

Efficacy and safety of platform myocardial stabilizer for off-pump coronary artery bypass grafting

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Abstract

It is important to have methods and devices for stabilizing the beating heart that are capable of maintaining atraumatic interaction with the surface of the beating heart over a wider range of conditions and orientations. Therefore, the development of simple and safe surgical methods that provide a stable and bloodless coronary anastomotic field is important for the successful coronary artery bypass grafting with a beating heart. In this article, we have tried to show the safety of our stabilizer in experimental operations.

Keywords: off-pump coronary artery grafting, CABG, OPCAB, myocardial, stabilizer

1. Introduction

In the 50 years since this landmark publication, coronary artery bypass grafting (CABG) has been enthusiastically developed by cardiac surgeons around the world. Currently, most coronary artery bypass grafting (CABG) procedures are performed using cardiopulmonary bypass (CPB). The use of CPB for CABG operations allows performing anastomosis of the coronary artery in a stable bloodless surgical field with myocardial protection, providing excellent long-term results (1).

The development of the off-pump coronary artery bypass grafting technique became possible with the development of technical aspects proposed by Lima et al. In the 1990s, the technique using a series of pericardial retraction sutures allowed access to the arteries of the lateral surface of the heart (2). Later, methods for improved visualization of the lateral wall were described using a traction suture in the oblique sinus of the pericardium (3). Further improvement in the technique of beating heart surgery is associated with Grundeman and Grunenfelder (4-5), who improved the OPCAB operation by applying vacuum fixation technologies to expose and stabilize coronary vessels. They studied spatial motion and the biological effects of stabilized absorption in an experimental laboratory and proved the superior stabilization of this method.

The ability to stabilize or immobilize the surgical site can significantly improve surgical accuracy and reduce the time required to complete a specific procedure (6). Methods and device for performing CABG on a beating heart are first

described in the publications of Benetti et al. (7). In some cases, devices that provide mechanical stabilization of the myocardium by compression encounter difficulties in providing mechanical pressure on the myocardial surface. Similarly, devices that use a vacuum (vacuum stabilizers) have great difficulty in creating and maintaining effective "suction" to the moving surface of the heart (8-9). Even when the beating heart has been effectively stabilized, the target coronary artery may be covered by layers of fat or other tissue, making it very difficult for the surgeon to visualize it. Moreover, the stabilizing devices can lead to the deformation of the tissue surrounding the coronary artery, or the coronary artery itself, so that the arteriotomy remains in an unfavorable position for anastomosis.

It is important to have methods and devices for stabilizing the beating heart that are capable of maintaining atraumatic interaction with the surface of the beating heart over a wider range of conditions and orientations. Therefore, the development of simple and safe surgical methods that provide a stable and bloodless coronary anastomotic field is important for the successful CABG with a beating heart. We aimed to evaluate the efficacy and safety of newly developed myocardial stabilizer in an experimental model in dogs..

2. Material and Methods

The cardiac surgery team has developed a platform-type myocardial stabilizer. The myocardial stabilizer contains a movable handle (1) with an attachment point (2) on the retractor, a rigid fastening frame (3) connected to the handle

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with an opening framing the operating field. On one side of the frame there is a hinge joint (4) for fastening the frame (3) with the handle (1) of the stabilizer. The mounting frame (3) consists of two parts, connected to each other by means of rods (5), in each of the frame parts there are two holes (6). Nylon threads are passed through these holes for a more rigid fixation of the frame parts. On the attachment point (2) there is a valve (7) for rigid fixation of the stabilizer on the retractor (Fig. 1.).

The mounting frame is square with a side length of 4 cm. This size fits easily into the incision in the patient's chest, providing good stability and visibility during surgery. The device is completely reusable, all parts are made of medical steel (ferrite-chromium), which allows them to be subjected to repeated sterilization. The device provides the required local stabilization and, due to its simplicity and the collapsible design of the mounting frame, allows the surgeon to quickly adjust and remove the stabilizing device.

This experimental study was performed in Experimental Department of Republican Research Center of Emergency Medicine (Tashkent, Uzbekistan), under the permission of the Republican Committee of Ethics (protocol №2/1-1496) during 2021. All animals were provided with humane care in accordance with the European Communities Council Directive of 24 November 1986 (86/609/EEC), UK National Medical Research Society's Guidelines for the Care and Use of Laboratory Animals and the Canadian Council on Animal Care (Association of Universities and Colleges of Canada) (10-11). Four mongrel dogs (12 to 20 kg) were included in this pilot study. Anesthetic management was provided with ketamine (20 mg / kg). (Fig. 2).

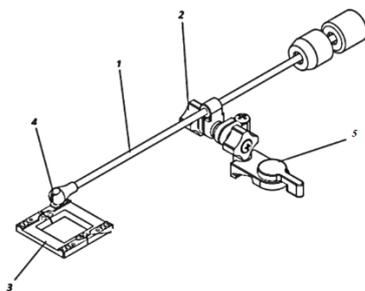


Fig. 1. Detailed view of the mechanical stabilizer: 1 - handle; 2- attachment point; 3- stabilizing frame; 4 - articulated joint; 5 - locking handle

The animals were ventilated with 100% oxygen at a rate of 0.5 l / s. Neuromuscular blockers were not used in this study. Then the animals were prepared for hemodynamic monitoring. Heart rate was measured using a continuous electrocardiographic monitor (model 90903A; SpaceLabs Inc, Redmond, Washington). Arterial oxygen saturation was measured with a sensor (Pulse-Oxymeter; Criticare Systems Inc, Redmond, WA) attached to the tongue.

Then a small anterior thoracotomy on the left side (8 cm) was performed in the fifth intercostal space, followed by complete mobilization of LIMA under direct visual control. The pericardium opposite to the LAD was fixed with silk sutures to the chest wall. At all stages of experimental interventions, hemodynamic parameters were continuously recorded. The LIMA - LAD anastomosis was performed according to the standard technique using the newly developed stabilizer using 8-0 Prolene sutures (Ethicon, Somerville, NJ). After making sure of adequate hemostasis and hemodynamic stability, the experimental intervention was completed in a standard manner, the pericardium was left open, the pleural cavity was drained with silicone drainage, followed by connection to a vacuum aspiration system.



Fig. 2. Intraoperative photos describing the experimental technique and monitoring of experimental animals

3. Results

All animals survived the procedure and maintained stable hemodynamic parameters both during and after manipulation (Table 1).

The use of the stabilizer did not adversely affect heart rate, cardiac output, or arterial oxygen saturation (Fig. 3).

As can be seen from the above graph, hemodynamic parameters and arterial blood saturation did not undergo any changes in dynamics, which allows us to conclude about the safety and effectiveness of the used myocardial stabilizer. Complications and deaths after the performed operations were not observed in experimental animals.

Table 1. Intraoperative parameters of experimental animals

Parameters	Before installing the stabilizer	After installing the stabilizer	p
Blood pressure	81.2±3.5	79.8±4.1	0.1
HR	178.9±12.8	182.6±11.2	0.1
Saturation	96.5±3.2	95.5±4.1	0.1
ST segment	N	N	0.1

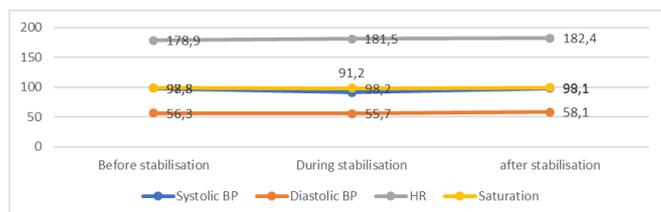


Fig. 3. Changes in key hemodynamic parameters before, during and after coronary artery bypass grafting using a myocardial stabilizer (BP - blood pressure; HR - heart rate)

4. Discussion

The myocardial stabilizer developed by our team allows performing coronary artery bypass grafting on a beating heart. No undesirable effects on any of the measured hemodynamic parameters were observed when using this stabilizer. Despite the small diameter of the coronary arteries in dogs and a high heart rate, coronary artery bypass grafting was successful and was not accompanied by complications and mortality in the experimental part of the work.

Several difficulties, however, have limited the use of the dog for such a purpose—mainly the high infection rate resulting from incision and uncontrolled tachycardia with the slightest manipulation of the heart, and even the risk of short periods of myocardial ischaemia.

Recent studies confirm that OPCAB should be considered technically more challenging than conventional CABG. To ensure optimal conditions for surgical intervention, three fundamental rules must be followed: the surgical field must be well open and accessible, stable and bloodless. During OPCAB, cardiac surgeons voluntarily violate these rules. However, to date, none of the available mechanical stabilization devices has been able to achieve a stable bloodless field comparable to the surgical field achieved with cardioplegic cardiac arrest and cardiopulmonary bypass. Moreover, a number of surgeons express doubts about the quality of coronary anastomoses in interventions on a beating heart. There is still no completely clear evidence. In 2001, Puskas et al. (12) reported an impressive 98% OPCAB patency rate at hospital discharge, while more recently Khan et al. (13) reported the results of a prospective randomized study with a graft patency rate at three months of 98% for patients operated on -pump, compared with 88% for patients operated off-pump ($P = 0.002$). The learning curve appears to play an important role in OPCAB, and many series have been published showing higher patency rates and lower incidence of unsatisfactory anastomoses as the surgeon grows in experience (14-15).

The movement of the heart occurs in three dimensions of space and can be described as a smoothly varying combination of sinusoidal waves, we found only a few publications in which the movement of the surface of the heart is quantified (16). In a pig model, Borst et al. (17) calculated the two-dimensional area (x and y axes) covered by the control point on the epicardium during free heartbeat

and after the installation of a mechanical vacuum stabilizer, showing a significant reduction in movement (from 73 ± 43 mm² to 1.3 ± 0.5 mm²) at stabilization of the heart. Koransky et al., (18) analyzed the three-dimensional movement of the coronary artery LAD in pigs using sonomicrometry techniques. Movement and speed were analyzed alternately in the x, y and z planes using triangulation theory before and after placement of the vacuum stabilizer. Stabilization led to a significant decrease in travel (11.36 ± 1.74 versus 5.99 ± 1.30 mm; $p < 0.05$), maximum Cartesian speed (141.80 ± 29.73 versus 86.55 ± 29.45 mm / s; $p < 0.05$) and the average Cartesian LAD velocity (44.30 ± 7.02 versus 21.46 ± 4.54 mm / s; $p < 0.05$).

In conclusion, it can be noted that the myocardial stabilizer developed by heart team of Republican Research Center of Emergency Medicine provides excellent stabilization of the target segments of the coronary artery and facilitates vascular anastomosis on the beating heart.

Limitations of this study are that this is an experimental study, which was conducted on a small amount of experimental animals.

Conflict of interest

Authors declared no conflict of interest.

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Authors' contributions

Concept: A.A.A., Design:A.A.A., Data Collection or Processing: O.M.A., Analysis or Interpretation: A.A.A., Literature Search: O.M.A., Writing: A.A.A.

References

1. Pfister AJ, Zaki MS, Garcia JM, Mispireta LA, Corso PJ, Qazi AG et al. Coronary artery bypass without cardiopulmonary bypass. *Ann Thorac Surg*. 1992; 54: 1085-1092
2. Lima RC, Escobar M, Wanderley Neto J, Torres LM, Elias DO, de Mendonca JT et al. Revascularização do miocárdio sem circulação extracorpórea: resultados imediatos. *Rev Bras Cir Cardiovasc* 1993;8:171-176.
3. Bergsland J, Karamanoukian HL, Soltoski PR, Salerno TA. "Single suture" for circumflex exposure in off-pump coronary artery bypass grafting. *Ann Thorac Surg* 1999;68:1428-1430. PubMed Abstract | Publisher Full Text
4. Grundeman PF, Borst C, van Herwaarden JA, Verlaan CW, Jansenet EW. Vertical displacement of the beating heart by the octopus tissue stabilizer: influence on coronary flow. *Ann Thorac Surg* 1998;65:1348-1352. PubMed Abstract | Publisher Full Text

5. Grunenfelder J, Comber M, Lachat M, et al. Validation of intracoronary shunt flow measurements for off-pump coronary artery bypass operations. *Heart Surg Forum* 2004; 7: 26–30. PubMed Abstract
6. Kowalewski M, Pawlitzak W, Malvindi PG, Boksanski MP, Perlinski D, Raffa GM et al. Off-pump coronary artery bypass grafting improves short-term outcomes in high-risk patients compared with on-pump coronary artery bypass grafting: Meta-analysis. *J Thorac Cardiovasc Surg.* 2016;151(1):60–77. doi:10.1016/j.jtcvs.2015.08.042. (PubMed) (CrossRef) (Google Scholar)
7. Benetti FJ, Naselli G, Wood M, Geffner L. Direct myocardial revascularization without extracorporeal circulation. *Chest.* 1991; 100: 312-315
8. Detter C, Deuse T, Christ F, Boehm DH, Reichensperner H, Reichart B. Comparison of two stabilizer concepts for off-pump coronary artery bypass grafting. *Ann Thorac Surg.* 2002 Aug;74(2):497-501. doi: 10.1016/s0003-4975(02)03734-7. PMID: 12173835.
9. Ammannaya GKK, Basantwani S, Mishra P, Khandekar JV. Effect of octopus tissue stabilizer on cardiac output during off-pump coronary artery bypass graft surgery. *Kardiochir Torakochirurgia Pol.* 2019;16(2):69-73. doi:10.5114/kitp.2019.86358
10. Poole TB. *The UFAW Handbook on the care and management of laboratory animals.* London: Longman Scientific & Technical; 1999.
11. *Guide to the care and use of experimental animals* Canadian Council on Animal Care; Association of Universities and Colleges of Canada. Ottawa, Ont. : The Council, c1980-198 .NLM ID: 8705895 (Book)
12. Puskas JD, Thourani VH, Marshall JJ, Staples JR, Glas KE, Marshall JJ, et al. Clinical outcomes, angiographic patency, and resource utilization in 200 consecutive off-pump coronary bypass patients. *Ann Thorac Surg.* 2001 May;71(5):1477-83; discussion 1483-4. doi: 10.1016/s0003-4975(01)02473-0. PMID: 11383786.
13. Khan NE, De Souza A, Mister R, Flather M, Clague J, Davies S et al. A randomized comparison of off-pump and on-pump multivessel coronary-artery bypass surgery. *N Engl J Med.* 2004 Jan 1;350(1):21-8. doi: 10.1056/NEJMoa031282. PMID: 14702424.
14. Jegaden O, Mikaeloff P. Off-pump coronary artery bypass surgery. The beginning of the end? *Eur J Cardiothorac Surg.* 2001 Mar;19(3):237-8. doi: 10.1016/s1010-7940(01)00591-7. PMID: 11251258.
15. Carthey J, de Leval MR, Reason JT. The human factor in cardiac surgery: errors and near misses in a high technology medical domain. *Ann Thorac Surg.* 2001 Jul;72(1):300-5. doi: 10.1016/s0003-4975(00)02592-3. PMID: 11465216.
16. Lemma M, Mangini A, Redaelli A, Acocella F.. Do cardiac stabilizers really stabilize? Experimental quantitative analysis of mechanical stabilization. *Interact Cardiovasc Thorac Surg.* 2005 Jun;4(3):222-6. doi: 10.1510/icvts.2004.098517. Epub 2005 Mar 29. PMID: 17670397.
17. Borst C, Jansen EW, Tulleken CA, Grundeman HJ, Mansvelt Beck HJ, van Dongen JW et al. Coronary artery bypass grafting without cardiopulmonary bypass and without interruption of native coronary flow using a novel anastomosis site restraining device ("Octopus"). *J Am Coll Cardiol.* 1996 May;27(6):1356-64. doi: 10.1016/0735-1097(96)00039-3. PMID: 8626944.
18. Koransky ML, Tavana ML, Yamaguchi A, Kown MH, Miniati DN, Nowlin W et al. Quantification of mechanical stabilization for the performance of off-pump coronary artery surgery. *Heart Surg Forum.* 2003;6(4):224-31. PMID: 12928205.