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A Novel Device for Clampless Proximal Anastomosis in OPCAB Surgery: The IPAD

Baron L. Hamman, MD, Cory H. White, BS

Clinical Cardiology Research Clinic, Baylor University Medical Center, Dallas, Texas, USA

ABSTRACT

The Coalescent IPAD (Coalescent Surgical, Sunnyvale, CA, USA) is a novel device that enables creation of a compliant proximal vein anastomosis to the aorta during off-pump coronary artery bypass (OPCAB) surgery while reducing the risk of cerebrovascular emboli and early stenosis. We performed IPAD-created anastomoses in 76 patients having standard OPCAB surgery. Following the procedures, no patients developed myocardial infarctions or reported angina, suggesting patency of the vein grafts to be of high quality. We found the device to be a useful adjunct for minimally invasive CAB graft surgery.

BACKGROUND

The clampless anastomosis of a vein to the ascending aorta is valuable in off-pump coronary artery bypass (OPCAB) surgery [Stump 1996, Traverse 2003]. There are several devices readily available for the easily created aortovein proximal anastomosis, but some of these require the implantation of a stent-like metallic object into the aorta, which is prone to early stenosis [Donsky 2002]. The Coalescent IPAD (Coalescent Surgical, Sunnyvale, CA, USA) (Figure 1) enables creation of a compliant proximal vein anastomosis to the aorta without using a clamp or touching the intima, thereby reducing the risk of cerebrovascular emboli [Donsky 2002]. The IPAD allows for a suture or a clip-like apparatus to be used, thereby discontinuing the elevated risk of early emboli but retaining the benefits of OPCAB.

METHODS

IPAD-created anastomoses were performed in patients having standard OPCAB surgery. The proximal anastomoses were created prior to the distal anastomoses by stabilizing the vein onto a hole cut into the ascending aorta with the aortic cutting device. Then the vein was attached to the aorta with interrupted Nitinol U-Clips (Coalescent Surgical) [Hill 2001] in between the legs of the parent mechanism. A technique similar to "Porcupine" distal technique described by the authors was employed (Hamman 2004). Patients were followed for 2 weeks to 8 months postoperatively for signs of clinical complications.

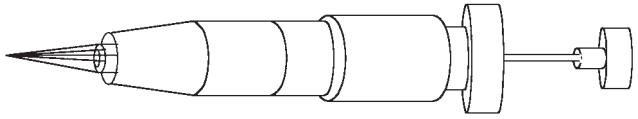

Figure 1. The IPAD anastomotic attaching device.

RESULTS

There were 111 IPAD proximal anastomoses created in 76 patients having OPCAB (mean, 1.5 anastomoses per patient). Overall cutting device average size during this study was 3.9 ± 0.3 mm, being slightly larger (approximately 8%) than the vein average size of 3.6 ± 0.5 mm, allowing for mobilization of the vein during and after anastomosis creation. The average length of time required for anastomosis creation was 6.3 minutes. Other values are totaled below (Table).

The average learning curves for the surgeons used in this study are depicted in Figure 2. As can be seen, the learning

IPAD-Assisted Clampless U-Clip Proximal Vein–Aorta Anastomoses (n = 111)

Measurement data, mean ± SD		
Vein size (outer diameter), mm	3.6 ± 0.5	
Size of aortic cutting device, mm	3.9 ± 0.3	
U-Clips used per anastomosis, n		
Primary (before IPAD removal)	6.8 ± 1.5	
Secondary (after IPAD removal)	1.6 ± 1.8	
Total per anastomosis	8.5 ± 3.0	
Blood loss, mL	10.6 ± 28.4	
Time to load vein, min	2.0 ± 2.0	
Time to secure anastomosis, min	6.3 ± 2.8	
Subjective findings	Optimal	Suboptimal
Ease of transfer	91.3%	8.7%
Seal quality	90.3%	9.7%
Anastomosis quality	100%	0%

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Address correspondence and reprint requests to: Baron L. Hamman, MD, CCRC, 1202 Barnett Tower, 3600 Gaston Ave, Dallas, TX 75246, USA; 1-214-841-2000; fax: 1-214-841-2015. (e-mail: BHamman@CDM.net).

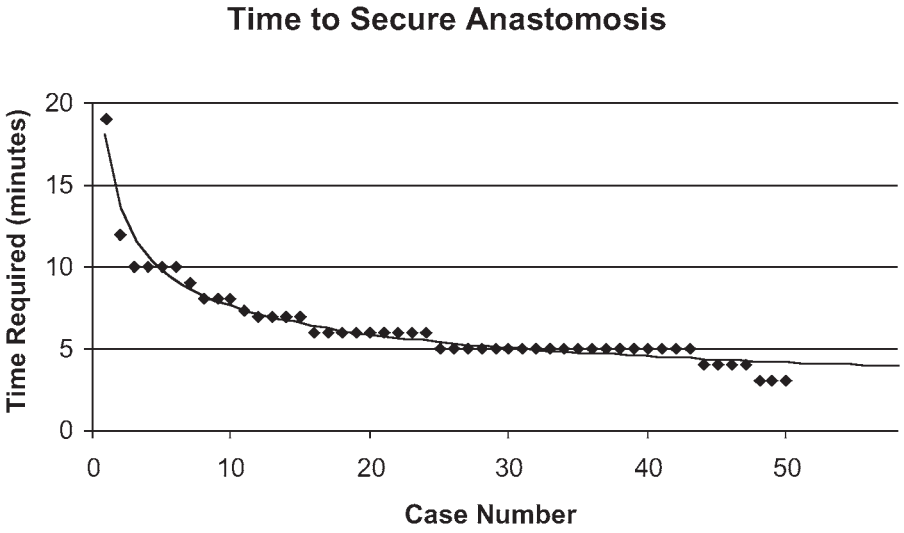

Figure 2. Mean learning curve of the surgeons for all 76 cases.

curve does decrease over time and experience with the IPAD device. The required time initially was approximately 19 minutes (overall average of first cases) and fell to 3 minutes (last case average for all surgeons), a decrease of approximately 84% in overall time to secure anastomosis.

Following the procedures, no patients developed myocardial infarctions or reported angina, suggesting patency of the vein grafts to be of high quality. Three patients (approximately 4%) continued to have congestive heart failure, which was diagnosed preoperatively, although the New York Heart Association grade was suppressed from a mean of 3.7 to 1.6.

CONCLUSION

The IPAD is easily used, safe, and effective in creating a clampless, compliant proximal anastomosis in OPCAB surgery. Implied patency suggests that the device is a useful adjunct for minimally invasive CABG. The device does have a learning curve, but the learning curve for the IPAD is closely related to that of any other anastomotic attaching device and employs the same principles used in mastering interrupted anastomoses with the U-clip.

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