BioGlue does not predispose to anastomotic pseudoaneurysm in thoracic aortic surgery

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Background

Questions have been raised concerning the safety of bovine serum albumin-glutaraldehyde (BSAG) glue (BioGlue®) used to reinforce graft anastomoses in aortic surgery. Concerns include possible transmigration of glue across suture holes, distal embolization, and false aneurysm or anastomotic disruption. We examined clinical experience with the use of BioGlue in thoracic aortic surgery, to determine if such problems were detected.

Methods

From review of our computerized database (10/15/1998-8/9/2005), we identified 97 consecutive patients (23 female and 74 male, age range 27 to 86 years) in whom BioGlue or similar product was used for reinforcement of thoracic aortic suture lines (n= 85 BioGlue, 12 GRF (French) glue). BioGlue was used selectively for acute aortic dissection and/or tissue fragility and was applied sparingly to avoid formation of a plastic-like mound. These cases included 79 ascending/arch procedures, 15 descending/thoracoabdominal procedures, and 3 encompassing both. The clinical outcome and post-operative CT scan findings were reviewed. Follow-up ranged from 1 to 90 months (mean: 15.1 months).

Results

Peri-operative survival was 93/97 (95.9%). Six patients (6.2%) required re-exploration for bleeding. There were 5 early post-operative neurological events and no late strokes or peripheral embolic events. CT scan follow-up was 84.9% complete (79 of 93 survivors) and identified 2 pseudoaneurysms, both of which were likely unrelated to BioGlue use.

Conclusion

Isolated problems associated with BioGlue have been reported. In this relatively large experience, we identified no obvious problems directly related to judicious use of BioGlue. BioGlue is a safe and effective adjunct in thoracic aortic surgery.

What is BioGlue?

- Bovine serum albumin-glutaraldehyde (BSAG) glue [BioGlue®, CryoLife, Inc., Kennesaw, GA]
- Polymer with adhesive *and* sealant properties
- Covalently binds to tissue surfaces via cross-linking agents
- Begins to polymerize within 20 to 30 seconds, reaches its bonding strength within two minutes

Patient Demographics		
Patients		97
Male		74 (76.3%)
Mean Age		63 (Range 27-86)
Aortic Lesion	Aneurysm	64 (66.0%)
	Dissection	33 (34.0%)
Location	Ascending	79 (81.4%)
	Descending	15 (15.5%)
	Both	3 (3.1%)
Emergent/Urgent Surgery		53 (54.6%)

Complications		
Perioperative Complications	Bleeding	6 (6.2%)
	Neurologic	6 (6.2%)
	Death	4 (4.1%)
Late Complications	Death	14
	Pseudoaneurysm	2
Mean Follow Up		15.1 months (range 1-90)
CT Follow Up		79 (84.9%)

Control Group without BioGlue use had similar incidence of pseudoaneurysm.

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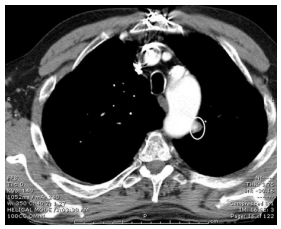
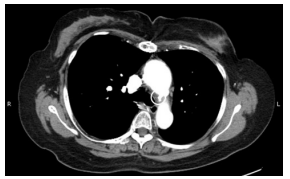
Figure 1:



CT scan of one of two patients who developed a likely pseudoaneurysm after BioGlue use. It is unlikely that BioGlue was the cause as the location was remote from the site of anastomosis and the proximal descending aorta is a common site of aneurysmal formation in late follow-up.

Figure 2:



CT scan of the second patient in whom tissue damage might have occurred secondary to BSAG glue use. The white circle identifies the ulceration in the mid-aortic arch. This patient had the same lesion at the same location prior to the original surgery, and it was expected that this might persist in late follow-up. Therefore, it is likely that this subsequent lesion was not due to BSAG glue but instead represents incomplete exclusion of the original ulcerative pathology.

References

1. Elefteriades JA: "How I do it: Utilization of high-pressure sealants in aortic reconstruction". J Cardiothorac Surg 2009 Jun 26;4:27.
2. Azadani AN, Matthews PB, Ge L et al.: Mechanical properties of surgical glues used in aortic root replacement. Ann Thorac Surg 2009 Apr;87(4):1154-1160.
3. Elefteriades JA, Griepp R: Surgical procedures: A primer. In Elefteriades JA (ed): Acute Aortic Disease. NY, Informa Healthcare, 2007, pp. 251–268.
4. LeMaire SA: Invited commentary. Ann Thorac Surg 2009 Apr;87(4):1160.
5. Bavaria JE, Brinster DR, Gorman RC, et al.: Advances in the treatment of acute type A dissection: An integrated approach. Ann Thorac Surg 2002 Nov;74(5):S1848-S1863.
6. Zehr KJ: Use of bovine albumin-glutaraldehyde glue in cardiovascular surgery. Ann Thorac Surg 2007 Sep;84(3):1048-1052.
7. Gundry SR, Black K, Izutani H: Sutureless coronary artery bypass with biologic glued anastomoses: Preliminary in vivo and in vitro results. J Thorac Cardiovasc Surg 2000 Sep;120(3):473-477.
8. LeMaire SA, Schmittling ZC, Coselli JS, et al.: BioGlue surgical adhesive impairs aortic growth and causes anastomotic strictures. Ann Thorac Surg 2002 May;73(5):1500-1506.
9. Chao HH, Torchiana DF: BioGlue: Albumin/glutaraldehyde sealant in cardiac surgery. J Card Surg 2003 Nov-Dec;18(6):500-503.
10. Kazui T, Washiyama N, Bashar AH, et al.: Role of biologic glue repair of proximal aortic dissection in the development of early and midterm redissection of the aortic root. Ann Thorac Surg 2001 Aug;72(2):509-514.
11. Coselli JS, Bavaria JE, Fehrenbacher J, et al.: Prospective randomized study of a protein-based tissue adhesive used as a hemostatic and structural adjunct in cardiac and vascular anastomotic repair procedures. J Am Coll Surg 2003 Aug;197(2):243-253.
12. LeMaire SA, Carter SA, Won T, et al.: The threat of adhesive embolization: BioGlue leaks through needle holes in aortic tissue and prosthetic grafts. Ann Thorac Surg 2005 Jul;80(1):106-111.
13. Downing SW: What are the risks of using biologic glue? Ann Thorac Surg 2003;75:1063.
14. Bernabeu E, Castella M, Barriuso C, et al.: Acute limb ischemia due to embolization of biological glue after repair of type A aortic dissection. Interact Cardiovasc Thorac Surg 2005;4:329–331.
15. Luthra S, Theodore S, Tatoulis J: Bioglue: A word of caution. Ann Thorac Surg 2008 Sep;86(3):1055-1056.
16. Goldberg SP, Campbell DN: Mechanical aortic valve dysfunction due to biological glue. Ann Thorac Surg 2009 Aug;88(2):671-672.
17. Mahmood Z, Cook DS, Luckraz H, et al.: Fatal right ventricular infarction caused by Bioglue coronary embolism. J Thorac Cardiovasc Surg 2004 Nov;128(5):770-771.
18. Lemaire SA, Ochoa LN, Conklin LD, et al.: Nerve and conduction tissue injury caused by contact with BioGlue. J Surg Res 2007;143:286–293.
19. Fürst W, Banerjee A: Release of glutaraldehyde from an albumin-glutaraldehyde tissue adhesive causes significant in vitro and in vivo toxicity. Ann Thorac Surg 2005 May;79(5):1522-1528.
20. Weissberg D: Surgical glue and necrosis of arterial wall. Ann Thorac Surg 2003 Mar;75(3):1063.
21. Ngaage DL, Edwards WD, Bell MR, et al.: A cautionary note regarding long-term sequelae of biologic glue. J Thorac Cardiovasc Surg 2005 Apr;129(4):937-938.
22. Calafiore AM, DiGiammarco G, Vitolla G: Aortic valve exposure through a combined right atrial-ascending aortic approach in redo cases. Ann Thor Surg 2002;73:318-319.
23. Erasmi AW, Sievers HH, Wolschläger C: Inflammatory response after BioGlue application. Ann Thorac Surg 2002 Mar;73(3):1025-1026.
24. Nakajima T, Kawazoe K, Izumoto H, et al.: Effective use of fibrin glue for acute aortic dissection. Ann Thorac Surg 2005 May;79(5):1793-1794.
25. Nakajima T, Kawazoe K, Kataoka T, et al.: Midterm results of aortic repair using a fabric neomedia and fibrin glue for type A acute aortic dissection. Ann Thorac Surg 2007 May;83(5):1615-1620.
26. Passage J, Jalali H, Tam RK, et al.: BioGlue Surgical Adhesive--an appraisal of its indications in cardiac surgery. Ann Thorac Surg 2002 Aug;74(2):432-437.

Modifications have been made to font size, layout and imagery from original poster in order to optimally view as a standard size handout, along with minor, non-material edits.

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