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CASE STUDY:

A New Era With Hybrid Operating Systems

Reducing invasiveness by employing therapeutic approaches combining catheterization and surgery

EDUCATIONAL SESSION REVIEW

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INTRODUCTION

While clinical outcomes in patients undergoing cardiovascular surgery have improved significantly in recent years through the use of new instruments, auxiliary measures and advanced technologies, cardiovascular surgery is still far more invasive than catheter based procedures. In January 2009, Mitsui Memorial Hospital in Tokyo was the first hospital in Japan to install the Hybrid operating suite from Toshiba Medical Systems Corporation.
This system consists of a ceiling mounted X-ray angiography system and a carbon fiber operating table that can also be used during X-ray fluorography. Following the introduction of the System, we have attempted to reduce surgical invasiveness by employing hybrid therapy techniques combining surgery and catheterization.

KEYS TO SUCCESSFUL HYBRID TREATMENTS

A hybrid system needs to have easy and convenient operability, and high definition imaging capabilities. Both surgeons and catheter physicians should be involved in the room design phase of Hybrid rooms. Large field of view flat panel detectors can broaden the range of procedures which can be performed in the hybrid lab. Close collaboration, clear decision making processes, and joint educational sessions involving appropriate divisions in the hospital involved in the hybrid procedures, can assist the successful implementation of hybrid procedures within a hospital.

What is a hybrid operating system?

The word “hybrid” originally referred to the result of interbreeding between two animals or plants of different species, but it has more recently been used to mean the combination of two different methods to achieve higher performance, as represented by hybrid cars. The hybrid operating room discussed in this paper can be described simply as the combination of an angiographic imaging system and an operating table installed in an operating theatre room, or alternatively, as the use of an operating table instead of a catheterization table in an angiography room (**Fig.1**).

System Functionality

Conventionally, when fluorography is required in an operating room, a mobile C-arm was previously used. Having the C-arm installed in the hybrid operating room has a number of advantages over mobile C-arm usage such as;
(1) high X-ray output (which provides clearer Fluorographic images)
(2) greater X-ray tube heat capacity (which helps to avoid overheating)
(3) a large field of view and high image quality due to the use of a flat panel detector (FPD)
(4) tableside operation of the C-arm.
On the other hand, one disadvantage is the need to employ the system for multiple applications in order to achieve a high enough utilization rate to cover the additional cost.
The large field of view FPD has an effective field size of 30cm x 40cm (12 × 16 inches) and a four-step image magnification function, making it possible to obtain images of sufficient size for detailed procedures. The FPD has additional benefits related to long-term stability and no image distortion.
The C-arm can be rotated and moved in the longitudinal direction and also in the lateral direction, which we see as a key advantage of the Toshiba systems in our hybrid room where lateral parking allows better flow of people and equipment, in a room with limited space.
The angular positions of the FPD can be controlled by the operator using a table side operating handle, and specific C-arm positions can be recalled using an auto-positioning function (including ceiling positions or angles of the C-arm).
The operating table, manufactured by

Figure 1. Hybrid operating room
A radiolucent operating table (ALPHAMAQUET 1150, MAQUET) and a ceiling mounted C-arm with FPD (TOSHIBA Infinix™-i INFX-8000H Angiographic imaging system) are installed in the hybrid operating room.
This room can also be used for cardiovascular X-ray diagnosis and interventional procedures.

MAQUET, is provided with a detachable tabletop. The head plate is mounted for conventional surgery, while the all-carbon tabletop is mounted when fluorographic imaging is required. The rails are movable, and the support pillar can be rotated.

Room Design

The physicians who will actually use the hybrid operating room must be involved in the design of the room. Regarding the table, if it is to be used mainly for surgical procedures, an operating table should be selected. If it is to be used mainly for catheterization procedures, a catheterization table should be selected.
Before the start of installation at our hospital, we visited Nationwide Children's Hospital in Columbus, Ohio, where a hybrid operating room with an operating table is located adjacent to a hybrid operating room with a catheterization table, with the appropriate room selected depending on the individual case.
The physicians must also be involved in the decision regarding the C-arm configuration, i.e., whether a floor mounted arm or a ceiling-mounted arm should be installed. Both options have advantages and disadvantages.
The ceiling-mounted type permits the set position and the park position to be selected on the Toshiba unit, with the park position providing sufficient clearance around the table. The disadvantage to ceiling mounted c-arm is the encumbrances to the ceiling, affecting the usual lighting and air handling capabilities.
The advantage of a floor-mounted c-arm is the relative lack of ceiling encumbrance. On the negative side, a floor mount cannot be parked as far away from the patient table and general work area when not in use.
Above all, it is essential to consider the overall layout of the room. The equipment mounted to the ceiling, such as surgical lights and monitors, and various floor mounted equipment must be taken into consideration. In particular, the layout must avoid interference or collision of all equipment when the C-arm is installed.
It is advisable to employ 3D-CAD to simulate the layout in advance as far as possible. In addition to the locations of the equipment and structural elements, it is also important to consider the workflow and movement of people in the layout (**Fig.2**).

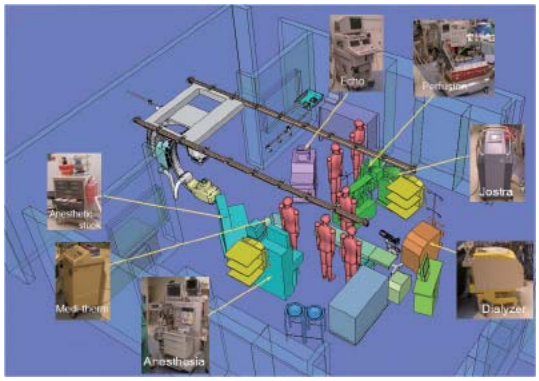

Figure 2. Importance of the layout of the hybrid operating room.
It is essential to design the layout of the hybrid operating room so as to minimize interference between the surgical equipment and the angiography system. The surgeons must be involved in the design process for the room, which should include 3D-CAD simulation of the layout as much as possible.

What procedures can be performed in a hybrid operating room?

The first example of a procedure that can be performed in a hybrid operating room is contrast enhanced imaging during or immediately after surgery, to help assess the successfulness of the surgery before the patient is moved from the operating theatre. Another example is slightly more invasive catheterization procedures that cannot be performed in a catheterization room, such as aortic stent grafting, trans-catheter valve replacement, or valvuloplasty. In addition, the room can support various so-called hybrid procedures such as the combination of percutaneous coronary intervention (PCI) with coronary artery bypass grafting (CABG), minimally invasive direct coronary artery bypass grafting (MIDCAB), and off pump coronary artery bypass (OPCAB). Examinations in this room are expected to expand further in the future.
At our hospital, the hybrid operating room has been used mainly for endovascular stent-graft placement in the aorta as well as coil embolization and stent placement in the peripheral arteries. For example, a 72-year-old man who had undergone total gastrectomy underwent stent-graft placement for an abdominal aortic aneurism (AAA). The vessels could be clearly visualized up to the renal arterial branches in this case, using the 16" FOV on the high definition FPD. A 55-year-old patient with AAA and dilated cardiomyopathy (DCM) underwent stent-grafting. Despite the poor washout of contrast medium due to the low cardiac output, the abdominal branches were clearly depicted. Another example is a 76-year-old man who was allergic to contrast medium. Even though the use of contrast medium was contraindicated, high-precision images could be obtained. These clear images supported transluminal endovascular grafting in the abdomen with the use of CO_2. We also treated a 60-year-old man who first underwent coil embolization of the internal iliac artery for an aneurysm of the right common iliac artery and then underwent stent-graft placement from the common iliac artery to the external iliac artery.
Another case is a 76-yearold man with arteriosclerosis obliterans (ASO) associated with angina pectoris. Percutaneous transluminal angioplasty (PTA) was performed from the left common iliac artery to the external iliac artery, followed by femorofemoral (F-F) and femoropopliteal bypass grafting. In all of these cases, the procedures were very well supported by the high-precision, wide-field images acquired using the C-arm, which helped us perform the surgery more smoothly and efficiently than ever before.
We have recently started performing hybrid procedures such as intravascular surgery for peripheral arteries combined with bypass, aortic stent-grafting combined with bypass, and aortic dissection branch stenosis/occlusion. For example, aortic stent-grafting + branch bypass (so-called debranching) is considered to be effective for high-risk patients, particularly those with aortic aneurysms in the thoracoabdominal region, but extremely precise images are

required for post-debranching stent placement, which is possible with the flat panel detector hybrid operating system. The hybrid operating room has also been used very effectively for patients with coronary artery disease, where pre- or intraoperative contrast imaging was used at the start of the case and that imaging was repeated following bypass surgery. The usefulness of contrast imaging immediately after the surgical procedure has been reported by researchers at Vanderbilt University in Nashville, Tennessee. Contrast images were acquired before closing the chest in a total of 515 patients undergoing graft surgery. Abnormalities were identified in 92 patients (18%). Major revision was required in 44 of these patients, with PCI performed in 30 patients and repeat surgery in 14 patients. Of course, the actual numbers will vary depending on the hospital, but nevertheless, the hybrid operating room allows the surgical outcome to be assessed immediately after the procedure is completed, and these findings can be fed back to improve the surgical methods and procedures.

Case report

A hybrid repeat procedure was performed for a patient with aortic stenosis (AS) following CABG at our hospital.
Patient: 56-year-old man
Medical history: In August 1995, CABG was performed involving the left internal thoracic artery – left anterior descending branch (LITALAD), great saphenous vein – first diagonal branch – posterolateral branch – segment 4 atrioventricular branch (SV-D1-PL-4AV), and gastroepiploic artery – segment 4 posterior descending branch (GEA-4PD). Seven years later, in May 2002, PCI was performed for the left circumflex branch (LCX). Subsequently, beginning in 2008, aggravation of cardiac failure due to AS and atrial fibrillation was noted.
Physical examination findings: Physical examination showed a grade II systolic murmur in the chest. The femoral pulses were absent bilaterally. Ultrasound showed an EF of 46%. The pressure difference across the calcified aortic valve was 52 mmHg. The valve orifice area was 0.8 cm2. Preoperative 3DCT showed that the LITA-LAD and SVD1- PL-4AV grafts were patent, while the GEA-4PD graft was occluded. The right coronary artery (RCA) was completely occluded at #2, the LAD was completely occluded at #6, and the LCX showed 90% stenosis at #11.
Assessment: It was determined that a repeat procedure was required for AS following CABG.
Surgical procedure: The surgical plan was to occlude the patent LITA with a catheter and to perform aortic valve replacement (AVR). First, prior to skin incision, the catheterization team placed a 6F sheath in the left brachial artery. The surgical team then implemented procedures to supply blood to the right subclavian artery and extract blood from the right femoral vein, followed by repeat thoracotomy. The area surrounding the ascending aorta was exposed, and a left ventricular vent was inserted from the right superior pulmonary vein to complete the pump setup. At this point, the catheterization procedures were resumed. A balloon was placed in the LITA via a retrograde approach, and was inflated to occlude the LITA for cardiac protection (**Fig.3**). Occlusion of the LITA was confirmed in contrast images, which also depicted the cross-clamps and the rib spreader (**Fig. 4**). Under these conditions, the surgical team performed valve replacement. After the balloon was removed, the LITA was contrast-enhanced to confirm that it was not damaged. The time required for the procedure was 8 hours and 36 minutes, including the catheterization procedures. The cardiopulmonary bypass (CPB) time was 185 minutes, and the aortic cross clamping (Axc) time was 132 minutes.

Figure 3.
Hybrid operating room (during a catheterization procedure).
A balloon was placed in the LITA (Left Internal Thoracic Artery) and inflated. The C-arm and the flat panel monitor are moved during such catheterization procedures.

Advantages of Hybrid Treatment

The reason for the effectiveness of hybrid procedures combining coronary artery stent placement and LITA-LAD bypass has been reported to be that SV grafting has greater survival benefits than pharmacological therapy. It has also been reported that survival rates are higher with IMA grafts than with SV grafts.
In particular, IMA grafts are extremely effective for the LAD, and at the present time, have not been surpassed by any other therapeutic methods, including catheter-based therapy. On the other hand, it has been reported that the restenosis rate following catheterization is highest in the LAD. Based on these findings, a therapeutic strategy employing non-LAD coronary stent placement + LITA-LAD bypass is considered to be very effective.
With regard to the treatment protocol, surgery can be performed either before or after PCI. Concurrent surgery should be considered for minimizing patient discomfort, shortening the total procedure time, and minimizing the risk of coronary events during the transition period. An important issue in concurrent surgery is the anti-platelet therapy regimen. Currently, the pre-surgical administration of clopidogrel is recommended when a drug-eluting stent (DES) is used. However, in hybrid surgery, the administration of clopidogrel was discontinued 7 days before the procedure, and only aspirin was administered. One possible protocol would be to confirm that no abnormalities are observed in contrast images following MIDCAB and then switch the drug back to clopidogrel before performing PCI. Researchers at Emory University in Atlanta, Georgia, reported their experience

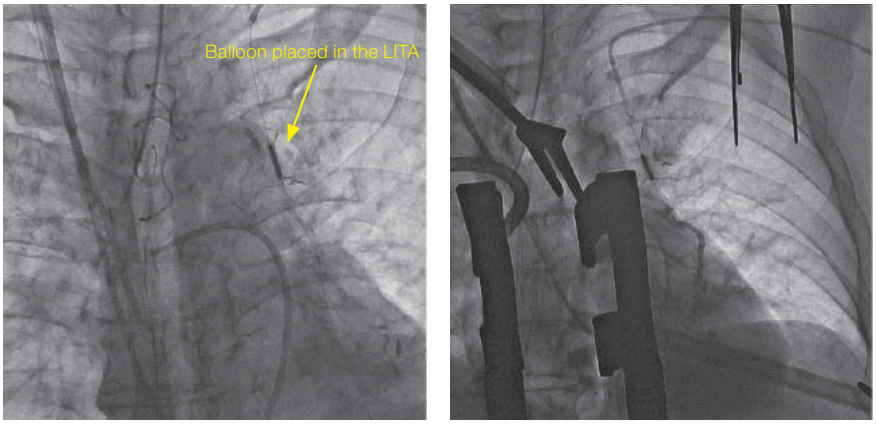

Figure 4.
Occlusion of the LITA with a balloon.
Following aortic cross-clamping, a Sophia balloon was placed in the LITA and inflated to 2 atmospheres of pressure to occlude the LITA. The cross-clamps and the rib spreader are depicted in the image on the right. Coronary blood flow was suspended, and the contrast medium in the SV graft via the collateral vessels remained with no washout. The LITA distal to the balloon showed no inflow of contrast medium, confirming that blood flow was blocked.

with hybrid treatment for the coronary arteries, in a total of 60 patients (CABG stent in 54 patients, and stent CABG in 6 patients) which were followed up for 9 months. Seven patients experienced major adverse cardiovascular events (MACE) and 5 of them developed re-stenosis.
The advantages of coronary artery hybrid treatment include reduced invasiveness, improved short-term outcomes, and a faster return to normal life. On the other hand, there are a number of disadvantages such as the risk of incomplete revascularization, the need for revascularization (mainly with the use of stents), higher cost, the lack of medical reimbursement, and unclear long term results. Nevertheless, patients with coronary artery disease are becoming older. This means there are a larger number of high-risk patients with concomitant conditions such as cerebral infarction or patients who cannot be expected to maintain PCI patency for a long period.
Given this situation, there is greater need to employ hybrid treatment. Valvular diseases can be treated using a catheterization procedure if a percutaneous approach is employed, but a hybrid operating room is required for a transapical approach.
Recently, in the field of congenital heart disease, a hybrid procedure for the treatment of hypoplastic left heart syndrome (HLHS) has been attracting attention. In this method, following banding of the pulmonary artery, a self-expanding PDA stent is placed in order to regulate pulmonary artery blood flow while maintaining systemic blood flow. Researchers at the Nationwide Children's Hospital mentioned above have reported that the first-stage mortality rate was dramatically reduced following the introduction of the hybrid procedure.

Conclusion

The key to successful hybrid procedures is close collaboration between various divisions in the hospital. In the past, each division provided services independently, and in special situations in which collaboration with other divisions was required, cross-functional work was conducted on an ad hoc basis. However, when hybrid treatment is to be employed, close interaction between various divisions is required on a daily basis. A system for cooperative decision-making as a team must be established, and such a framework for smooth collaboration cannot be established instantly. It is also essential for internists to expand their knowledge and understanding of surgical treatment, and vice versa. To achieve this, new policies involving the entire hospital should be instituted, such as holding cross-functional joint conferences and encouraging specialists to participate in the conferences held by other divisions.

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