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ORIGINAL ARTICLE

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How to implant the Jarvik 2000 post-auricular driveline: evolution to a novel technique

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Abstract

The post-auricular (PA) driveline positioning for percutaneous power delivery is a specific feature of the Jarvik 2000 FlowMaker LVAD. We applied several technical refinements to optimise the PA implant. Here, we present and discuss these modifications. We retrospectively reviewed all patients implanted with Jarvik 2000 at our Institution. Different PA implant techniques were described. A machine learning analysis was performed to evaluate the determinants of driveline infection. From December 2008 to December 2017, 62 patients were implanted with Jarvik 2000, at our Institution. The PA connection was managed through the "question mark-shaped" incision in 24 patients (39%) and with the "C-shaped" in 18 (29%), whereas 10 (16%) cases received the "vertical incision" and 10 (16%) the "orthogonal incision". The implant technique resulted highly predictive of driveline infection. The rate of driveline infections was numerically lower among cases managed with the last two techniques. After evolving through different implant techniques, we propose and suggest the "orthogonal incision" to maximise the advantages of the Jarvik 2000 post-auricular driveline.

Keywords Jarvik 2000 · Post-auricular · Driveline · LVAD · Left ventricular assist device

Introduction

Jarvik 2000 FlowMaker® (Jarvik-Heart Inc. New York, NY, US) is an intra-pericardial implantable left ventricular assist device (LVAD) used as either bridge to transplant or destination therapy [1]. The post-auricular (PA) driveline positioning for percutaneous power delivery is one of its peculiarity, designed to improve patient comfort and decrease the driveline infection rate [2]. In our experience, the procedure of PA implant has been refined by applying several variations to the traditional method. In this work, we described and discussed the different positioning techniques adopted at our centre.

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Materials and methods

Study design and patient population

All consecutive implants of Jarvik 2000 at our Institution were retrospectively reviewed.

Driveline infection (DLI) was defined in accordance with the International Society of Heart and Lung Transplantation recommendations [3]. It was, thus, identified by the presence of local signs of infection (redness and swelling, pain, purulent discharge, wound dehiscence) with or without microorganism isolation or signs of systemic infection (fever, leukocytosis, increased inflammatory markers, positive blood cultures).

The study was approved by the Institutional Review Board; all subjects provided written informed consent to data use for research purposes.

Surgical technique

Before surgery, the head is shaved. Depending on the planned surgical approach for Jarvik 2000 implantation, the PA site can be either on the right side (applied to

median sternotomy, mini-sternotomy or right upper mini-thoracotomy) or on the left side (used in left thoracotomy). After induction of anaesthesia and patient positioning, the PA site is identified at about 5 cm behind and slightly above the ear, which is gently folded and hold with a tape. A relatively flat area of skull is chosen, taking care to avoid the mastoid air cells. The incision site can be marked with a dermographic pen. The patient is, then, prepped and draped, providing access to scalp and neck.

At the beginning of our experience, the PA driveline placement was managed with a "question mark-shaped" incision (Fig. 1a). This technique entailed creating a full-thickness flap of about 5–6 cm width, at the centre of which a hole of appropriate diameter was produced with a puncher, to tunnel the percutaneous part of the titanium pedestal. The flap was, then, repositioned with the pedestal through the hole, and sutured. Afterwards, we discontinued the incision inferiorly, moving from the "question mark-shaped" to the "C-shaped" (Fig. 1b): the dimension of the tissue flap was slightly reduced, whereas the pedestal was passed through, in the centre, similarly. Subsequently, we introduced a modification of this procedure adopting a "vertical incision" technique (Fig. 1c): the tissue flap was no longer performed; the

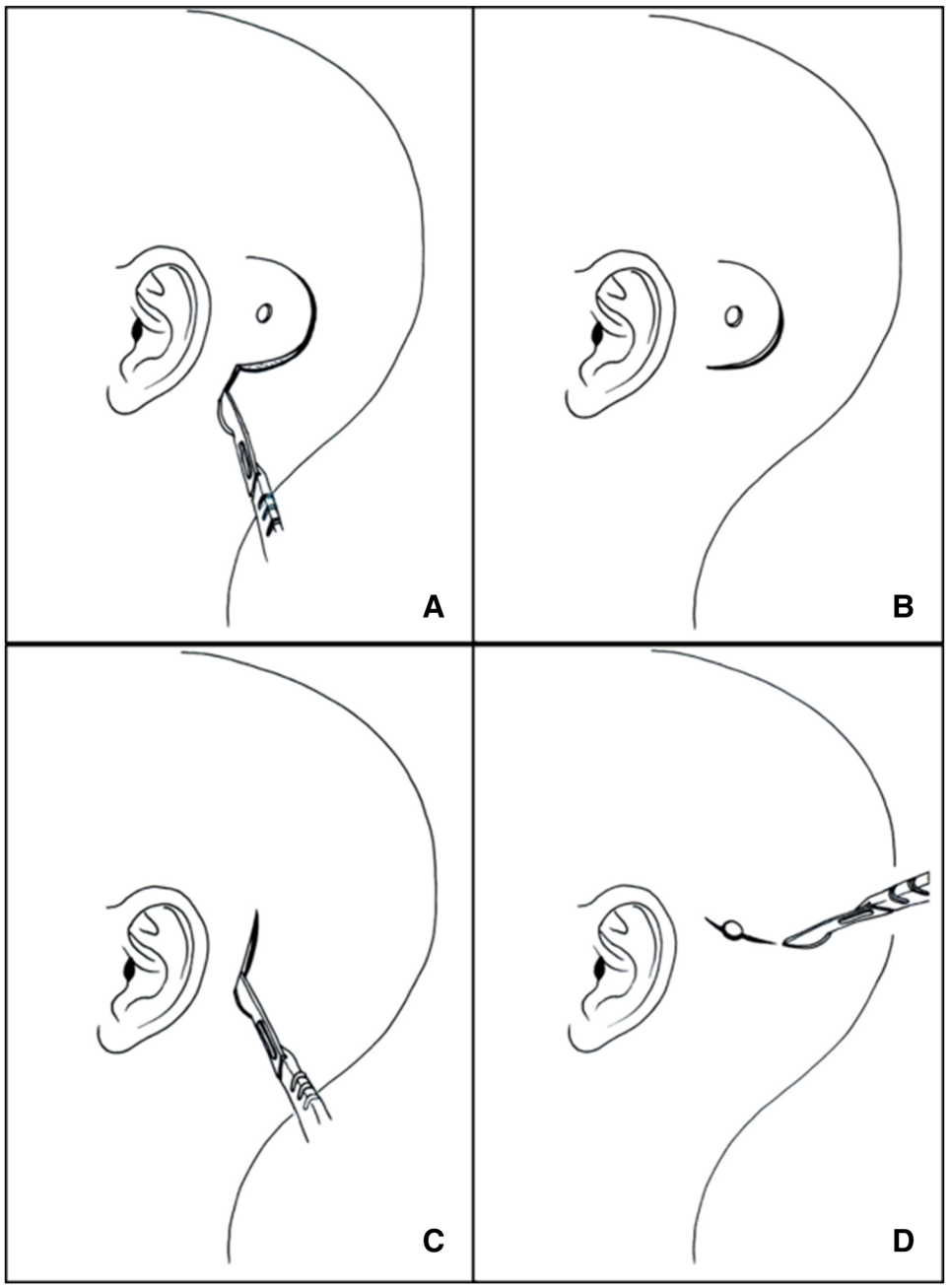

Fig. 1 Jarvik 2000 post-auricular driveline implant techniques. **a** "Question mark-shaped" incision; **b** "C-shaped" incision; **c** "vertical incision"; **d** "orthogonal incision"

skin was vertically incised for about 4 cm, with little facing notches on each side, corresponding to the percutaneous part of the pedestal. Here, we present a further modification of the procedure: the "orthogonal incision" technique (Fig. 1d and Video). First, a cork bore-type instrument is used to create a hole of the same diameter of the pedestal at the chosen site, and then a 3-cm incision is made, extending one-third before and two-thirds after the hole. The incision is horizontal, perpendicular to the axis of the power cable. A retractor is used during pedestal positioning. The periosteum is elevated and moved to the edges of the incision; any skull irregularity is burred off, to give a flat surface. With the aid of a template, the position of the bone screws is defined; a specific hand drill is used to obtain the corresponding holes, which are subsequently threaded. The power cable is passed through from the chest to the neck, where a little incision is made as intermediate station, and, then, to the PA site. Tunnelling is performed creating a duct with a smooth tip instrument, through which an umbilical tape is inserted, which is connected to the tip of a chest drain. The 3-pin connector is introduced within the distal end of the chest drain and pulled back through the duct. Once tunnelled to the PA site, the connector is inserted into the titanium pedestal, which is fixed to the skull with the bone screws. Periosteum and sub-cutaneous tissues are re-approximated with absorbable sutures. Preferably, the skin is closed with separate polypropylene stitches.

The remaining procedure of pump implantation was described elsewhere [1, 4].

PA site management

After intervention, the PA site is covered with a sterile dressing and cleaned with a sodium hypochlorite solution twice a week. After the first 2 weeks, stitches are removed, and, after the first 3 months, the PA site is left uncovered. Patients and caregivers are educated and trained to perform the PA site medication autonomously after discharge.

Cases of DLI are treated according to their severity. All cases are managed with local debridement and daily medication with sodium hypochlorite solution and sterile dressing. All patients receive an appropriate antibiotic therapy, in accordance with the extension of the infection and the microorganism isolated, as previously described [2].

Statistical analysis

Due to purposes of the study (observational and descriptive in presenting a case series), no formal calculation of sample size has been performed. In addition, due to the small observed sample size, the high ratio between number of covariates and observations, and in view of the mainly exploratory purposes of the study, no traditional statistical testing has been performed.

However, beside basic descriptive analyses of the sample, data have been analysed using a random forest (RF) approach, which is a machine learning model capable to deal with situations of more variables than observations in a competing risk scenario [5]. This analysis was directed to the identification of determinants of DLI.

Time to event has been modelled in a competing risk framework using a Survival Random Forest [6] and a modified weighted log-rank splitting rule based on Gray's test. Most important variables in predicting outcomes were selected using a minimal depth methodology [7]. The minimal depth of a maximal subtree measures the predictiveness of a given variable. The smaller is the minimal depth, the higher is the impact of a variable on prediction. All pre-operative and post-operative variables were considered in the random forest analysis, including: age at implant; sex; body surface area (BSA); device strategy; cardiac aetiology; INTERMACS class; diabetes; chronic obstructive pulmonary disease (COPD); peripheral vascular disease; redo surgery; baseline bilirubin and glomerular filtration rate (GFR); pre-operative continuous veno-venous hemofiltration (CVVH), intra-aortic balloon pump (IABP) and paracorporeal support (ECMO, LVAD); operative time; post-operative time of mechanical ventilation, RVAD, cerebral event, CVVH, surgical revision, VAD thrombus, abdominal complication.

Analyses have been performed using the R System [8].

Results

From December 2008 to December 2017, 62 patients were implanted with Jarvik 2000 at our Institution. The PA connection was managed through the "question mark-shaped" incision in 24 patients (39%) and with the "C-shaped" in 18 (29%), whereas 10 (16%) cases received the "vertical incision" and 10 (16%) the "orthogonal incision". Baseline patients' characteristics are summarised in Table 1. Post-operative outcomes are listed in Table 2. A driveline infection occurred in 12 (19%) patients: 6 (25%) of those managed with the "question mark-shaped" incision, 4 (22%) with the "C-shaped", 2 (20%) with the "vertical incision" and 0 (0%) with the "orthogonal incision". Random forest-based multivariable analysis selected five variables as relevant for predicting events (Table 3). PA implant technique resulted highly predictive of each competing event.

Table 1 Baseline patients' characteristics

	Question mark ($n=24$)	C-shape incision ($n=18$)	Vertical incision ($n=10$)	Orthogonal incision ($n=10$)
Age at implant	63 ± 9	58 ± 10	59 ± 8	69 ± 4
Female	1 (4%)	5 (28%)	1 (10%)	1 (10%)
BSA	1.9 ± 0.2	1.8 ± 0.2	2 ± 0.2	1.8 ± 0.1
INTERMACS class				
1	6 (25%)	9 (50%)	8 (80%)	2 (20%)
2	7 (29%)	2 (11%)	1 (10%)	0 (0%)
3	7 (29%)	2 (11%)	0 (0%)	2 (20%)
4	4 (17%)	5 (28%)	1 (10%)	6 (60%)
Cardiac aetiology				
Ischemic heart disease	14 (58%)	14 (78%)	7 (70%)	8 (80%)
Idiopathic dilated	8 (33%)	2 (11%)	3 (30%)	2 (20%)
Other	2 (8%)	2 (11%)	0 (0%)	0 (0%)
Device strategy				
DT	18 (75%)	7 (39%)	1 (10%)	5 (50%)
BTT	2 (8%)	9 (50%)	8 (80%)	3 (30%)
BTC	4 (17%)	2 (11%)	1 (10%)	2 (20%)
Diabetes	8 (33%)	3 (17%)	3 (30%)	5 (50%)
Peripheral vascular disease	9 (38%)	3 (17%)	2 (20%)	3 (30%)
COPD	2 (8%)	1 (6%)	0 (0%)	1 (10%)
Redo surgery	8 (33%)	3 (17%)	1 (10%)	1 (10%)
Bilirubin (mg/dL)	1.2 ± 0.8	1.6 ± 2.2	2.9 ± 2.7	0.5 ± 0.2
GFR (mL/min/m^2)	58 ± 23	65 ± 24	99 ± 46	58 ± 28
CVVH	5 (21%)	2 (11%)	2 (20%)	0 (0%)
Inotropes	17 (71%)	14 (78%)	8 (80%)	3 (30%)
ECMO	5 (21%)	7 (39%)	5 (50%)	0 (0%)
LVAD	0 (0%)	6 (33%)	6 (60%)	0 (0%)
Mechanical ventilation	1 (4%)	2 (11%)	4 (40%)	0 (0%)
IABP	2 (8%)	4 (22%)	2 (20%)	1 (10%)

BSA body surface area, *DT* destination therapy, *BTT* bridge to transplant, *BTC* bridge to candidacy, *COPD* chronic obstructive pulmonary disease, *GFR* glomerular filtration rate, *CVVH* continuous veno-venous hemofiltration, *ECMO* extracorporeal membrane oxygenation, *LVAD* left ventricular assist device, *IABP* intra-aortic balloon pump

Table 2 Post-operative outcomes

	Question mark ($n=24$)	C-shape incision ($n=18$)	Vertical incision ($n=10$)	Orthogonal incision ($n=10$)
Time on device (months)	21 ± 19	13 ± 14	19 ± 15	16 ± 11
Death	14 (67%)	6 (33%)	3 (30%)	4 (40%)
Heart transplant	4 (17%)	8 (44%)	2 (20%)	0 (0%)
Driveline infection	6 (25%)	4 (22%)	2 (20%)	0 (0%)
Microorganism isolation	5 (83%)	0 (0%)	2 (100%)	0 (0%)
Surgical revision of PA site	1 (17%)	2 (50%)	0 (0%)	0 (0%)
Healing	3 (50%)	0 (0%)	0 (0%)	0 (0%)

PA post-auricular

Table 3 Results of the random forest variable selection

	Overall depth	driveline infection	Death	Heart transplant
PA implant technique	2.07	0.046	−0.008	0.042
Time on device	2.08	0.02	0.101	0.021
Device strategy	2.73	−0.004	0.009	−0.007
Post-operative CVVH	2.78	−0.004	0.018	0.023
Mechanical ventilation time	2.56	0.008	−0.006	0.021

Variables selected as having the highest predictiveness of outcomes (overall depth) and of each competing event (driveline infection, death, heart transplant). The smaller the depth in absolute value, the higher the predictiveness of the variable

PA post-auricular, *CVVH* continuous veno-venous hemofiltration

Discussion

Left ventricular assist devices (LVADs) have nowadays established as a valid therapeutic option for end-stage heart failure [1, 9–11]. The Jarvik 2000 is an axial flow pump with intra-pericardial implant. One of its specific features is the PA driveline, which is designed to increase patient comfort and reduce the risk of driveline infection [2]. It requires a relatively simple procedure, to which we applied some modifications to improve the results. The "question mark-shaped" and the "C-shaped" incision techniques entail creating a large full-thickness flap. Though this can simplify pedestal positioning, the involvement of a larger skull area is required, with a higher risk of injuring adjacent structures such as the mastoid emissary vein, or the transverse or sigmoid sinus. The healing process can cause tissue retraction around the percutaneous connector, with exposure of the underlying part of the pedestal. Moreover, a large scar is produced, potentially increasing the risk of infection. Pedestal detachment is a known complication of the Jarvik 2000 support and the management of this event is more complex with these implant techniques. The "vertical incision" avoids the drawbacks of the tissue flap and allows a reduction of the wound dimension. However, with the suture lying on the axis of the power cable, the medication of PA driveline and the treatment of a potential wound complication become more difficult. The "orthogonal incision" overcome all these issues and permits a further reduction of the wound dimension.

Due to the reduced sample size and the small number of events, we opted for a machine learning model to identify determinants of outcomes. This analysis recognised the PA implant technique as a variable highly predictive of driveline infection. In our experience, the DLI rate was remarkably lower with the use of the last two techniques, reaching 0% in the "orthogonal incision" group. Moreover, a surgical revision of PA site was only required in cases managed with "question mark-shaped" of "C-shaped" incisions.

Conclusions

In conclusion, after evolving through different implant techniques, we propose and suggest the "orthogonal incision" to maximise the advantages of the Jarvik 2000 post-auricular driveline. A larger sample size is needed to refine the statistical analysis.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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