Medtronic

Pump-assisted beating heart CABG

Technique guide

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Dr. John Luber has been practicing cardiac surgery for 40 years and resides in the Tacoma, Washington area.

He has acquired vast experience during his academic career as Principal Investigator in over 35 FDA Phase I-III Clinical Trials, author or co-author of over 50 peer-reviewed publications, and Thoracic Residency Directorships. He has performed over 1,800 pump-supported coronary bypass procedures and continues to perform, perfect, and evolve the concepts of myocardial revascularization without cardioplegic cardiac arrest.

The techniques, views, and opinions in this guide are those of Dr. Luber unless otherwise noted.

John Luber, M.D.

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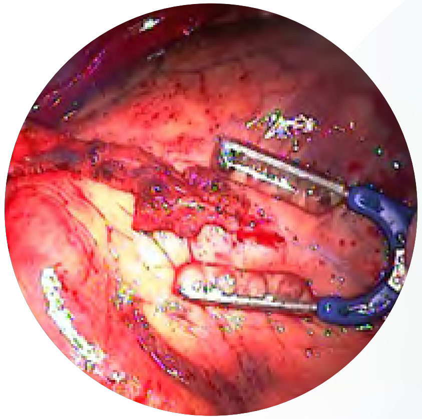
1.1 Concept
To conduct coronary artery bypass grafting (CABG) using CPB supporting the normothermic beating heart with the aid of cardiac tissue stabilizers and heart positioners to facilitate the distal anastomoses. The core concept is avoidance of hypothermic cardiac arrest, allowing the heart to be revascularized sequentially while in the beating, non-working state.

1.2 Procedural
The specific variations from off-pump beating heart surgery will be discussed and compared to both arrested heart and pump-assisted CABG. These have been optimized after over 500 off-pump cases which then led to the establishment and evolution of the pump-assisted concepts.

Variances in the application of these concepts will exist between surgeons. Each practitioner should seek to cultivate techniques that blend best with their individual technical strengths and level of skill. The core concept should be to optimize the outcomes in our increasing older population with an escalating incidence of comorbidities. Each surgeon must configure a program which is sensitive to the available resources including all OR personnel, nurses, technologists, and anesthesiology expertise.

The program should take an incremental approach to implementation and rely on continuous data collection, entry, analysis, and retrieval along with frequent scheduled staff educational events.



Stabilizer with completed LIMA-LAD graft.

1.0 Pump-assisted CABG fundamentals

1.3 Anesthesia

One cannot overemphasize the importance of a dedicated group of cardiac anesthesiologists in cardiac surgery. However, the burden placed upon the anesthesiologist with the pump-assist techniques is substantially less than that with off-pump beating heart, making it more easily adopted in a broad spectrum of institutions with varying levels of support.

The fundamentals are simple. Normothermia is a fundamental of this technique; therefore, the operating room is kept at 68–70 degrees F. Maintenance of normothermia is easily achieved throughout the procedure and ACTs are measured, as usual, every 30 minutes, with a target of > 480 seconds. We have stopped using pulmonary artery catheters, even in patients with EF < 15. If a cardiac output is needed in the ICU, a non-invasive cardiac output monitoring system may be utilized.

Information from intra-operative transesophageal echo has proven useful to evaluate both peri-op ventricular and valve function, as well as volume status. Recognizing pre- and post-graft wall motion abnormality is helpful to assure appropriate revascularization.

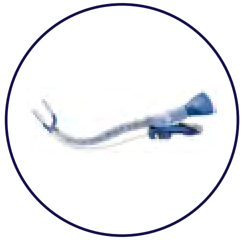
Anesthesia involvement is intimate, akin more to off-pump than arrested heart CABG. Proactive intervention to maintain perfusion pressure, heart rate, and volume status is a key component to success. Use of low-dose narcotics and maintenance of the anesthetic state with gaseous agents are key to early extubation after return to the ICU and rapid mobilization with movement toward early discharge, even in the patient with severe preoperative ventricular impairment.

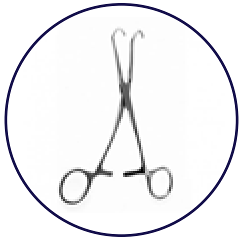
Important fundamentals
Operating room 68–70 degrees Fahrenheit
Patient normothermic 98.6 degrees Fahrenheit
ACT every 30 minutes, target > 480 seconds
Use of TEE
Early extubation-in ICU
Rapid mobilization
Use of temporary pacing wires (TPW)

1.0 Pump-assisted CABG fundamentals

1.4 Nursing
Few differences exist for the OR nursing staff in case preparation. As the patient is kept normothermic, no ice or ice-slush needs to be available. The use of cardiac stabilizers, heart positioners, and misted CO_2 blowers may be new to teams, as well the use of warm fluids throughout the procedure. The surgical instrument setup is virtually identical to that of arrested heart procedures. Alternative instruments for performing proximal anastomoses need to be on the field or ready to open. Although partial occluding, side biting clamps, such as Cooley-Derra partial occlusion clamps, are available and routinely used, the team needs to be familiar with non-clamp alternatives such as a proximal anastomoses device that facilitates the construction of the anastomosis with the aid of a novel arteriotomy occlusion device within the aorta.

Post-operatively, nursing care mimics that of the post-op arrested heart patient. The staff will soon become comfortable with minimal monitoring and lower drug requirements in these patients. The lower drug requirements and the virtual absence of any need for mechanical support, such as the intra-aortic balloon pump (IABP), will be a welcome change. Once comfortable with these patients, the staff will even find that minimal monitoring can and should be adopted for the majority of the patients who undergo surgery with hypothermic cardioplegic arrest.


Octopus™ Evolution AS


Cooley-Derra clamp


Urchin™ Evo Heart Positioner


DeBakey atraumatic vascular clamp

It should be noted that alternative side biting or partial occlusion clamps, such as Cooley-Derra partial occlusion clamps, are often used for the creation of proximal anastomoses when there is limited ascending aorta. These clamps offer a smaller "footprint" upon the aorta compared to other conventional partial occlusion clamps and can be positioned to potentially avoid many ascending plaques or areas of calcification.

Cardiac tissue stabilizers, heart positioners, misted blowers, and the strict use of warm fluids may be new to some cardiac teams.

1.0 Pump-assisted CABG fundamentals

1.5 Perfusion

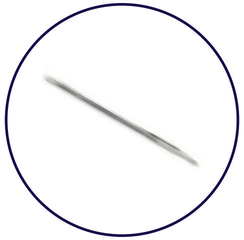
There are some common practices that facilitate this procedure and may be applied to all patients undergoing cardiopulmonary bypass. Minimizing tubing volume by decreasing the tubing length, use of 3/8ths tubing in patients with body surface area (BSA) < 1.6 m2, low-profile MC2™ Two Stage Venous Cannulae (Medtronic) and EOPA™ (Elongated One-Piece Arterial Cannula, Medtronic) are useful in both blood conservation as well as minimizing factor and blood element consumption contributing to successful blood management. The cardio pulmonary bypass (CPB) circuit is also coated with a bioactive coating, Balance™ Biosurface, in an effort to reduce inflammation and preserve platelet function. In addition, we routinely utilize retrograde autologous prime (RAP) techniques prior to the institution of cardiopulmonary bypass.

A 40 cc prime centrifugal pump (Affinity™ CP centrifugal blood pump with Balance Biosurface, Medtronic) is used along with a hard-shell cardiotomy reservoir to complete the CPB circuit. There is no cardioplegia setup required, and the use of cell salvage prevents virtually all shed blood from returning to the CPB circuit.

There are times when, with a massively enlarged heart, lifting the heart to expose the lateral wall obstructs right-sided venous return. In these cases, the heart becomes distended, ischemic, and occasionally asystolic, making the performance of an elegant anastomosis impossible. In these cases, a weighted sump vent is placed through a horizontal mattress plegetted stitch in the main pulmonary artery (PA). This effectively and safely decompresses the heart. Once the lateral wall has been revascularized, the vent is removed.

Affinity CP centrifugal blood pump

EOPA cannula



MC2 two stage venous cannulae

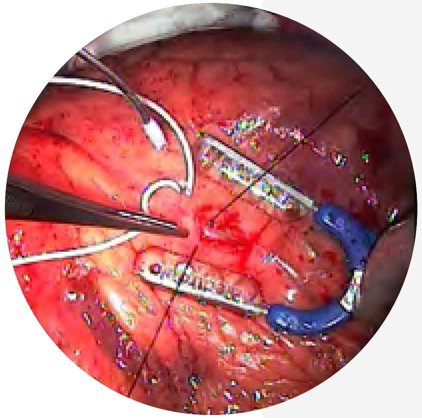
1.0 Pump-assisted CABG fundamentals

1.6 Surgery

Once sternotomy and harvesting of the IMA and other arterial or venous conduits are complete, cannulation proceeds. Venous cannulation, using the low-profile venous cannula directly into the right atrium (RA) and inferior vena cava (IVC), is then followed with the EOPA cannula arterial cannulation into the aortic arch. The need for the PA vent is deferred until the heart is lifted to expose the lateral wall while on CPB.

Positioning the beating heart to access distal targets is done using an Urchin heart positioner (Medtronic) and then stabilization of the selected vessel with the Octopus Evo AS tissue stabilizer (Medtronic). Both devices require independent vacuum sources and attachment to the OctoBase™ sternal retractor (Medtronic). Antegrade arterial inflow is occluded with an air-cushioned silastic loop, placed around the coronary artery to construct a temporary tourniquet. If there is substantial retrograde flow, a second air-cushioned silastic loop is applied to the vessel distal to the selected anastomotic site. It should be noted that the arteriotomy is always performed prior to occlusion with the tape in order to minimize the opportunity to injure the back wall with the knife blade. These are removed prior to tying the distal suture line.

Grafting strategy has been created to reduce the number of proximal anastomoses, minimizing aortic manipulation and the potential for embolic phenomena. If the operation consists of left internal mammary artery (LIMA) and saphenous vein as conduits, the LIMA-LAD is performed last to reduce risk of graft avulsion during cardiac positioning. Should there be multiple arterial conduits, the sequence is adjusted to minimize the distraction of previously performed distal anastomoses, arterial or venous.



LAD stabilized with epicardial retraction and temporary tourniquet proximal to the planned arteriotomy.

Effort has been made to keep the CABG procedure simple, without the need to develop many new skills or dependency upon the anesthesiologist, as is intimately required with off-pump CABG.

1.0 Pump-assisted CABG fundamentals

1.6 Surgery (cont'd.)
Benefits of grafting to a beating heart in this experience are:

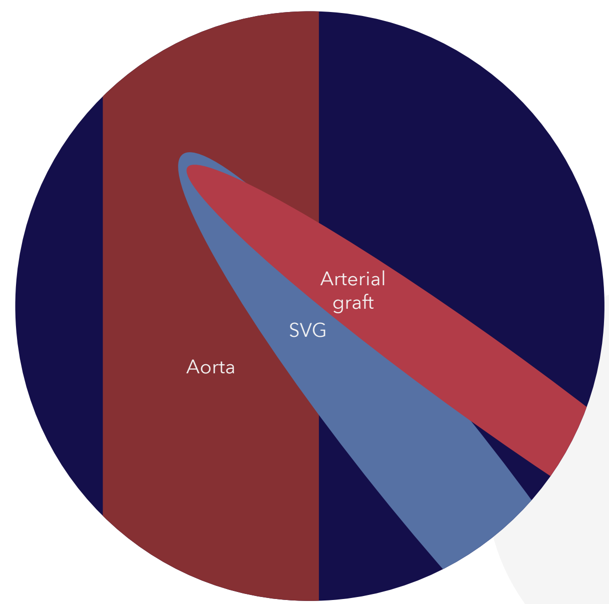
- Easier graft length measuring with a full beating heart
- Enhanced visualization of coronary artery graft landing zones/anastomosis target site
- Improved visualization of small coronary targets

Minimizing proximal anastomoses requires the use of more sequential grafting and the use of the saphenous vein proximal hood as a landing zone for free arterial grafts, in both internal mammary and radial arteries.

The greatest challenge here is becoming comfortable, efficient, and effective with the creation of sequential anastomoses, as well as the challenge of operating on a moving target. The targets, however, are better visualized as they have blood flowing through them.

Techniques to learn include:

- Use of cardiac stabilizers
- Use of heart positioners
- Mastering the creation of sequential grafts and sewing upon the beating heart



2.0 Pump-assisted CABG vs. off-pump CABG: Author's experience

Observations and comparisons to arrested heart CABG and off-pump CABG have uniformly increased our confidence in the switch to PA BH CABG. Operating on a beating heart, which can be "emptied" or "filled" as needed without increasing to any extent myocardial oxygen consumption or ischemia during the procedure, offers these grafting benefits:

- Evaluate "full metal jacket" and "touchdown" options more accurately
- Visualize small coronary targets
- Assess current blood flow in relation to lesion dynamics
- Measure conduit length(s)
- Graft all three regions of the coronary circulation, safely and effectively
- Improved ability to bypass difficult vessels
  - Less issues with "toe" and "heel" stenosis
  - Identify difficult-to-find vessels more easily

Additionally, separation from CPB in patients with significant left ventricular dysfunction is routinely accomplished with:

- Less pharmaceutical intervention
- Virtually no need for mechanical support, including balloon pump counter-pulsation
- Decreased operative times

2.0 Pump-assisted CABG vs. off-pump CABG: Author's experience

Off-pump CABG procedures were first used decades ago. Substantial data has now been accumulated and the outcomes have been controversial.

The challenges of off-pump CABG led to the continued search for alternatives that allow the average surgeon to successfully navigate the minefield of severe ventricular dysfunction and alternatives that diminish dependency on anesthesia during coronary artery bypass grafting.

Our extensive experience with off-pump CABG has facilitated personal comparisons to PA BH CABG. Among the benefits of the pump-assist are:

Less	Increased
Dependence upon "advanced" anesthesia techniques	Number of graft completion
Blood product use	Confidence of complex graft patency
No urgent conversions to CPB in mid-case	

Decreased

- OR time
- Return to OR
- ICU length of stay (LOS)
- Hospital LOS
- Mortality

Decreased direct material costs

- No cardioplegia solution
- No cardioplegia administration set
- No ice making set
- No IABP
- No pulmonary artery catheter

3.0 Peer-to-peer published data supporting pump-assisted beating heart CABG

There are growing bodies of clinical literature, including retrospective and prospective studies, regarding pump-assisted beating heart CABG. A published review similar to the author's observations includes a literature review corroborating the above observations and comparisons. Outcomes of PA BH CABG compared to traditional CABG and off-pump CABG:[1,2]

Summary of meta-analysis[1]

- Less myocardial damage
- Superior in patients with
  - LV dysfunction
  - Acute MI
  - Hemodynamically unstable
- Less neurological complication
- Greater number of grafts per patient compared to OPCAB
- Superior in hemodialysis patients
- Superior to conventional CABG when need to convert to OPCAB to CPB

Single-center comparisons[2]

OP-CAB conversion to CPB			
Variables	**Cardioplegic arrest group (n = 55)**	**On-pump beating heart group (n = 49)**	**P value**
Number of anastomoses/patient	3.33 (0.82)	3.18 (0.63)	.317
CPB time (min)	129.25 (39.24)	104.96 (35.64)	.001
Reason for conversion			
Hemodynamic instability	47 (85.5%)	44 (89.8%)	.504
Cardiac arrest	5 (9.1%)	3 (6.1%)	.571
Hemorrhage	2 (3.6%)	1 (2.0%)	.627
Graft occlusion	1 (1.8%)	1 (2.0%)	.491
Maximum cYnl (ng/mL)	11.97 ± 18.13	4.9 ± 9.76	.017
Blood requirements (%)	19 (34.5%)	12 (24.6%)	.264
New IABP (%)	19 (34.5%)	8 (16.3%)	.034
Post-operative MI (%)	10 (18.2%)	6 (12.2%)	.402
New-onset AF (%)	12 (21.8%)	11 (22.4%)	.938
Pulmonary complications (%)	17 (30.9%)	7 (14.3%)	.045
Hemodialysis (%)	8 (14.5%)	3 (6.1%)	.163
Stroke (%)	2 (3.6%)	1 (2.0%)	.627
Infective complications	9 (16.4%)	4 (8.2%)	.207
Duration of inotropic support (d)	5.07 (2.81)	3.49 (1.99)	.001
Reoperation for bleeding (%)	4 (7.3%)	1 (2.0%)	.213
Time to extubation (h)	95.9 (67.4)	50.0 (45.5)	.000
Post-operative hospital stay (d)	15.6 (5.5)	11.8 (4.5)	.000
In-hospital mortality (%)	14 (25.6%)	3 (6.1%)	.008

4.0 Author's summary

As the population of coronary artery disease patients increases in complexity and risk, therapies need to be developed that will offer uniformly excellent outcomes, which are reproducible and effective in the hands of most CV surgeons, not simply CABG "specialists." PA BH CABG is such a therapy, providing improved clinical outcomes for the impaired LV and less burden on hospital resources. The effective adoption of these techniques can bring to each cardiac surgery program the ability to offer effective care to patients previously felt to be beyond the spectrum of risk that could be reasonable and consistently dealt with successfully.

PA BH CABG is a therapy that can be readily adopted and requires few new skills and changes to current CV practice. The ease of separation from CPB, less dependency upon advanced anesthesia management, and reduced hospital resource utilization, along with improved outcomes, will sustain the advancement of this therapy.

References

[1] Samuels L, Samuels M. Pump-Assisted Beating-Heart Coronary Artery Bypass Grafting: The Pursuit of Perfection. *J Clin Exp Cardiolog*. 2017;8(9).

[2] Yu L, Gu T, Shi E, et al. On-pump with beating heart or cardioplegic arrest for emergency conversion to cardiopulmonary bypass during off-pump coronary artery bypass. *Ann Saudi Med*. July-August 2014;34(4):314-319.

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Important safety information

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. For a listing of indications, contraindications, precautions, and warnings, please refer to the Instructions for Use.

Risks

- Key risks of Octopus™ tissue stabilizers include: hematoma, laceration, ischemia, EKG/ECG changes, abrasion.
- Key risks of Urchin™ heart positioners include: hematoma, laceration, ischemia.
- Key risks of the OctoBase™ sternal retractor include: laceration, infection.
- Risks associated with extracorporeal support during CPB may include, but are not limited to: blood loss, embolism, coagulopathy, activation (coagulation/complement), circulatory compromise, infection, ischemia, organ dysfunction, hemolysis, or hypovolemia.
- Patients undergoing an off pump coronary artery bypass grafting procedure are at risk of the following, not inclusive: stroke, myocardial infarction, renal failure, infection, need for transfusion, death.