Integrated myocardial revascularization

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Abstract

The integration of minimally invasive coronary artery bypass grafting with catheter-based interventions is being practiced with increasing frequency both in the standard and high risk patient populations. The procedures can be staged on different days or done concurrently in either an operative cathlab or an operating room with imaging capabilities. The new clinical issues raised with these new approaches are reviewed for practitioners considering adopting this new treatment strategy. © 1999 Elsevier Science B.V. All rights reserved.

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1. New issues with a new approach

The treatment of ischemic coronary artery disease has undergone a significant evolution over the past decade. Therapy has traditionally been stratified depending upon the extent of the coronary lesions identified. Catheter-based interventions (CBI) have been employed for limited one or two vessel coronary disease and surgical coronary artery bypass grafting (CABG) for more extensive disease. Limited but unfavorable anatomic lesions are now addressed with minimally invasive direct coronary artery bypass (MIDCAB) grafting [1–3]. Patients with severe diabetes have also been shown to benefit from earlier surgical revascularization[4,5].

Lately those therapeutic boundaries have become blurred as CBI has been combined with focal MIDCAB grafting in a planned treatment strategy during the same hospital admission [6–8]. This achieves complete multi-vessel revascularization without the patient undergoing conventional CABG including exposure to the cardiopulmonary bypass circuit and a full sternal incision. However the advent of this new avenue of therapy further complicates the decision making process with respect to how individual patients are selected for a particular revascularization strategy. The overlap in therapies is also placing more pressure on interventional and surgical practitioners to consider re-organizing into single business units to better coordinate the decisions, the therapies, and the tracking of the data for these combined approaches.

Physicians and their patients can now consider several different approaches for the treatment of multi-vessel coronary artery disease. Conventional CABG remains an excellent option in some settings and multi-vessel CBI is being done with increasing frequency and success [9,10]. Minimally invasive multi-vessel coronary artery bypass grafting can be done with percutaneous transfemoral perfusion techniques that allow for exposure of multiple coronary grafting sites through a small directed incision. In high-risk cases incomplete revascularization is sometimes accepted as the best and safest approach for a particular patient. Now the option of combining surgical and catheter-based therapies offers additional possibilities that need to be considered when selecting the best revascularization strategy.

The terms and definitions for this new array of techniques can sometimes be duplicative and confusing. MIDCAB is most often defined as focal one or two vessel coronary artery bypass grafting using a pedicled arterial conduit through a small directed incision without the support of cardiopulmonary bypass. Off pump coronary artery bypass (OPCAB) describes a transsternal approach for multi-vessel grafting also without cardiopulmonary bypass. When an OPCAB approach is selected there is usually no need to also consider the addition of a CBI. The combination of MIDCAB grafting with a CBI of one or more vessels has often been referred to as hybrid revascularization. However there has been a number of other terms used to essentially describe the same approach. These include integrated, complementary, combined, and adjunctive coronary revascularization. For the purposes of this manuscript I have elected to use the term ‘integrated’ to describe this revascu-
larization strategy. If the CBI was unplanned and done for persistent or recurrent symptoms or for a failed MIDCAB graft, this is additional unplanned therapy and does not come under the definition of a planned integrated approach. In the future integrated coronary revascularization may truly become integrated myocardial revascularization as it comes to also include additional therapies such as direct myocardial revascularization comprising both transmyocardial laser revascularization (TMLR) and the injection of various angiogenic substances to enhance perfusion in regions without treatable native coronary arteries [11,12].

Integrated coronary revascularization addresses the primary coronary target such as the LAD with MIDCAB grafting using a pedicled arterial conduit. Grafting the primary target is felt to be associated with both relief of symptoms as well as enhanced patient survival. Additional targets thought to be a possible source of symptoms but not directly related to patient survival are then treated with a CBI. Initially this was a strategy for patients requiring multi-vessel grafting who were felt to be too high a risk for a conventional CABG. In short, they were felt to not have other realistic options for complete revascularization. As experience with integrated therapy has increased, patients who do have other reasonable options for multi-vessel grafting are now requesting and are being considered for an integrated approach. The indications for integrated therapy will continue to expand as collaboration between interventionalists and surgeons increases on both the clinical and organizational levels.

There are a number of advantages in being able to offer multi-vessel revascularization using an integrated approach. Firstly the surgical grafting involves MIDCAB grafting and not conventional CABG [13,14]. Following the MIDCAB with a CBI allows for angiographic checking of the new arterial graft in situ to confirm that the conduit, anastomosis, and distal native coronary are all properly configured and working well. In patients where the site being treated with a catheter is in a dominant coronary distribution, prior surgical grafting enhances overall myocardial perfusion before the temporary occlusion is done during the CBI. Not inconsequential is the fact that the interventionalist remains actively involved in his or her own patient’s care.

There are also disadvantages to the integrated approach. If the CBI is done prior to the MIDCAB, there are limitations as to how much anti-coagulation and anti-platelet therapy is advisable prior to surgery [15]. If the CBI is done after the MIDCAB as is usually the case, then there is the possibility that the interventionalist will not be able to accomplish the desired CBI or achieve an optimal result. There is also the subsequent possibility that the CBI site will
re-stenose at a later date and the remote possibility that at that time a further CBI will not be successful. Finally, the incremental cost of going to the cathlab after a MIDCAB in the operating room brings the overall cost and hospital charges for the multi-vessel revascularization close to that of conventional CABG. A subsequent re-stenosis would presumably push the overall resource expenditure for multi-vessel revascularization beyond that required for a conventional CABG.

The majority of integrated therapy being done today involves MIDCAB grafting followed by a CBI allowing the surgical graft to be checked angiographically and affording the interventionalist maximal freedom with respect to anti-platelet therapy [16]. The timing for these two procedures can vary considerably depending upon the clinical circumstances. Usually the CBI is done the day after the MIDCAB in a closely staged fashion. If renal function is severely impaired or there are other significant co-morbidities which need to be stabilized after surgery, then the CBI may be remotely staged later during that hospital admission or even a set number of days after hospital discharge. However the new approach receiving the most attention at this time is concurrent integrated therapy where the MIDCAB and CBI are done the same day in the same location under the same anesthetic.

Concurrent integrated therapy is just beginning to emerge as an alternative to the more established staged approach. Most of the advantages and disadvantages of integrated therapy stated above apply to concurrent therapy as well. However it is felt that there is the additional possibility of significantly reducing the cost of integrated therapy using a concurrent approach since the patient does not enter two distinct procedural settings to accomplish the multi-vessel revascularization [17]. In addition the ‘same day’ format should presumably slightly reduce overall length of stay in this patient group as well. However these theoretical benefits will ultimately need to be convincingly demonstrated by comparative series of staged and concurrent patients where these parameters are specifically tracked within single institutions. In this quest for efficiency and cost reduction, potential new clinical issues will also have to be monitored to confirm there are no new patient management problems that might outweigh the system benefits. One of the greatest concerns is the fact that surgery, in this case MIDCAB grafting, can be associated with bleeding and yet a concurrent CBI requires concurrent anti-platelet therapy. There needs to be careful planning of anti-coagulation and anti-platelet protocols so as to appropriately balance these competing agendas.

The best physical setting for concurrent integrated therapy has not yet been established. The two possibilities are a purpose-made operative cathlab or a cardiac operating room with a carbon fiber operating table and the latest generation digital C arm imaging system (OEC Medical Systems Inc., Salt Lake City, UT). Each environment has new issues for the clinician which are currently being defined as concurrent...
integrated experience develops. Introducing a new table and C arm into the operating room is relatively simple from a physical standpoint (Fig. 1). However, the additional logistics include coordinating the interventionalist to arrive at the precise time the MIDCAB is finished and working out the best route of vascular access for the subsequent CBI. In general, when only a perioperative catheterization is being done to check a MIDCAB graft, the radial artery is used for access to image the new internal mammary artery graft. However, when a concurrent integrated CBI is planned, usually the femoral artery is accessed at the beginning of the operation prior to draping the patient along with placement of the other monitoring lines for cardiac surgery. The goal is to minimize the additional total operating room time used to accomplish the CBI. The most important issue with respect to the operating room venue is whether the interventionalist ultimately feels the operating room affords adequate image quality and procedural control to equal the results achieved in a fixed cathlab environment.

Concurrent integrated revascularization can also be done in purpose-made or converted operative cathlabs. This is a familiar environment for the interventionalist but a foreign environment for the surgeon and the operating room team. The room must be of sufficient size to accommodate both MIDCAB surgery and the cardiopulmonary bypass machine should an unexpected conversion to conventional CABG be required (Fig. 2). The X-ray gantry should be able to swing at least 45° away from the head of the bed to allow full anesthesia access during the MIDCAB portion of the procedure. The cathlab ventilation system often has to be upgraded to operating room specifications and there needs to be adequate wall receptacles for power, gases, and suction to support both the anesthesia and the perfusion team. If the operative cathlab is not near the main operating rooms, then surgical grade scrub sinks and autoclaves will also need to be installed. The most important feature of the operative cathlab is the carbon fiber table. This is usually fixed to the floor as in standard cathlabs and is capable of standard four way float motion for the interventionalist. However, in addition the table ideally will also articulate through the range of motions desired by the surgeon (Fig. 3). This includes powered up and down motion, Trendelenberg, and side to side 15° tilting. These tables are just now becoming available to meet the specific requirements of these new operative cathlabs (Stille Beta Inc., Akron, OH).

Performing concurrent integrated therapy raises a number of new logistical points as well. The case is booked both with the cathlab and operating room to alert anesthesia, operating room nursing, and perfusion about the cathlab procedure. Monitoring line placement is usually done in the standard pre-anesthesia holding area and the patient then moved to the cathlab and induced once in final position on the table. The two nursing teams need to be coordinated during their respective portions of the procedure and the
patient is kept asleep and monitored by anesthesia after the MIDCAB during the CBI. The patients remain intubated during transfer at the end of the integrated procedure until they have safely arrived and are settled into the surgical postoperative intensive care environment.

New clinical management issues arise when you perform MIDCAB grafting and a CBI concurrently. Immediately after the integrated procedure there are two distinct clinical services interested in managing their respective aspects of the patient’s recovery. When problems arise there needs to be a clear delineation as to what issues relate to which service and when each service is to be notified. The best example of this is postoperative bleeding in the intensive care unit where the surgical service wants to promote coagulation and the interventional service is still interested in some level of anti-coagulation. Thresholds of when to transfuse, what to transfuse, and when to return to the operating room for bleeding all need to be thought through ahead of time. Even smaller issues such as a postoperative cardiac enzyme rise or EKG change can be confusing since it is not initially clear whether this might be due to the interventional site or the surgical grafting. If there is associated hemodynamic compromise there needs to be a low threshold for returning to the cathlab for a re-evaluation of all the treated coronary sites.

Administrators also must consider a number of new and unique issues when helping to set up a concurrent integrated treatment program. Since two previously established but separate treatment modalities are now being done concurrently, are the risks of the new clinical issues such that Institutional Review Board approval should be obtained? With the two very different procedures being done in the same room, what is the actual ‘room rate’ which should be charged for these interventions? With the two procedures being done on the same day, how should the clinicians bill these combined procedures which may be seen as a single treatment episode by certain payers? And finally, should it be anticipated that ultimately further interventions such as TMLR or injections to promote angiogenesis will also become part of this concurrent integrated treatment strategy?

As with all new clinical initiatives, the important questions will only be definitively answered with accurate and specific clinical data. As clinicians move forward with concurrent integrated therapy, there are some particular data points that are going to be very important in evaluating whether this approach truly affords the advantages it is purported to bring. Actual combined procedural times and post procedural hospital stays will clearly be the factors that most significantly define potential patient benefit and reductions in treatment cost. Careful comparisons of cost and charge data need to be done between the concurrent and staged integrated approaches, particularly compared to the patients where the staged CBI is done efficiently the following day. Post procedure bleeding, transfusions, and returns to the operating room or cathlab need to be closely monitored to confirm that there are no significant clinical variances from the standards of care. Long-term, the relief, persistence, or recurrence of symptoms and subsequent need for re-intervention or reoperation should be followed a minimum of 12 months after treatment.

The advancements in therapy for ischemic coronary artery disease have blurred the boundaries between clinicians and their respective disciplines. In the process we are reminded that the ultimate goal is myocardial revascularization with a lasting relief of symptoms and not the successful application of any specific therapy. Recent innovations are accomplishing this with less trauma and discomfort for the patient. As we further integrate these clinical interventions, the hope is that we also achieve significant reductions in the overall healthcare expenditure required for the management of coronary artery disease.

References


