.4 Patient selection should be done by a multidisciplinary team experienced in managing end-stage refractory biventricular heart failure in patients needing a heart transplant, for whom a donor organ is not expected to be available before their own heart fails completely.

1.5 This technically challenging procedure should only be done in centres specialising in heart transplantation. Only cardiothoracic surgeons with specific

expertise and training in inserting the device should carry it out.

1.6 NICE encourages further research into total artificial heart implantation as a bridge to transplantation for end-stage refractory biventricular heart failure, including well matched comparative studies. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Biventricular heart failure results from structural or functional abnormalities of the heart. It leads to reduced blood flow to body tissues and oedema in the lungs (causing breathlessness) and the periphery (causing swelling of the legs). Other symptoms include reduced exercise tolerance, fatigue and malaise.

2.2 Medical treatment of heart failure involves drugs, such as diuretics and inotropic agents, to improve heart function. Invasive therapies, such as electrophysiological interventions, coronary revascularisation, valve replacement or repair, may also be used for patients with end-stage refractory biventricular heart failure. When these therapies no longer work, left ventricular or biventricular assist devices or heart transplantation may be considered.

3 The procedure

3.1 A total artificial heart (TAH) can be implanted to provide circulatory support with the aim that the patient survives while waiting for a donor heart to become available (a technique known as 'bridge to transplantation'). In this procedure, the device replaces the heart function completely.

3.2 Implantation of a TAH is done with the patient under general anaesthesia and on cardiopulmonary bypass. The native left and right ventricles, and all 4 cardiac valves are excised. The TAH device is implanted and attached to the atria, for blood inflow, and pulmonary artery and aorta, for blood outflow. Depending on the type of TAH, power is supplied either by drive lines connected percutaneously to an external biventricular pneumatic pump (which may be portable or static) or by batteries that are implanted internally and can be recharged through the skin using a transcutaneous energy transfer system. When the device begins to pump and restores blood flow around the body, cardiopulmonary bypass is stopped and the chest incision is closed.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 In a non-randomised prospective comparative study of patients at risk of imminent death from irreversible biventricular heart failure, total artificial heart (TAH) implantation (n=81) was compared with no TAH implantation (matched historical controls; n=35). The rates of survival to heart transplantation were 79% (95% confidence interval [CI] 68% to 87%) in the TAH group compared with 46% in the control group (p<0.001). The 1-year survival to heart transplantation rates were 70% (95% CI 63% to 77%) and 31% respectively (p<0.001).

In a non-randomised retrospective comparative study (United Network of Organ Sharing [UNOS] database analysis) comparing TAH support (n=212) with biventricular assisted device (BIVAD) support (n=366) as a bridge to transplantation (BTT) in adult patients, device support survival rates were similar in both groups (p=0.8): 95% compared with 93% at 30 days and 77% compared with 69% at 1 year.

In a non-randomised retrospective comparative study comparing TAH support (n=81) with paracorporeal BIVAD support (n=67) as a BTT in 148 adult patients, device support survival rates were similar between the groups (p=0.87): 76% compared with 72% at 30 days; 63% compared with 61% at 2 months; and 46% compared with 53% at 6 months respectively.

In a case series of 101 patients at risk of imminent death from irreversible biventricular heart failure and eligible for transplant, survival to heart transplantation with TAH implantation as a BTT was 68% (69/101). In a case series of 90 patients with biventricular failure treated by TAH implantation as a BTT, actuarial survival on device was 74±5%, 63±6% and 47±8% at 30, 60 and 180 days after implantation respectively. In a case series of 27 patients with TAH implantation as a BTT, 44% (12/27) of patients were discharged from hospital within a median of 88 days after implantation (range 35 to 152 days). Support time between discharge and transplantation was spent out of hospital in 87% of

patients.

4.2 In the non-randomised prospective comparative study comparing patients with TAH implantation (n=81) with matched historical controls (n=35), the survival rates at 1 and 5 years after transplantation in the TAH group were 86% and 64% compared with 69% and 34% in the control group respectively (p values not reported). In the non-randomised retrospective comparative study (UNOS database analysis) comparing TAH support with BIVAD support, survival rates after transplantation were 88% compared with 93% at 30 days, 78% compared with 83% at 1 year, and 67% compared with 73% at 3 years respectively (p=0.06). In the non-randomised comparative study of 148 patients, survival rates after transplantation in the TAH group (n=51) and the paracorporeal BIVAD group (n=39) were similar (p=0.60): 77% compared with 76% at 1year; 72% compared with 70% at 3 years; and 70% compared with 58% at 5 years. In the case series of 101 patients with TAH implantation, survival after transplantation at 1, 5 and 10 years was 77%, 61% and 41% respectively. In the case series of 90 patients with TAH implantation, actuarial survival rates after transplantation were 78±6%, 71±6% and 63±8% at 1, 5 and 8 years respectively. In the case series of 27 patients with TAH implantation, survival after transplantation (n=12) at a median 20-month follow-up was 91%.

4.3 In the non-randomised prospective comparative study comparing patients who had TAH implantation (n=81) with matched historical controls (n=35), the overall survival rate at 1 year was 70% (95% CI 63% to 77%) and 31% respectively (p<0.001). In the case series of 101 patients with TAH implantation, the overall survival at 1, 5, 10 and 15 years was 55% (n=56), 43% (n=35), 28% (n=18), and 26% (n=3) respectively.

4.4 In the non-randomised prospective comparative study comparing patients with TAH implantation (n=81) with matched historical controls (n=35), quality of life in the TAH group improved significantly: 75% of patients were out of bed 1 week after implantation and mobility (defined as ability to walk more than 100 feet) was seen in 61% of patients (method of measurement not reported). In the case series of 27 patients with TAH implantation, the quality of life results for 12 patients at home (measured using a modified ED-5D defined by INTERMACS) showed that only 1 young patient was able to return to school. Patients and families reported the console's noise as bothersome.

4.5 The specialist advisers listed the key efficacy outcomes as survival to hospital discharge, survival and successful BTT at 6 and 12 months, and survival after transplantation.

5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 In a non-randomised retrospective comparative study of 578 patients (United Network of Organ Sharing [UNOS] database analysis), rates of deaths were not significantly different between total artificial heart (TAH) and biventricular assisted device (BIVAD) groups: 10% (22/212) compared with 12% (45/366), p=0.7 while on support; and 30% (64/212) compared with 30% (111/366), p=0.9 after transplantation. The causes of death while on device support (infection, multi-organ failure, stroke or haemorrhage) and after heart transplantation (acute rejection, infection, cardiac arrest, multi-organ failure and stroke) for both groups were also similar. In a non-randomised prospective comparative study of 130 patients, rates of death before transplantation were 21% (17/81) in the TAH group compared with 54% (19/35) in the control group (p value not reported). Causes of the 17 deaths before transplantation in the TAH group were multi-organ failure (7), procedural or technical complications (4), bleeding (2), sepsis (2), congestive heart failure (1) and pulmonary oedema (1). In the same group after transplantation, there were 6 deaths (3 graft failure, 1 sepsis, 1 procedural or technical complication and 1 multi-organ failure). Rates of deaths in a non-randomised retrospective comparative study of 148 patients were not significantly different between TAH and BIVAD support groups while on support (37% compared with 39%; p=0.87). Death occurred in 32% (32/101) of patients in a case series of 101 patients with TAH implantation; 70% were within the first 14 days. Causes of deaths were multi-organ failure (13), pneumonia or pulmonary oedema (6), sepsis (5), neurologic injury (4, including 1 stroke, 1 hypoxic damage from hypotension and 2 intracranial haemorrhage), pancreatic abscess (1), small intestinal ischaemia (1), disseminated intravascular coagulopathy (1), and disseminated coccidiodomycosis (1).

5.2 Bleeding events were reported in 62% (59/95) of patients in the TAH group in the non-randomised prospective comparative study of 130 patients. Of these events, 50% occurred during TAH implantation and were mainly tamponade or mediastinal bleeding (needing surgery and blood transfusion) within 21 days. Two

patients died from bleeding: 1 during TAH implantation and 1 during heart transplantation). Bleeding (from various sites) at a mean of 4 days was reported in 43% (43/101) of patients in the case series of 101 patients. Reoperations for haemorrhage (mediastinal explorations) were done in 25% (25/101) of patients. The surgical revision rate for bleeding or haematoma was significantly lower in the TAH group than the BIVAD group in the non-randomised comparative study (23% [17/81] compared with 42% [28/67] respectively; p=0.03). Surgical re-exploration for bleeding, haematoma or infection was reported in 39% (35/90) of patients while on device support in the case series of 90 patients. Haemorrhagic events (at a median time of 249 days) were reported in 14% (7/47) of patients in the case series of 47 patients with TAH support for more than 1 year. These included cerebral haemorrhage (n=3), subarachnoid haemorrhage (n=2), and gastrointestinal bleeding (n=2).

5.3 Device malfunction events were reported in 17% (16/95) of patients in the TAH group in the non-randomised prospective comparative study of 130 patients. One patient died because of perforation in 1 of the layers of the device's left ventricular diaphragm on day 124. Fitting complications were reported in 5% (5/95) of patients in the TAH group in the same study; 2 patients died because of poor fitting and 3 patients had repeat surgery to reposition the device. Device failure was reported in 10% (5/47) of patients in the case series of 47 patients with TAH support for more than 1 year; there were 3 membrane ruptures (2 patients died), 1 air hole in the driveline and 1 lower pump output. Device malfunction (technical problems with the alarm and computer monitoring system needing console change) was reported in 1 patient during hospitalisation in the case series of 27 patients. Malfunctions were reported in 25% (3/12) of patients discharged home after TAH implantation. In 2 patients, an air leak occurred in the driveline to the ventricle, which was sealed with a silicon band. In 1 patient, alarm triggering was caused by auricular compression during some movements (stretching and yawning) and the patient was advised to avoid them.

5.4 The renal failure rate was significantly higher in the TAH support group than the BIVAD support group after implantation (24% [52/212] compared with 10% [35/366]; p<0.0001) and after transplantation (26% [56/212] compared with 14% [49/366]; p=0.0001) in the non-randomised retrospective comparative study (UNOS database analysis). Renal failure (needing postoperative renal replacement therapy) was reported in 64% (30/47) of patients in the case series of 47 patients

with TAH support for more than 1 year. Recovery of renal function occurred in 73% (22/47) of patients but therapy continued in 17% (8/47) of patients.

5.5 The infection rate after implantation was significantly lower in the TAH group than the BIVAD group (22% [46/212] compared with 28% [104/366]; p=0.005) in the non-randomised retrospective comparative study (UNOS database analysis). Infections (7 blood, 50 respiratory, 5 mediastinal, 28 genitourinary, 12 gastrointestinal, 17 driveline and 6 in catheters) were reported in 77% (73/95) of patients in the TAH group in the non-randomised prospective comparative study of 130 patients. Infections contributed to death in 7 patients and delayed transplantation in 5 patients. Infections (commonly in the lungs and urinary tract) were reported in 64% (64/101) of patients in the case series of 101 patients. Rates of postoperative mediastinitis (TAH 12% [9/81] compared with BIVAD 5% [3/67]; p=0.14) or driveline infections (1 patient with TAH compared with 2 patients with BIVAD; p=0.61) were similar in both groups during support in the non-randomised comparative study of 148 patients.

5.6 Neurologic events (10 stroke, 4 transient ischaemic attack, 5 anoxic encephalopathy, 1 metabolic encephalopathy, 4 seizure and 1 syncope) were reported in 27% (26/95) of patients in the TAH group in the non-randomised prospective comparative study of 130 patients. Transplantation was delayed in 6 patients. Neurologic events were reported in 16% (16/101) of patients in the case series of 101 patients. Strokes were reported in 8% (8/101) of patients (5 within 9 days). Peripheral emboli (1 celiac artery, 2 spleen, 1 superior mesenteric artery, 2 kidney, 2 retina) were reported in 8% (8/101) of patients, 4 of whom died. Strokes rates were not significantly different between the TAH and BIVAD groups during support in the non-randomised prospective comparative study of 148 patients (TAH 12% [9/81] compared with BIVAD 24% [16/67]; p=0.08). Strokes were reported in 10% (9/90) of patients while on device support in the case series of 90 patients with TAH implantation. Thromboembolic events (at a median time of 500 days) were reported in 19% (9/47) of patients in the case series of 47 patients with TAH support for more than 1 year; 6 had a transient ischaemic attack and 3 had a major cerebrovascular accident with hemiparesis or aphasia.

5.7 Technical or procedural problems (obstruction of the mechanical tricuspid valve of the TAH because of migration of the central venous catheter) were reported in 3% (3/95) of patients in the TAH group in the non-randomised prospective

comparative study of 130 patients. This caused death in 1 patient. Catheter entrapment of a central line in the tricuspid valve was reported in 2 patients in the case series of 101 patients with TAH implantation. Both these patients had irreversible brain damage from device arrest and died.

5.8 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not describe any anecdotal or theoretical adverse events.

6 Further information

6.1 Patient commentary was sought but none was received.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 602 has been migrated to HealthTech guidance 459. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.