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Expanding the Role of Percutaneous Pulmonary Valve Implantation

By Sara M. Trucco, MD and Jacqueline Kreutzer, MD

Introduction

Right Ventricular Outflow Tract (RVOT) dysfunction with progression of pulmonary stenosis and insufficiency is a challenging problem that occurs often following repair of various forms of congenital heart disease.[1] Although surgical revision of the RVOT is associated with low morbidity and mortality,[2,3] the limited lifespan of the surgical implants (right ventricle to pulmonary artery homografts, valved conduits and bioprosthetic valves) subjects these patients to multiple open-heart procedures,[4,5] with significant cumulative morbidity. In the 1990's, bare-metal stenting was introduced as an option to prolong conduit longevity.[6] Although stent implantation is an effective means of reducing conduit stenosis, this is achieved at the expense of free pulmonary valve insufficiency. The long-term deleterious effects of chronic severe pulmonary valve insufficiency are well-known, leading to decreased exercise capacity, fatal arrhythmias and progressive right ventricular (RV) failure.[7-9] Percutaneous pulmonary valve (PPV) implantation offers a minimally invasive approach to address RVOT dysfunction without the resulting pulmonary insufficiency.

The first PPV was designed and implanted by Dr. Phillip Bonhoeffer in the year 2000.[10,11] This design, with subsequent modifications, was later adopted for the development of the Melody Valve™, which is currently commercially available through Medtronic (Figure 1). The Melody Valve™ consists of a bovine jugular venous valve sewn into a platinum iridium stent, and was the first percutaneous valve approved for human use in the United States by the Food and Drug Administration (January of 2010).[12] Specifically,

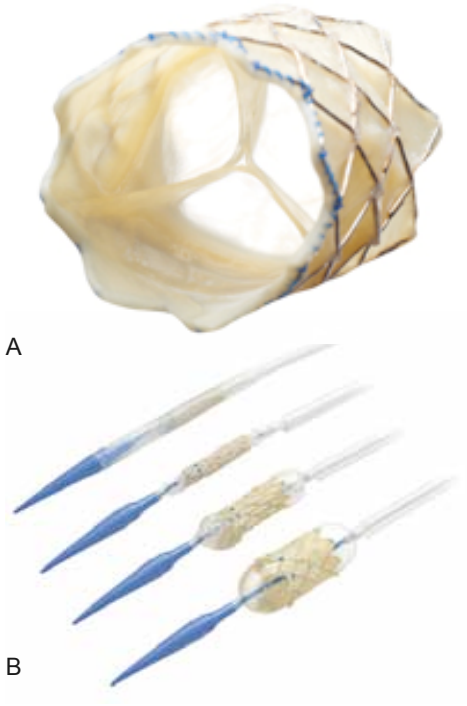

Figure 1 A& B: Melody Valve™ (A). 20 mm Ensemble® Balloon Delivery System (B) with valve crimped and loaded (B).

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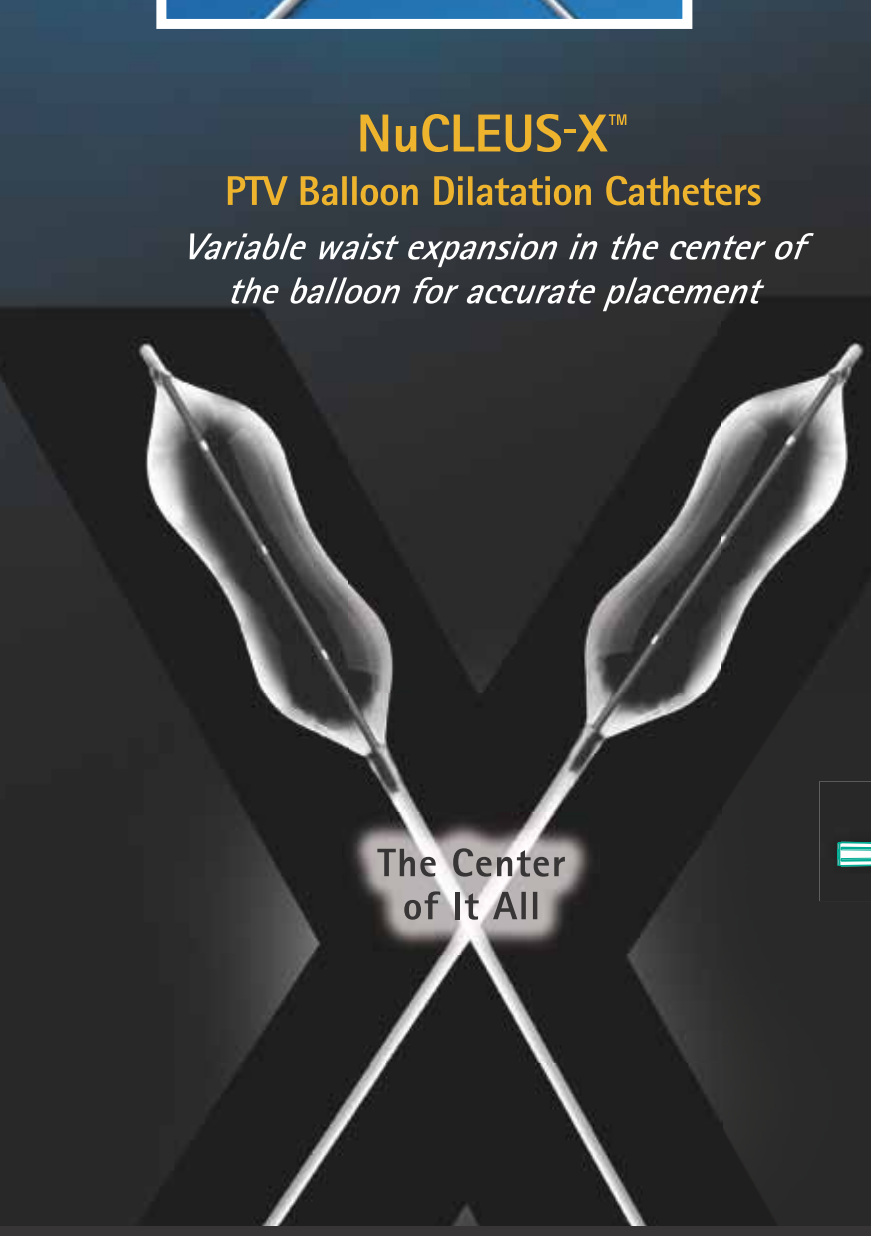

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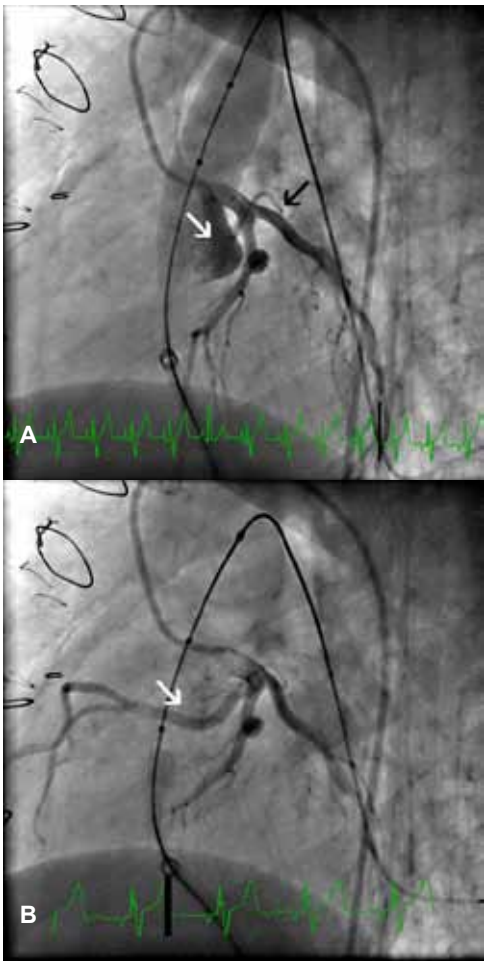

Figure 2 A & B: (A) Selective coronary angiography performed in long axial oblique projection with simultaneous conduit balloon dilation in a patient with a single left coronary artery (black arrow) and anomalous right coronary artery crossing the right ventricular outflow tract. With the balloon inflated, the left coronary fills but flow to the right coronary artery is completely occluded (white arrow). (B) With deflation of the balloon, blood flow is restored to the right coronary artery (white arrow). This is a contraindication for Melody Valve ™ implantation.

the Melody Valve™ is approved in the USA as a humanitarian device for use in dysfunctional conduits with an original implantation size of at least 16 mm in diameter, with either a mean gradient of 35 mmHg or at least moderate pulmonary valve insufficiency. PPV implantation is considered a Class II AHA recommendation for conduits with moderate to severe stenosis or insufficiency provided the patient meets the inclusion/exclusion criteria for the available valve (Level of evidence B) as *per recent Scientific Statement from the American Heart Association on indications for cardiac catheterization and Intervention in pediatric cardiac disease (Circulation. 2011;123:2607-2652*). In the last ten years, PPV implantation has quickly changed the treatment of RVOT dysfunction, and is currently performed in over 150 centers worldwide with more than 3,000 patients treated.[13] This article reviews the common use of the Melody Valve™ and explores innovative uses that remain to be further studied.

Morphologic Considerations

When hemodynamic inclusion criteria is met, the size and shape of the RVOT, as well as its proximity to the coronary arteries, must also be evaluated prior to PPV implantation. The RVOT will need to measure between 16 and 22 mm to accommodate the Melody Valve™. Morphologically, a straight or hourglass-shaped conduit is more favorable for Melody Valve™ implantation than a divergent or pyramidal shape,[14] but shape rarely precludes implantation. Additionally, the anatomy and course of the coronary arteries in relation to the RVOT must be determined. In cases where the coronaries arise anomalously or appear to course in proximity of the conduit, selective coronary angiography with simultaneous conduit balloon dilation must be performed (Figure 2) to prevent coronary compression with stent placement.[16, 17]

An accommodating RVOT morphology is critical to successful Melody Valve™ implantation, and thus preparing an adequate "landing zone" has become a key component of the procedure. This is particularly true in patients in whom the predominant indication for PPV implantation is stenosis, as these conduits often become narrow and stiff over time. In these patients, the RVOT is prepared by sequential angioplasties and stent implantations within the conduit, often with use of ultra-high pressure balloons. Once the target diameter has been achieved, implantation of the Melody Valve™ is a relatively simple component of the procedure.

Table 1 summarizes our experience at Children's Hospital of Pittsburgh and illustrates the change in conduit diameter achieved with bare metal stenting and eventual Melody Valve™ implantation. On average, the conduits had narrowed by 30 to 33% of their original size. All but one patient required pre-stenting with a bare metal stent, which expanded the conduit by an average of 13% in the AP view, and 29% in the lateral projection. Melody Valve™ implantation further expanded the area by an average of 10 to 13% (Table 1).

Typical indication: Percutaneous Melody Valve™ implantation for Combined Conduit Stenosis and Insufficiency

Clinical History

The patient is a 16-year-old female with truncus arteriosus type I. She underwent full repair in the neonatal period with placement of a 13 mm RV to PA conduit. Five years later, she underwent conduit revision with placement of a 21 mm homograft and left pulmonary arterioplasty. During the six months prior to cardiac catheterization, the patient had progressive worsening of symptoms including exercise intolerance, shortness of breath, chest pain, palpitations, recurrent migraines and generalized lethargy. She reported these

Table 1: Biplane Dimensions of the Conduits Before and After Intervention in Our Patient Population

Patient (#)	Original Conduit/ Valve Size (mm)	Pre-Stent AP Diameter (mm)	Pre-Stent Lateral Diameter (mm)	Total RVOT Stents (#)	Post-Stent AP Diameter (mm)	Post-Stent Lateral Diameter (mm)	Post-Melody AP Diameter (mm)	Post-Melody Lateral Diameter (mm)
1	25	13.2	16.7	2	15	18.5	18	20.2
2	24	17	14.8	2	16.1	17	19.2	19.8
3	22	14.9	10.71	2	15.8	16.2	16.9	19.9
4	17	10.3	12.76	1	18	15.1	15.9	16.3
5	18	14.4	9.5	1	12.9	14	17.9	17.6
6	25	16	14.1	2	19	18.3	19	18.6
7	25	16.5	12.1	2	16.6	17.5	21.3	20.7
8	17	13.7	15.2	1	17.5	18.8	18.2	18.3
9	24	17	14.4	2	17.6	18.1	20	21.6
10	22	15.3	17.3	1	16.6	19.7	17.9	20.9
11	20	14.7	16.7	1	15.3	18.4	19.9	19.9
12	22	11.4	11.6	2	16.6	18.3	17.5	19.5
13	19	16.2	16	1	16.7	18.8	17.4	19.4
14	21	14.3	10.3	3	15.6	16.6	18.2	20
15	21	17	17.2	2	17	18.4	20.8	19.8
16	25	19.1	21.9	0	x	x	19	21
17	17	14.8	13.7	2	17.9	18.1	16.5	17.1
18	18	14.7	11.9	2	16	17	18	17.7

Note that most conduits are not perfectly round. The most gain in diameter is achieved with bare metal stenting. Minimal further expansion occurs with Melody valve implantation. In general, the ending dimensions tend to be slightly smaller than those of the original diameter of the surgical conduit.

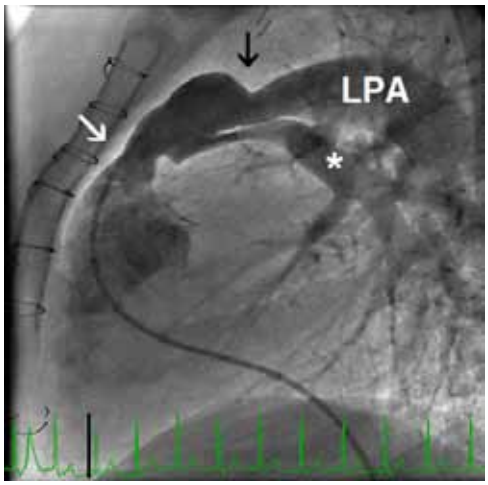

Figure 3: Main pulmonary artery angiogram performed in lateral projection reveals a narrowed conduit (white arrow) with free pulmonary valve insufficiency. The conduit measures 14.3 mm by 10.3 mm. There is bilateral-branch pulmonary artery stenosis (black arrow), affecting the right pulmonary artery (*) greater than left (LPA).

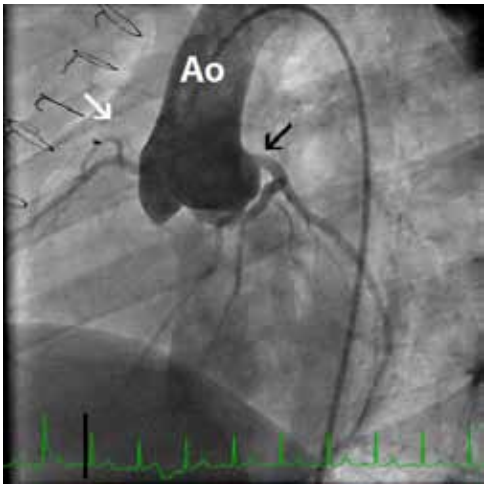

Figure 4: Aortic root (Ao) angiography demonstrates mild truncal valve insufficiency and normal origin of the right (white arrow) and left (black arrow) coronary arteries. The course of the coronary arteries and branches is not in proximity to that of the right ventricle to pulmonary artery conduit.

symptoms with casual walking and while climbing one flight of stairs, rendering her New York Heart Association Class II to III. Echocardiogram revealed moderate conduit stenosis and insufficiency, a mildly dilated RV with preserved systolic function, and bilateral branch PA stenosis, right greater than left. Her truncal valve had mild insufficiency. The peak gradient through the conduit was 72 mmHg with a mean gradient of 40 mmHg. Cardiac MRI confirmed the moderate conduit stenosis and insufficiency, with a regurgitant fraction of 41%. Given her significant symptoms and imaging findings, she was referred for cardiac

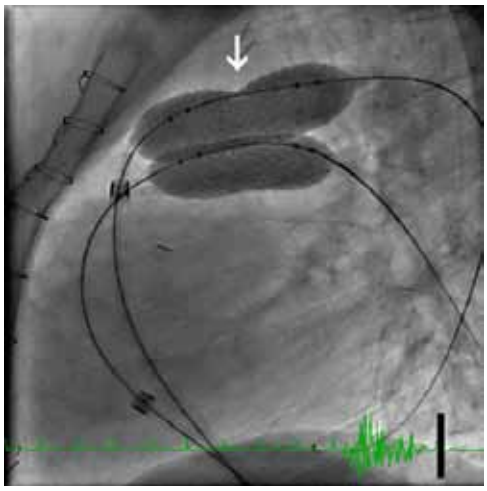

Figure 5: Simultaneous inflation of a 16 mm X 4 cm BIB balloon and 26 mm EV3 Max LD stent in the LPA and a 14 mm X 4 cm BIB balloon in the previously placed EV3 Max LD stent in the RPA. There remains a mild waist in the LPA stent (arrow).

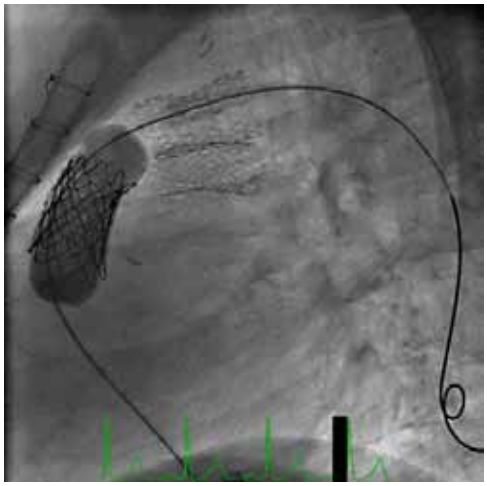

Figure 6: Melody Valve™ (arrow) implantation into the RV to PA conduit using a 20 mm Ensemble® Balloon Delivery System.

catheterization to undergo PPV implantation using the Medtronic Melody Valve™ along with branch pulmonary artery rehabilitation.

Cardiac Catheterization Procedure

The patient was placed under general anesthesia and access was obtained in the right femoral artery and vein. The patient was heparinized and a full right and left heart cardiac catheterization was performed for hemodynamic and angiographic evaluation. The RV systolic pressure was 60 mmHg or ¾ systemic, with a 40mmHg peak to peak gradient into the main pulmonary artery (MPA), thus meeting hemodynamic criteria for conduit replacement or Melody Valve™ implantation.[15] There was a further 7mmHg gradient into the right pulmonary artery (RPA) with no gradient into the left. The MPA diastolic pressure was low with a

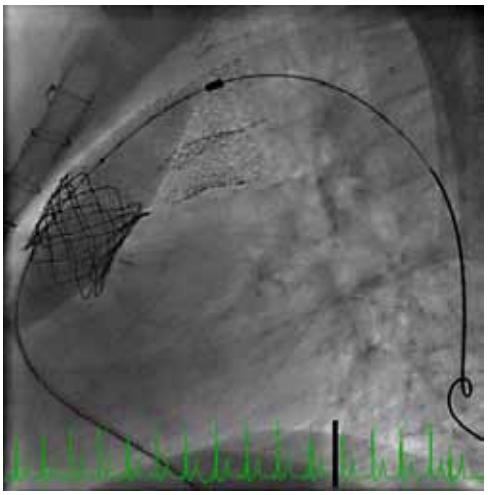

Figure 7: Post-dilation of the Melody Valve™ with a 20 mm X 2 cm ATLAS® balloon.

ventricularized tracing, consistent with free pulmonary insufficiency. The cardiac index was normal (3.3 L/m/m2) with no evidence of intracardiac shunting. Angiography showed a calcified and narrow conduit measuring 14.3 mm by 10.3 mm with free insufficiency filling a mildly dilated RV. The branch pulmonary arteries demonstrated significant narrowing at the proximal RPA and mild narrowing of the proximal left pulmonary artery (LPA) (Figure 3). Aortic root angiography revealed mild truncal valve insufficiency and normal coronary arteries whose course did not come near the RV to PA conduit (Figure 4). Given the finding of bilateral branch PA stenosis, a second venous sheath was placed in the left femoral vein.

RPA angioplasty was performed using a 12 mm X 2 cm ATLAS® balloon catheter. Despite full expansion of the balloon, repeat angiography demonstrated significant recoil. The RPA branch stenosis was then treated with a 26 mm long EV3 Max LD Intrastent hand-crimped onto a 14 mm X 4 cm balloon-in-balloon (BIB) catheter. Repeat angiography showed complete resolution of the RPA stenosis.

Attention was then turned to the LPA. A second 26 mm long EV3 Max LD Intrastent was hand-crimped onto a 16 mm X 4 cm BIB balloon and expanded in the proximal LPA with simultaneous inflation of the 14 mm X 4 cm BIB balloon in the previously placed RPA stent (Figure 5). This resulted in relief of the branch RPA and LPA stenosis without stent compression or protrusion into the RV to PA conduit.

Having completed the branch pulmonary artery rehabilitation, attention was then turned to the RV to PA conduit. Compliance testing had revealed significant recoil of the conduit, and therefore pre-stenting prior to Melody Valve™ implantation was undertaken. Additionally, pre-stenting has been shown to reduce the occurrence of PPV stent fractures, the leading cause of PPV reintervention.[16, 17] A 26 mm long EV3 Mega LD Intrastent was hand crimped onto a 18 mm X 4.5

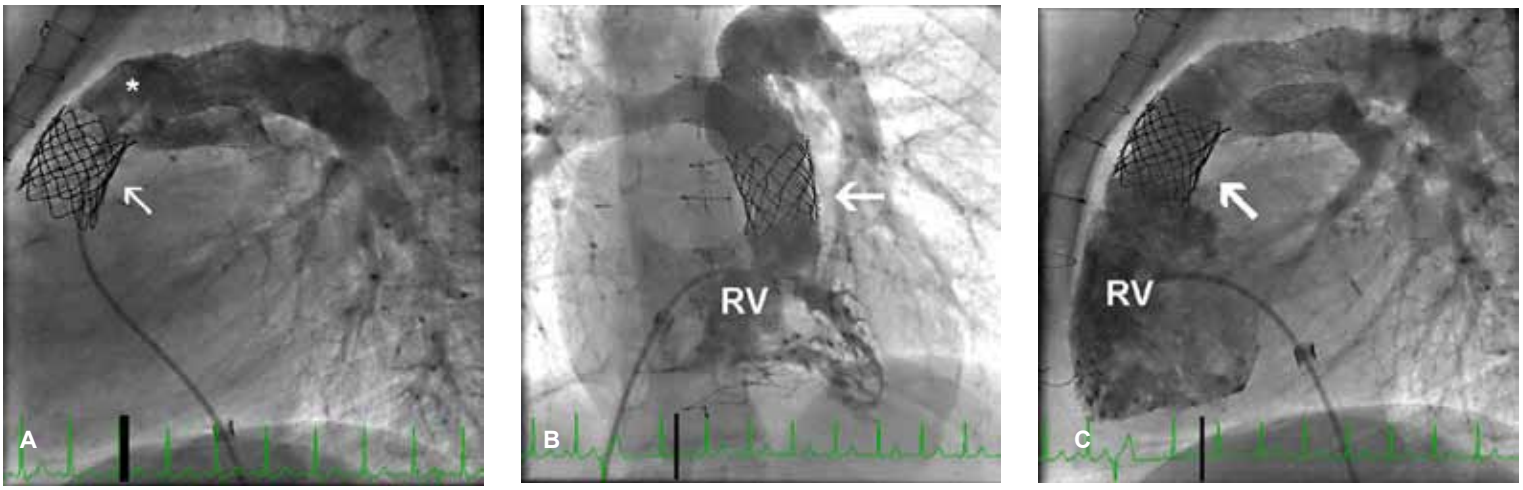

*Figure 8 A, B & C: Following interventions main pulmonary artery angiogram demonstrates no significant pulmonary valve insufficiency (A). A right ventriculogram (B & C) demonstrates no residual conduit stenosis and unobstructed distal flow into the bilateral branch pulmonary arteries. RV: Right ventricle; * Main pulmonary artery.*

cm BIB balloon and expanded into the stenotic waist of the RV to PA conduit. Great care was taken to avoid jailing of the previously placed RPA and LPA branch stents. As stent recoil was observed in the lateral projection, further stenting was undertaken with placement of two Cordis Palmaz XL 10 mm X 30 mm stents. The RV to PA conduit stents were then further dilated with an 18 mm X 2 cm ATLAS® balloon. Repeat angiography showed significant improvement in the conduit stenosis. The Melody Valve™ was then implanted using a 20 mm Ensemble® Balloon Delivery System (Figure 6) and post dilated with a 20 mm ATLAS® balloon to full expansion (Figure 7).

Following PPV implantation, angiography demonstrated no pulmonary insufficiency and resolution of the conduit stenosis (Figure 8). The RV systolic pressure dropped to 36 mmHg, or 1/3 systemic, with no significant gradient across the Melody Valve™ stent. There remained a minor gradient into the branch pulmonary arteries, though distal mean PA pressures rose from 12 mmHg to 17 mmHg.

Follow-up

The patient tolerated the procedure well without complication and was discharged home the following morning. She reported mild procedural groin and chest pain, which resolved within a week of the procedure. Discharge echocardiography demonstrated normal biventricular function with minimal pulmonary stenosis (mean gradient of 8 mmHg) and trivial pulmonary insufficiency.

At six months follow-up, the patient reports an improvement in her stamina with increase in her energy level and significant reduction in her migraine frequency. Echocardiogram reveals normal RV systolic function with normal RV systolic pressure (25 mmHg plus RA pressure by tricuspid regurgitation jet). There is minimal pulmonary stenosis (peak gradient of 18 mmHg, mean of 9 mmHg) and trivial pulmonary insufficiency. The branch PAs are not well seen by transthoracic imaging; however, color Doppler demonstrates no significant stenosis. Fluoroscopy of the valve reveals no stent fractures.

Expanding the Role of the Melody Valve™: Non-Conventional Delivery Approaches / Indications

Only approximately 15% of potential patients with RVOT dysfunction can accommodate the currently approved implantable valves.[18] Many patients remain poor Melody Valve™ candidates due to their small physical size, limited vascular access, or the size and shape of their RVOT. These limitations have led some physicians to explore innovative, off-label techniques utilizing the Melody Valve™. Additionally, alternative PPV stents are being designed in hopes of treating both large and small RVOT morphologies.

An RVOT greater than 22 mm is a contraindication for Melody Valve™ implantation due to the risk of dislodgement.[1] Additionally, a prior RVOT patch repair is considered a relative contraindication to PPV implantation due to the unfavorable resulting morphology identified in early studies.[14, 19] More recently, pre-stenting with bare-metal stents has been reported as a way to "prime" the RVOT in patients with prior RVOT patch repair, thus permitting subsequent successful PPV implantation.[20] In patients with large and distensible RVOT conduits, a hybrid approach combining intra-operative PPV implantation with simultaneous conduit down-sizing has been undertaken with some success.[21] Alternatively, Melody Valve™ implantation into the bilateral branch pulmonary arteries has been proposed as a minimally invasive, though still experimental, option in patients with large and insufficient conduits.[22, 23] Heterotopic implantation of the Melody Valve™ has since expanded, with recent reports of its use in the tricuspid valve position in patients with both single ventricle and two ventricle physiologies.[24-26] In recent months, a small series describing the use of the Melody Valve™ in the aortic and mitral positions has been reported.[27] It should be noted that implantation of the Melody Valve™ in the aortic position does require device modification and extreme care, so to not occlude the coronary ostia with the covered portion of the stent. Although preliminary, the short-term results of this series were promising, and demonstrated durability of the Melody Valve™ function despite exposure to the high-pressure hemodynamics of the systemic circulation.[27]

On the opposite end of the spectrum are small patients whose physical size may not accommodate a 22 French delivery system and those whose conduit measures less than 16 mm in diameter. Such small patients are not typical Melody Valve™ candidates.[12] However,

hybrid procedures using the subxyphoid or per-ventricular approach have been successful in overcoming some of these limitations.[21,28] Fetal trans-apical bare metal stent implantation into the MPA has recently been described in an animal model, suggesting the possibility for prenatal PPV implantation in the future.[29] Direct intra-operative Melody Valve™ implantation is an alternative technique that has been used successfully in young infants, such as the case described below, allowing for serial balloon dilation of the valve as the child grows.

Pulmonary valve stent technology continues to evolve with the goal of treating a larger percentage of patients with RVOT dysfunction with the percutaneous technique. The Edwards SAPIEN™ transcatheter heart valve can be used in patients with larger RV to PA conduits, as it is sized as large as 26 mm.[30] The US Food and Drug Administration recently approved the use of the SAPIEN™ valve under the Human Device Exemption regulation for aortic indication. Self-expanding nitinol pulmonary valve stents offer the potential of treating larger RVOT morphologies with a low-profile design, but are still under investigation.[18,31] Custom PPVs designed to fit a patient's unique RVOT have also been described, with at least one successful human implantation, but are currently prohibitively expensive for routine use.[32] PPV options for small patients remain limited, though the implantation of a custom handmade stent in an infant has been reported.[33]

Example of Intraoperative Melody Implantation in an Infant

Clinical History

The patient is a female infant with Tetralogy of Fallot and Alagille Syndrome. Her cardiac disease was first diagnosed in the early neonatal period after evaluation of cardiac murmur by echocardiogram revealed mild to moderate pulmonary stenosis and a moderate-sized ventricular septal defect (VSD). At two months of age, follow-up echocardiography demonstrated progression of her lesion with severe pulmonary stenosis and infundibular narrowing. Her pulmonary arteries appeared severely hypoplastic, but could not be well visualized by ultrasound. At this time she was noted to have worsening jaundice, and thus underwent a full gastrointestinal evaluation, which included a liver biopsy. This revealed significant liver dysfunction consistent with Alagille Syndrome.

Cardiac Catheterization Procedures

She underwent her first cardiac catheterization at two months of age, to better delineate the anatomy of the pulmonary arteries prior to surgical repair. Angiography demonstrated a diffusely hypoplastic RVOT with continuous, though small, pulmonary branches. She had a normal cardiac index of 3.6 L/m/m2 with a Qp/Qs of 0.7 to 1 consistent with right to left intracardiac shunting. One week later, she was

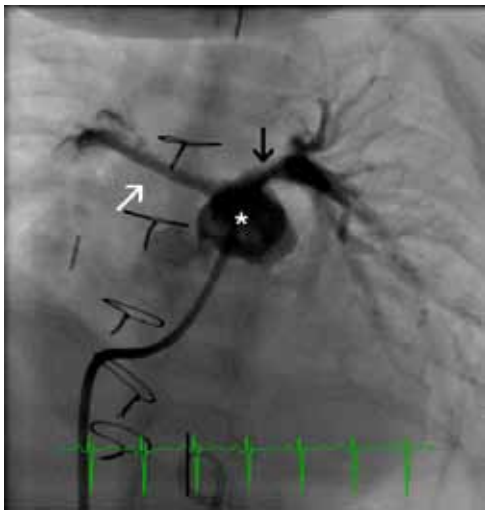

Figure 9: Main pulmonary artery (MPA) angiography demonstrates severely hypoplastic branch pulmonary arteries with the LPA measuring 3.8 mm (black arrow) and the RPA measuring 2.5 mm (white arrow). The MPA is dilated.

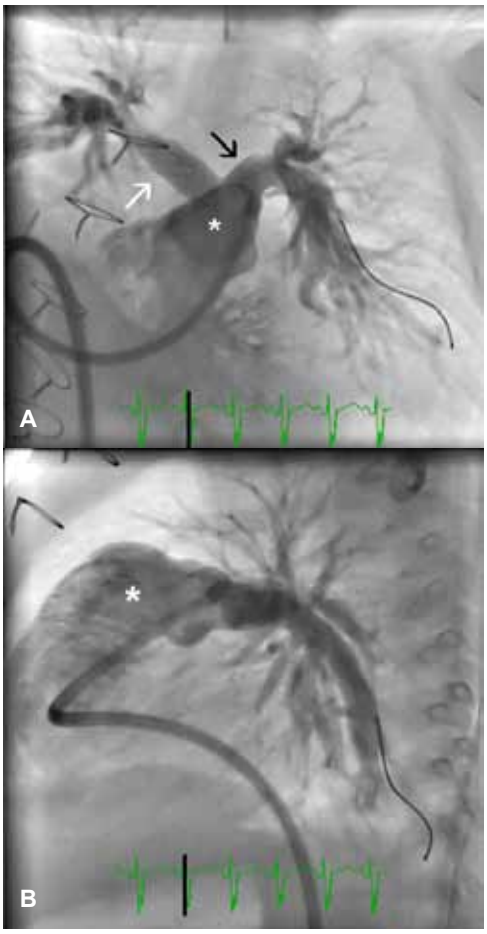

Figure 10 A and B: (A) Main pulmonary artery (*) angiogram performed following implantation of two 7 mm X 12 mm Cook Formula premounted stents in the LPA (black arrow) and RPA (white arrow) demonstrates significant improvement in vessel diameter. (B) In lateral projection the free pulmonary valve insufficiency is appreciated through a dilated RVOT following surgical patch. The branch pulmonary arteries are improved in caliber with no residual stenosis.

taken to the operating room and underwent RVOT reconstruction with transannular patch augmentation extending to the PA bifurcation. Due to the small nature of her distal PA anatomy, it was felt that the VSD could not be closed at that time.

At four months of age, the patient was doing relatively well from a cardiac perspective, with oxygen saturations in the high 80's to low 90's, no evidence of heart failure or cyanosis, and steady weight gain. Her liver dysfunction, however, had progressed significantly, raising concerns regarding the need for liver interventions including transplantation. As the unrepaired cardiac condition with right ventricular hypertension was a contraindication for liver transplantation, she was brought to the catheterization laboratory for pulmonary artery rehabilitation in hopes of rendering her a candidate for full cardiac surgical repair.

In the catheterization lab, hemodynamic evaluation revealed no gradient into the MPA, but significant gradients (60 to 65 mmHg) into the right and left pulmonary arteries. Her cardiac index was normal with a Qp/Qs of 1.37. Angiography demonstrated hypoplastic branch pulmonary arteries with the proximal RPA measuring 2.5 mm and the proximal LPA measuring 3.8 mm (Figure 9). Angioplasty did not succeed in resolving the stenosis, as there was marked vessel recoil, and thus, both proximal pulmonary arteries were stented with two 7 mm X 12 mm Cook Formula premounted stents respectively. Repeat angiography showed improvement in the caliber of both branch pulmonary arteries with normal flow to all branches (Figure 10). The gradient across the branch pulmonary arteries dropped to 22 mmHg to the RPA and 14 mmHg to the LPA. The cardiac index remained normal and the Qp/Qs rose significantly to 2.9. These hemodynamics were considered favorable for complete repair and closure of the ventricular septal defect, and therefore the patient was admitted to the cardiac ICU for observation prior to her full repair.

Melody Valve™ Insertion

In the days following her catheterization, the patient was discussed at our joint Cardiothoracic Surgery and Cardiology conference. The patient had severe pulmonary valve insufficiency secondary to the original surgical transannular patch. Although well-tolerated at the moment, the concern was raised that, given the high likelihood of needing liver transplantation, in the future, hemodynamics would have to be optimized. In addition, as the liver disease continues to progress, the patient would become high-risk for future cardiac bypass and pulmonary valve replacement. Finally, optimal hemodynamics would be necessary for survival at the time of future liver transplantation. Therefore, it was decided that the patient should undergo intraoperative Melody Valve™ insertion at the time of closure of the ventricular septal defect, to provide pulmonary valve function, optimize hemodynamics and allow for minimally-invasive serial dilations of the valve in the future as she grew.

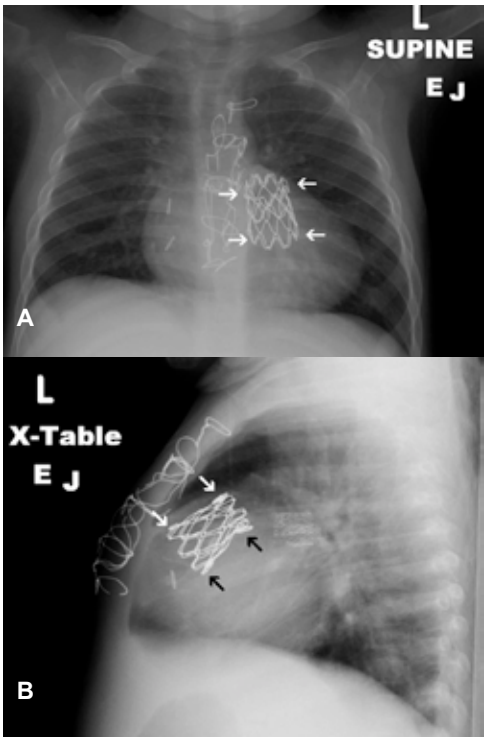

Figure 11 A and B: Chest X-ray obtained following intraoperative Melody Valve™ implantation in antero-posterior (A) and lateral projections (B). Note that the proximal and distal edges of the Melody Valve™ (arrows) have been modified (folded over) to achieve a decrease in length. The branch PA stents are again seen and appear widely patent without fracture.

One week after her bilateral pulmonary arterial stenting procedure, the patient was taken to the operating room for closure of the ventricular septal defect and Melody Valve™ insertion. She was placed under general anesthesia and the previous median sternotomy was incised. The heart was cannulated, the patient cooled to 35 degrees Celcius, and cardiopulmonary bypass was instituted. During the cross-clamp period, the ventricular septal defect was closed with patch material. The Melody Valve™ was crimped slightly using a 5 ml syringe, asymmetrically so that the distal end reached 16 mm in diameter, while the proximal end was wider, close to the original size. Then, it was positioned into the RVOT. In order to decrease the length for optimal fitting, Dr.

Morell folded over the proximal and distal edges of the Melody Valve™ stent (Figure 11), which did not alter valve function and allowed the shortening of the valve so as to fit within the right ventricular outflow tract. Additional patch material was used to repair the RVOT further to provide an optimal anchor for the valve. The patient's atrial septal defect was then closed primarily using 5-0 Prolene. Transesophageal echocardiography showed preserved biventricular function with optimal Melody Valve™ function and no residual intracardiac shunts.

Follow-Up

The patient tolerated the procedure well. Her post-operative recovery was complicated by the development of hemolysis, thought to be due to a tiny anterior paravalvular leak. She received a packed red blood cell transfusion and was started on pentoxifylline with good response. Approximately one week following surgery, the patient developed a fever and was found to have Enterococcus Faecalis growing from both peripheral and Broviac blood cultures. Given the proximity in time to her surgical repair, and the multiple stents and patch materials within her heart, the patient was treated for 6 weeks with IV antibiotics for presumed endocarditis, although endocarditis was never documented.

At six month follow-up, the patient is doing clinically well with no symptoms referable to the cardiovascular system. Echocardiogram reveals normal RV systolic function with normal RV systolic pressures by TR jet (23 mmHg). There is mild pulmonary stenosis and trivial pulmonary insufficiency. Her liver disease, for the moment, remains severe, but is being medically managed. The hemolysis is resolved.

Concluding remarks

The development of PPV stents such as the Medtronic Melody Valve™ has quickly revolutionized the treatment of RVOT dysfunction. The pulmonary stenosis and insufficiency that previously required an open-heart procedure, can now be safely and effectively treated with minimally invasive percutaneous techniques.[1,10,12] Although a large percentage of patients with RVOT dysfunction do not currently meet morphologic criteria for PPV implantation, innovative techniques partnered with evolving stent technology offer hope that many more patients will benefit from PPV implantation in the near future.[1, 8, 20, 30, 31]

From our experience with Melody Valve™ implants, we have learned a few technical tips:

1. The key component of the procedure is successful preparation of a perfect landing zone for the valve. This is particularly difficult in stenotic, stiff and calcified conduits, but can also be tricky with compliant conduits. It is most difficult to predict how the conduits will respond to intervention, and thus, procedures tend to be of highly variable duration.
2. Stent recoil is common in stenotic conduits, particularly when positioned immediately underneath the sternum. Preparing the site for Melody Valve™ also implies minimizing the chances of PPV stent recoil, and thus, it may be necessary to use one or more stents with the highest hoop strength to assure optimal landing zone diameter.
3. The use of ultrahigh pressure balloons has been essential to achieve wide patency of the stented conduits, but should preferably be used prior to implantation of the valve itself. The effect that ultrahigh pressure dilation can have on the Melody Valve™ stent can be unpredictable (Figure 12).

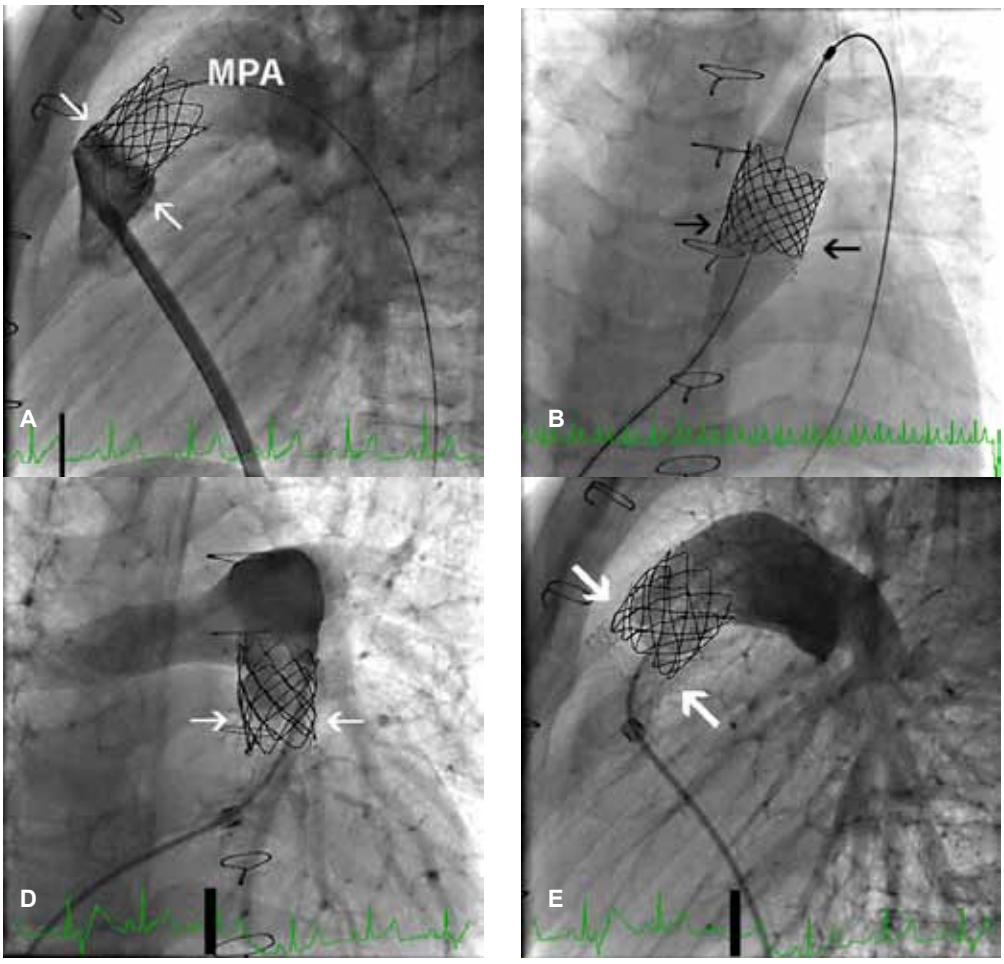

Figure 12 A-E: Right ventricular outflow tract angiogram following Melody Valve™ implantation demonstrates valve in good position (A). Note that the valve stent extends slightly into the right ventricular outflow tract proximally (arrows). There was a mild residual gradient. With the aim to eliminate the gradient, this patient underwent repeat dilation with ultrahigh pressure balloon (B & C). Note the shortening of the stent and stretching of the struts during inflation (arrows). Post dilation fluoroscopy and angiograms (D & E) showed significant Melody Valve™ stent recoil, as demonstrated by the narrower dimensions of the stent post dilation compared with that at maximal dilation. The residual gradient was unchanged. In this patient, post dilation of the valve with ultrahigh pressure balloon was of no benefit.

4. Most homografts are not compliant, but on occasion they can be. When stenosis is mild, compliance testing with an angioplasty balloon is essential to determine candidacy for Melody Valve™ implantation. If no waist is present at 20-22 mm dilation, Melody implantation is contraindicated as embolization will be highly likely.
5. Evaluation for risk of coronary artery compression should always be performed. Although there are obvious cases of coronary compression (Figure 2), there are times when this can be subtle, and difficult to interpret. One should consider that the external diameter that the old conduit will achieve after Melody Valve™ placement is likely larger than that at the time of compliance testing (one would have to add the wall thickness of the Melody Valve™ plus that of the stents used). Thus, when possible compression is suspected during testing, given that proximity of the course or distortion of the coronary is seen at the time of balloon inflations, a conservative approach is recommended.
6. When short length of the conduit or MPA raises concern for the potential risk of occlusion of pulmonary artery side branches with Melody Valve™ implantation, the use of open cell design stents at the time of pre-stenting can be most helpful. Even though these may have a higher recoil rate, they allow for strut dilation and reopening of a pulmonary artery branch (Figure 13) if overlapped by the stent.
7. If covered stents of appropriate sizes were readily available for implantation, it is likely that the use of the Melody Valve™ could be expand to conduits of less than 16 mm in original diameter, as covered stent implantation would minimize the risk of conduit tear.

As the experience with the Melody Valve™ continues to grow, its applications expand. Several non-conventional indications have emerged as outlined above. Off-label use of existing PPV stents via hybrid and intraoperative implantation may benefit a select group of high-risk patients whose comorbidities render traditional surgical valve replacement unacceptable.[21,23,28]

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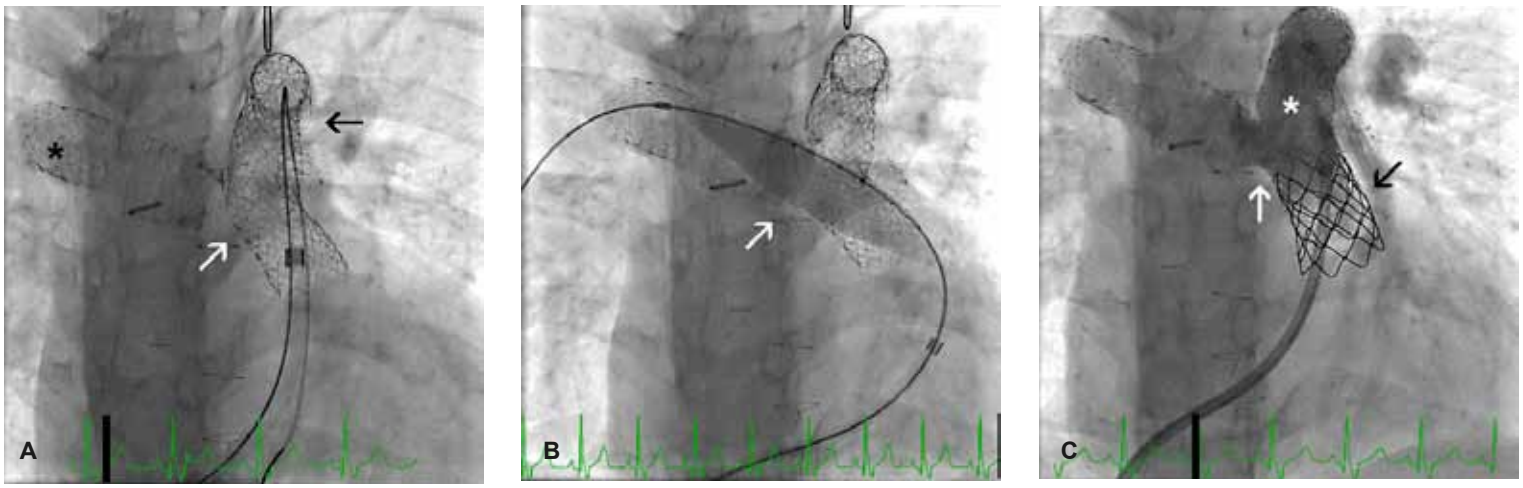

Figure 13 A-C: (A) Spot cine performed in a patient following stenting of a stenotic right ventricle to pulmonary artery conduit. Extensive pulmonary artery stenting had been performed in both left (black arrow) and right (asterix) pulmonary artery. The conduit stent overlaps the takeoff of the right pulmonary artery (white arrow). (B) After sequential balloon angioplasties with progressively larger balloons the proximal right pulmonary artery is dilated with a 16 mm Altas balloon without waist. The open cell design stent allows for expansion of the stent strut without major difficulty. (C) Following Melody Valve™ implantation (black arrow), a main pulmonary artery (asterix) angiogram demonstrates no significant pulmonary valve insufficiency and open flow pattern into the right pulmonary artery which had no pressure gradient (white arrow).

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Indications

The Melody® Transcatheter Pulmonary Valve is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic Right Ventricular Outflow Tract (RVOT) conduits with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting.
- Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted.
- The intended lifetime for the Melody® device is 2 years.

Contraindications

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath; Implantation in left heart;
- Unfavorable right ventricular outflow tract for good stent anchorage;
- Severe right ventricular outflow obstruction, which cannot be dilated by balloon;
- Obstruction of the central veins;
- Clinical or biological signs of infection;
- Active endocarditis;
- Known allergy to aspirin or heparin;
- Pregnancy.

Potential Complications / Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

For additional information, please refer to the Instructions For Use provided with the product.

The Melody® Transcatheter Pulmonary Valve and Ensemble® Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe. Additionally, a Medical Device Licence has been granted and the system is available for distribution in Canada.

Effect of Endotracheal Suctioning on Dynamic Lung Compliance after Manual Hyperinflation in Mitral Valve Replacement Surgery Patients

By Nizamuddin, MPT; Faizan Ahmed, MPT; Muhammed Abid Geelani, MD, MCH; Jamal Ali Moiz, MPT, PhD

Abstract

Objectives: Mitral valve disease patients have reduced lung compliance due to the pathology of the disease itself. In addition to the disease, anesthesia, cardiopulmonary bypass and mechanical ventilation further reduce lung compliance. Endotracheal suctioning has been reported to produce decreased lung compliance and it is still widely practiced. Therefore, the objective of our study is to investigate the effect of endotracheal suctioning and manual hyperinflation (MHI) on dynamic lung compliance (Cdyn) in mechanically ventilated mitral valve replacement surgery patients.

Methods: A prospective randomized control trial was conducted with a sample of 30 mechanically-ventilated patients who had undergone mitral valve replacement surgery. Both the experimental and control group underwent four sets of eight compressions of Manual Hyperinflation procedure at 10-12 breaths/min with 2:1 ratio at 40 cm H_2O. The experimental group underwent tracheal suctioning for a maximum of 15 seconds after every eight compressions of hyperinflation. Cdyn, heart rate (HR), PCO_2, PaO_2 and SaO_2 were measured five minutes before, 1 minute after, and 30 minutes after (for experimental group only) an intervention.

Results: No significant ($p>0.05$) Between-group difference was observed for Cdyn ($p=0.841$), HR ($p=0.846$), PCO_2 ($p=0.324$), PaO_2 ($p=0.450$) and SaO_2 ($p=0.718$) immediately after intervention. Within group analyses showed a non-significant increase in Cdyn ($p=0.174$) and SaO_2 ($p=0.859$) and non-significant decrease in PCO_2 ($p=0.7$) and PaO_2 ($p=1.0$) immediately after intervention in the experimental group whereas, a significant increase in Cdyn ($p=0.001$), HR ($p=0.0001$) and PaO_2 ($p=0.031$) was noted in the control group immediately after intervention and a non-significant increase in SaO_2 ($p=0.358$) and non-significant decrease in PCO_2 ($p= 0.348$) immediately after intervention.

Conclusions: Manual hyperinflation, when performed with and without suction, with a pressure of 40 cm H_2O on a group of post-mitral valve replacement surgery patients no deleterious effect on arterial blood gas value and dynamic lung compliance. Therefore, this study suggests that endotracheal suctioning in conjunction with manual hyperinflation does not produce any deleterious changes in dynamic lung compliance and oxygenation in mechanically ventilated mitral valve replacement surgery patients.

Keywords: Endotracheal suctioning; Manual hyperinflation; Dynamic lung compliance; Respiratory mechanics; Hemodynamics.

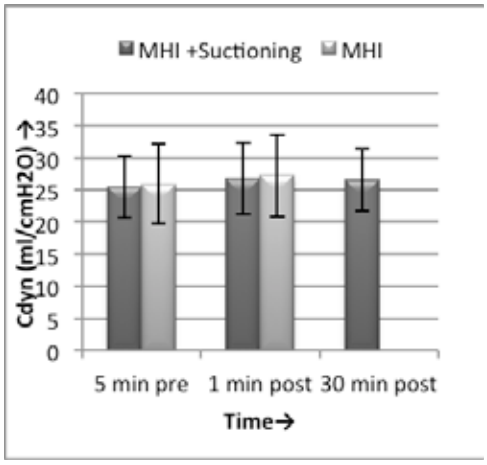

Figure 1. Comparison of dynamic lung compliance.

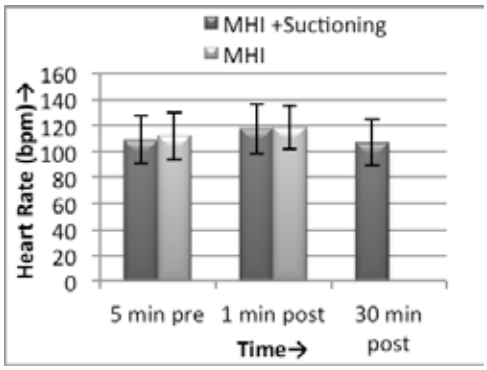

Figure 2. Comparison of heart rate.

Introduction

Mitral valve disease is frequently associated with various pathological changes in respiratory function such as: decreased lung volumes, diffusing capacity and decreased static and dynamic lung compliance.[1]

Chronic disease is especially associated with increased pulmonary vascular pressure which invariably reduces the lung compliance and increases airway resistance.[2,3] During cardiac surgery, the use of general anesthesia muscle paralysis, mechanical ventilation, thoracotomy and cardiopulmonary bypass further substantially influences lung function.[1] General

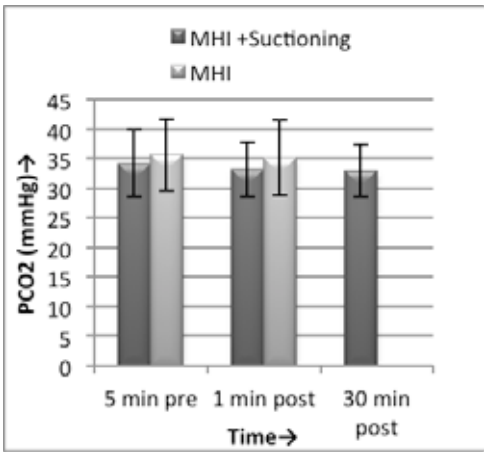

Figure 3. Comparison of PCO_2.

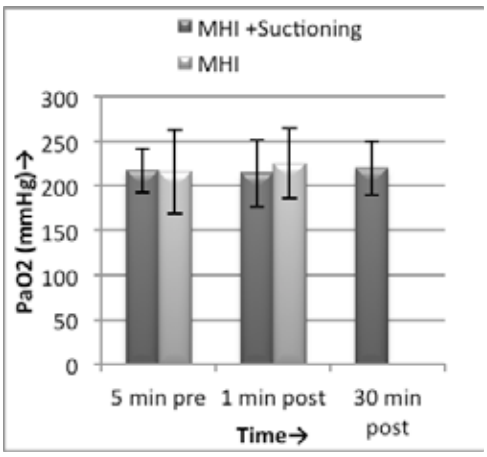

Figure 4. Comparison of PaO_2.

anesthesia has been reported to cause depression of mucociliary functioning resulting in decreased mucus clearance in the perioperative period.[4] Cardiopulmonary bypass has been reported to produce a significant decrease in dynamic and static lung compliance during perioperative and postoperative period.[5,6] Moreover, mechanically ventilated patients are incapable of removing secretion from their airway as the glottis cannot be closed for an effective cough. This has been the rationale behind the practice of applying routine endotracheal suctioning to these patients.[7] Although endotracheal suctioning has been reported to have many adverse effects, including reduced lung compliance, it is still widely practiced in intubated patients. The disconnection of a patient from the ventilator during open-tracheal suctioning allows pressure to fall to atmospheric pressure,[7,8] which invariably reduces lung volume resulting in further decrease in lung compliance.[9] In mechanically

Table 1. Demographic Data					
Characteristics	Mean ± Std. Deviation (SD) (n=30)	MHI + Suction (n=15)	MHI (n=15)	t	p
Age (years)	29.73 ± 9.38	31.07 ± 10.33	28.40 ± 8.47	0.773	0.446
Height (meters)	1.58 ± 0.06	58.67 ± 5.86	157.53 ± 5.70	0.537	0.596
Weight (Kg)	43.30 ± 7.3	42.40 ± 5.88	44.20 ± 8.64	-0.67	0.510
BMI (Kg/m2)	17.275 ± 2.46	3.80 ± 0.49	3.68 ± 0.63	0.61	0.549
Cardiopulmonary bypass time (minutes)	82.10 ± 28.04	88.67 ± 31.55	75.53 ± 23.26	1.29	0.205

Table 2. Between-Group Comparison				
Variables	MHI Suctioning	MHI	t-test	
	Mean ± SD	Mean ± SD	t	p
Cdyn BL	25.57 ±4.87	25.97 ±6.25	-0.189	0.851
Cdyn 1 min	26.84 ±5.58	27.29 ±6.38	-0.203	0.841
HR BL	108.53 ±18.19	111.73 ±18.44	-.478	0.0636
HR 1 min	117.20 ±18.89	118.47 ±16.53	-0.195	0.846
PCO_2 BL	34.17 ±5.72	35.74 ±6.08	-0.730	0.471
PCO_2 1 min	33.17 ±4.59	35.21 ±6.38	-1.004	0.324
PaO_2 BL	217.53 ±24.46	215.71 ±47.47	0.132	0.896
PaO_2 1 min	214.20 ±36.85	224.80 ±38.84	0.450	0.450
SaO_2 BL	99.41 ±0.52	99.30 ±1.12	0.740	0.740
SaO_2 1 min	99.55 ±0.35	99.47 ±0.77	0.718	0.718

ventilated patients suction is always performed after chest physiotherapy and/or after a manual hyperinflation session so as to clear a larger amount of secretion from airways. However, both manual hyperinflation and suctioning produces an alteration in respiratory mechanics in addition to the effects of cardiopulmonary bypass and anesthesia in these patients. The combined effects of both the techniques on static lung compliance have been well-documented, but the effects on dynamic compliance have not been demonstrated. Some studies suggest a decrease in static lung compliance[8,10,12] while others suggest an increase in static lung compliance.[4,11] In contrast to static lung compliance very limited studies can be found on dynamic lung compliance. Most of the studies on dynamic lung compliance, were conducted on a pediatric population and reported a decrease in dynamic lung compliance after suctioning.[10,12,13]

Only a few studies have been reported on the effect of suctioning on dynamic lung compliance in adults and even lesser studies are found on combined effect of manual hyperinflation and endotracheal suction. There is almost no study that can be found on the effect of endotracheal suction and manual hyperinflation on mitral valve replacement surgery patients. Therefore, the present study is intended to determine whether suction and manual hyperinflation improves or diminishes the lung compliance in those mitral valve disease patients who are already having reduced lung compliance due to disease, which is further reduced during anesthesia, cardiopulmonary bypass and mechanical ventilation.

Methods

Design

The study was a prospective, pre-test post-test control group, interventional, randomized study.

Procedure

The approval of the study was obtained by the board of studies of the institution. A day before surgery patients scheduled for mitral valve surgery were approached and explained about the type and nature of study. All the agreed subjects were requested to sign the informed consent form preoperatively. Three to four hrs after a standardized surgical procedure a detailed evaluation was performed on the mechanically ventilated mitral valve replacement surgery patients. Then a total sample of 30 subjects was selected according to inclusion and exclusion criteria.

The inclusion criterion consists of post-mitral valve replacement surgery patients, Intubated and mechanically-ventilated patients with continuous mandatory ventilation (CMV) mode, age group 20-50 years. Subjects with arterial oxygen saturation ≤ 90%, associated lung pathology e.g. COPD and acute Respiratory Distress Syndrome (ARDS).[11] Unstable blood pressure[11] (MAP < 75 mmHg), requiring high respiratory support[11] (FiO_2 ≥0.7 and PEEP > 10cm H^2O), air leakage,[14] severe bronchospasm[14] were excluded. All the patients recruited in the study were ventilated with a Siemens Servo 300 Ventilator on volume control mode with FiO_2 of 50% after surgery.

The selected patients were then randomized into two groups, Group-A (MHI+Suctioning) or Group-B (MHI), equally. On the day of measurement, each patient was positioned in supine and undisturbed for 15 minutes prior to data collection. All sterile measures were carefully taken before touching the patient. Five minutes before the intervention the first data (baseline) was collected. At the end of five minutes, relevant intervention, according to the group assigned, was delivered to the patient. Group-A patients were delivered manual hyperinflation along with suctioning according to standard protocol using a two-liter sterile ShineBall® (Taiwan) self-inflating resuscitator bag and a sterile FG-12 suction catheter respectively. The suction pressure was set to -150 mmHg. Group-B patients received only manual hyperinflation using a two-liter sterile resuscitator bag as an intervention. The second set of data was collected one minute after the completion of the respective intervention. After collecting the second data control group (Group-B), patients were given endotracheal suctioning to remove the collected secretion in the trachea. The third set of data was collected 30 minutes after the intervention in an experimental group only, and couldn't be collected for Group-B patients, as the same sample got contaminated due to the suctioning procedure performed after collecting second set of data (1 minute after intervention).

Protocol

Group A: Manual Hyperinflation and Endotracheal Suctioning

Four sets of eight bag compressions, connected to 100% oxygen (15 L/min), with both hands were delivered during each

Table 3. Within-Group Comparison of the Experimental (MHI+Suctioning) Group								
Variables	BL (n=15)	1 Min Post	30 Min Post	ANOVA		Post Hoc Significance (p)		
	Mean ± SD	Mean ± SD	Mean ± SD	F	p	BL to 1 Min	1 Min to 30 m	BL To 30 Min
Cdyn	25.575 ± 4.87	26.842 ± 5.58	26.59 ± 4.84	3.13	0.077	0.174	1.0	0.063
HR	108.53 ±18.19	117.20±18.89	106.60 ±17.48	27.69	0.0001	0.0001	0.427	0.0001
PCO_2	34.17 ± 5.72	33.167 ± 4.59	32.99 ± 4.45	1.05	0.379	0.70	0.467	1.0
PaO_2	217.53 ±24.46	214.2 ±36.85	219.47 ±29.63	0.63	0.088	1.0	1.0	0.803
SaO_2	99.41 ± 0.52	99.553 ± 0.35	99.43 ± 0.58	0.75	0.490	0.859	1.0	1.0

Table 4. Within-Group Comparison of Control (MHI) Group			
Variables	BL	1 Min	p
	Mean ± SD	Mean ± SD	
Cdyn	25.96±6.52	27.2 ±6.38	.001
HR	111.73±18.44	118.47±16.53	.0001
PCO_2	35.74±6.08	35.2 ±6.38	.348
PaO_2	215.71±47.47	224.80±38.84	.031
SaO_2	99.30±1.12	99.47±0.77	.358

manual hyperinflation session. The rate of inflation was 10-12 breaths/minute with inspiratory: expiratory ratio of 2:1. A pressure manometer was attached to the self-inflating resuscitator bag and each compression was delivered to a peak airway pressure of 40 cm H_2O, aiming to maximize lung volume and followed by a two-second inspiratory pause and then a quick release of the bag to enhance the expiratory flow rate. Tracheal suctioning was applied after delivery of eight manual hyperinflation breaths. The duration of each pass of suction was limited to 15 seconds. Tracheal suctioning was performed once per set of eight bag compressions.[11]

Group B: Manual Hyperinflation

Four sets of eight bag compressions, connected to 100% oxygen (15 L/min), with both hands were delivered during each manual hyperinflation session. The rate of inflation was 10-12 breaths/minute with inspiratory: expiratory ratio of 2:1. A pressure manometer was attached with the self inflating resuscitator bag and each compression was delivered to a peak airway pressure of 40 cmH_2O, aiming to maximize lung volume and followed by a two-second inspiratory pause and then a quick release of the bag to enhance the expiratory flow rate. After every eight compressions, the patient was reconnected to ventilator for one minute then, again eight compressions was delivered.[11]

Statistical Analysis

The complete data was analyzed using SPSS 15.0 for Windows® software. First a detailed description was obtained using descriptive statistics and then the data was analyzed to find any baseline differences. An Independent t-Test was used to analyze the Between-group differences. A repeated measure ANOVA was performed for analysis of within subject differences. The repeated measure of time was baseline, one minute after and 30 minutes post-intervention. The repeated measure test was applied only to the experimental group, as there was no post-30 minutes data for the control group. The paired t-Test was used for analysis of subject differences between baseline and one-minute post-intervention (immediately) in the control group.

Results

Sample

A total sample of thirty subjects (n=30) with age group between 20-50 years with mitral valve replacement surgery was used for the study.

Patients Characteristics

The demographic data and baseline differences in the data for all the subjects are mentioned in Table 1. There were no statistically significant differences found between the baseline data of the two groups. The sample contained a greater number of women 66.67% (n=20) than men 33.33% (n=10). Thirty-six point sixty-seven percent (n=11) of total patients were implanted with bioprosthetic valves, and the remaining 63.33% (n=19) of subjects were implanted with mechanical valve.

Outcome Measures

Between-group comparisons showed no statistically significant (p>0.05) difference between the variables of two groups (MHI + Suctioning and MHI group). The dynamic compliance showed a non-significant (p=0.841) improvement immediately (1 minute) after intervention (p=0.841). The heart rate (p=0.85), PCO_2 (p=0.32), PaO_2 (p=0.45) and SaO_2 (p=0.71) also showed a non-significant (p>0.05) change Between-group analyses of immediate post-intervention data.

Within-group analysis of the experimental group showed a non-significant (p=0.174) increase (4.97%) in dynamic lung compliance from baseline (25.575 ± 4.873) (Mean ±SD) to 1 minute post-intervention (26.842 ±5.582). Similarly, 1 minute post-intervention data when compared with 30 minute post (26.59 ±4.839) intervention data also resulted in non-significant (p=1.0) decrease (0.93%) in dynamic lung compliance. Baseline data compared with 30 minute post-intervention data also showed non-significant (p=0.063) improvement (3.989%) in dynamic lung compliance, whereas, the control group (MHI), showed a significant (p=0.001) increase (5.1%) in dynamic lung compliance from baseline (25.962 ± 6.250) to 1 minute post-intervention (27.286 ± 6.379).

The heart rate in the experimental group showed a significant (p=0.0001) increase (8.018%) from baseline (108.53 ±18.197) to 1 minute post-intervention (117.20 ±18.895).

Baseline data, when compared with 30 minute post-intervention (106.60 ±17.484) data, resulted in non-significant (p=0.427) decrease (1.75%) in heart rate. Similarly, 1 minute post-intervention data with 30 minute post-intervention data resulted in a significant (p=0.0001) decrease (9.04%) in heart rate. The control group showed a significant (p=0.0001) increase (6.03%) in heart rate.

Within-group analysis of the experimental group showed a non-significant (p=0.70) decrease (2.926%) in PCO_2 between baseline (34.167 ± 5.717) to 1 minute post-intervention (33.167 ± 4.596) data. Similarly, comparison between 1 minute post-intervention data with 30 minute post-intervention (32.99 ± 4.448) data and baseline data with 30 minute post-intervention data also showed a non-significant decrease (p=0.467) (3.436%), (p=1.0) (0.525%) in PCO_2 respectively. The control (MHI) group also showed a non-significant (p=0.348) decrease (1.4%) in PCO_2 between baseline (34.16 ± 5.717) and 1 minute post intervention data (33.167 ± 4.596).

A non-significant (p=0.70) decrease (2.93%) in PCO_2 was found between baseline (34.167 ± 5.717) to 1 minute post-intervention (33.167 ± 4.596) data in the experimental group. One minute post-intervention data compared with 30 minute post-intervention (32.99 ± 4.448) data, also showed a non-significant (p=0.467) decrease (3.45%) in PCO_2. The comparison between the baseline data and 30 minute post-intervention data, also resulted in non-significant (p=1.0) decrease (0.52%) in PCO_2.

In the control (MHI) group comparison between baseline and 1 minute post-intervention data resulted in a non-significant (p=0.348) decrease (1.4%) in PCO_2 from 34.16 ± 5.717 to 33.167 ± 4.596 was found respectively. The experimental group in the Within-group analysis, showed a non-significant (p=1.0) decrease (1.51%) in PaO_2 baseline (217.53 ± 24.462) to 1 minute post-intervention (214.20 ± 36.848) data. One minute post-intervention data compared with 30 minute post- intervention (219.47 ± 29.63) data also resulted in a non-significant (p=0.803) increase (2.4%) in PaO_2. Similarly, baseline compared with 30 minute post-intervention data also resulted in a non-significant (p=1.0) increase (0.92%) in PaO_2. The control group showed a significant (p=0.031) increase (4.22%) in PaO_2 from baseline (215.71 ± 47.47) to 1 minute post (224.80 ± 38.84) intervention data.

SaO_2 showed a non-significant (p=0.859) increase (0.15%) from baseline (99.407 ± .518) to 1 minute post-intervention (99.553 ± .354) data in the experimental group. One minute post-intervention data compared with 30 minute post-intervention (99.43 ± .58) data resulted in a non-significant (p=1.0) decrease in SaO_2. The decrease was 0.12%. Comparison between baseline data and 30 minute post-intervention data also showed a non-significant (p=1.0) increase (0.03%) in SaO_2. In the control group, the comparison resulted in a non-significant (p=0.358) increase (0.17%) in SaO_2 from baseline (99.300 ± 1.118) to 1 minute post -intervention (99.473 ± 0.770).

Discussion

To our knowledge this is the first study to investigate the effect of ET suctioning and MHI on dynamic lung compliance in sedated, paralyzed mitral valve replacement surgery patients during volume control mode of ventilation on the day of surgery.

Both of the groups showed a non-significant increase in dynamic lung compliance from the baseline values. Between-group comparison of dynamic lung compliance showed a non-significant change which shows that, suction along with MHI does not produce any adverse effects on pulmonary function; it does, however, produce a similar change in dynamic lung compliance as is produced by manual hyperinflation alone. The probable reason for this might be the dominating effect of manual hyperinflation on the suctioning. Since the suction catheter was passed only for once per eight bag compression the adverse effect of suctioning would have been less on pulmonary function and the application of manual hyperinflation with a larger-than-normal tidal volume breath, together with an inspiratory pause, may have facilitated collateral ventilation and effective recruitment of alveoli, thereby, preventing the adverse effect of suctioning and resulting in increased dynamic lung compliance.[11]

Within-group comparison of the experimental group showed an improvement of 4.97% in dynamic lung compliance which was statistically insignificant in immediately post-intervention duration. The result of the present study was comparable with the study by Morrow et al, in 2007[12] where, when recruitment maneuver was performed after ET suction, a non-significant increase in dynamic lung compliance was observed immediately after intervention. Five minutes after an ET suctioning procedure was used on pediatric patients, MHI was performed. The researchers reported that the decrease in dynamic lung compliance from suctioning resolved spontaneously with an unchanged ventilator setting. In the present study, MHI was given immediately in conjunction with suctioning. Therefore, the effect produced was not due to ventilator settings. The present study is also supported by the study by Blattner et al. in 2008[4] where, when MHI was applied following suctioning a significant increase in static lung compliance was reported in fifty-five myocardial revascularization patients. In another similar study by Siu-Ping et al in 2005,[11] when manual hyperinflation and suction was applied on fifteen adult mechanically-ventilated pneumonia patients, a significant increase (22%) in static lung compliance was observed. In another similar study by Patman et al in 2000,[15] when manual hyperinflation alone was administered to mechanically ventilated CABG patients, they showed a significant increase (15%) in static lung compliance. All the above studies showed an increase in lung compliance.

In contrast to the above studies, some have reported a decrease in dynamic lung compliance after the application of intervention. A study by Morrow et al, in 2006,[13] where when, suction alone was administered to mechanically-ventilated, seventy-eight pediatric patients a significant decrease in dynamic lung compliance was reported. In an animal study by Almgren et al, in 2004,[8] when suction alone was administered to subjects with pressure controlled and volume controlled ventilation, a significant decrease in dynamic lung compliance was reported. The suction procedure in the present study might have caused a decrease in lung compliance in the ventilated patients. Since the suction catheter was introduced only once per eight bag compressions, the fall in lung compliance might have been less, and the effect of manual hyperinflation might have overcome the adverse effect of suctioning; therefore, the immediate improvement in dynamic lung compliance which occurred in the present study might have been caused by the manual hyperinflation procedure. Furthermore, none of the patients in the present study produced large amount of secretions, and only minimal amounts of secretions were removed during the manual hyperinflation and suction interventions. This minimal change in the airway clearance and the additive effect of manual hyperinflation might

have been the additional probable reason for a non-significant improvement in the dynamic lung compliance in 1 minute post-intervention (immediately). In the post 30 minute period the dynamic lung compliance demonstrated a fall of 0.93% from 1 minute post-intervention to 30 minute post-intervention in the experimental group. This fall in dynamic lung compliance is also statistically non-significant. The probable cause of fall in the lung compliance in the post-30 minute period may be due to a cascade fall in the number of reinflated alveoli and the supine position.

heart rate also showed a non-significant change when compared for Between-Ggroup analyses. Both the group showed increase in heart rate from the baseline, but the difference between the groups was non-significant. Within-group comparison of experimental group showed a significant increase (8.02%) in heart rate in immediate post-intervention duration. The result of the present study can be comparable to a study by Lee et al, in 2001 where, they reported a significant increase in heart immediately after first pass and second pass of open suctioning procedure in fourteen adult ventilated patients.[16] The result of the present study is also consistent with the study results found by Stone et al, in 1991, where a statistically significant increase in heart rate was observed from baseline after the three lung hyperinflation-suctioning sequences in CABG patients.[17] This indicates that suctioning along with manual hyperinflation increases heart rate. The probable cause for an increase in heart rate in the present study may be the activation of sympathetic receptors present in large airways, and the discomfort that occurred due to the suctioning procedure.[18] At the 30 minute post-intervention, the heart rate reduced (9.04%), significantly returning to the baseline value in experimental group. The probable reason for reduction in the heart in the present study, may be due to the relief from suction discomfort. Involvement of parasympathetic activity and vagal stimulation, may be the other valid cause of decrease in heart rate.[19,20]

Between-group analysis of PCO_2 resulted in a non-significant change in the immediate post-intervention period. This indicates that both the group results in similar amounts of CO_2 washout in immediate post-intervention duration. The PCO_2 value did not alter significantly after any intervention, indicating that minute ventilation remained adequate.[21] Within-group comparison of experimental group also resulted in a non-significant decrease (2.93%) in PCO_2 at 1 minute post-intervention and 30 minute post- intervention (3.43%). Since the number of breaths for MHI was kept constant (10-12 breath/min), the minute ventilation might have remained adequate. This is in agreement with the attempts made to maintain alveolar ventilation by decreasing the respiratory rate and increasing the tidal volume for hyperinflation. Maintained ventilation of the alveoli during hyperinflation may have prevented a marked washout of CO_2 from the blood. The present finding is supported by Paratz et al. where PCO_2 did not alter post-MHI as alveolar ventilation was maintained.[22]

PaO_2 also showed a non-significant difference between the groups at 1 minute post-intervention. Although the difference in PaO_2 is non-significant, the improvement was found to be greater in control (MHI) group. This may be due to the fact that MHI might have recruited the atelectatic lung units and might have created a better room for gaseous exchange.[23] Between-group comparison also showed a non-significant increase in PaO_2 in experimental group at 1 minute post (1.52%) and at 30 minute post-intervention (2.47%). This indicates that suction did not produced any adverse effect on PaO_2 value, rather that PaO_2 value increased 30 minute after intervention in the experimental. Studies have suggested that suction, when applied in mechanically-ventilated patients, produces a significant decrease in PaO_2 levels in the blood.[8,20,24] In the present study, a decrease in PaO_2 was non-significant, which means the fall in PaO_2 was less, which indicate that lung function has mot much deteriorated after suctioning procedure.

The application of MH may utilize intercommunicating channels, or collateral ventilation within the lungs, to facilitate the mobilization of secretions and the recruitment of atelectatic lung units, thereby, improving FRC.[25] This might be the cause for better gaseous exchange. Since both suctioning and manual hyperinflation were used in the present study, the manual hyperinflation might have masked the adverse effect of suctioning by opening the collateral channel in the lungs and improving the alveolar recruitment and gaseous exchange.

No statistically significant difference in SaO_2 was found between the two groups. Within-group comparison of SaO_2 also showed a non-significant increase at 1 minute post (0.15%) and at 30 minute post-intervention (0.12%). Under normal condition the value of PaO_2 is ≥ 95 mmHg and value of SaO_2 is ≥ 97%. The maximum value of saturation under normal condition is 100%. In the present study all the patients have a saturation value above 97%. Therefore, the change observed in patients was very small and it was clinically insignificant. Since the value of PaO_2 affects the saturation a non-significant change in PaO_2 may be the other probable cause for non-significant change in SaO_2.

Limitation of the study includes the inability to use a more accurate method of measuring dynamic lung compliance in mechanically ventilated patients. The 30 minute post-intervention data could not be collected in the control group, as suctioning was required to be done immediately after intervention in order to remove collected mucus in the central airway. Another limitation includes the lack of fixed dosimetry for suctioning procedure.

Further study is required to be done in various groups of population, including double-valve replacement surgery patients. The sample size used in the study was insufficient to generalize the result therefore a study with a larger sample size is need to be done. Furthermore, study with different protocol of manual hyperinflation and suctioning is required to be done. This study have found the short-term effects of manual hyperinflation and suction on dynamic lung compliance, long-term effect of the same is required to be done in future.

Conclusion

In conclusion, our results show that manual hyperinflation when performed with and without suction with a PIP of 40 cm H_2O on a group of post-mitral valve replacement surgery patients has no deleterious effect on arterial blood gas value; dynamic lung compliance was found. Therefore, this study suggests that endotracheal suctioning in conjunction with manual hyperinflation does not produce any deleterious changes in dynamic lung

compliance and oxygenation in mechanically ventilated mitral valve replacement surgery patients.

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Medical News, Products and Information

Unique Cardiac Training Gives NewYork-Presbyterian/Columbia Doctor Ability to Treat Heart Patients With Hybrid Approach

Patients with coronary artery disease -- blockages of the vessels that feed the heart -- can be treated in a number of ways. With their doctor, they decide on the best course of action: surgery, stent placement or medication. Sometimes, a combination of these is the best approach.

Hybrid cardiac revascularization procedures, a combination of bypass and stenting, can reduce the stress of surgery, speeding recovery and potentially improving outcomes.

Dr. Mathew Williams, one of the only physicians in the world trained as both a cardiothoracic surgeon and interventional cardiologist, performs the hybrid procedures at NewYork-Presbyterian Hospital/Columbia University Medical Center.

"Because of my training, I am particularly aware of the benefits and risks of bypass and stenting, and can recommend a customized treatment plan that works best for the patient whether it's one or the other, or both," says Dr. Williams, Surgical Director of Cardiovascular Transcatheter Therapies at NewYork-Presbyterian Hospital/Columbia University Medical Center and Assistant Professor of Surgery in Medicine at Columbia University College of Physicians and Surgeons.

The hybrid approach usually involves minimally invasive surgery using the internal mammary artery to bypass the most important coronary branch, the left anterior descending (LAD). This is followed by a stenting procedure in which tiny metal scaffolds are inserted through an artery in the patient's groin and positioned to prop open the other blocked arteries.

The next step is for both procedures to be performed concurrently. This is possible in a specially-equipped hybrid operating room at the Vivian and Seymour Milstein Family Heart Center at NewYork-Presbyterian Hospital/Columbia University Medical Center.

Dr. Williams also offers a hybrid approach for other cardiac procedures, including treatment for aneurysms and aortic valve replacement. NewYork-Presbyterian/Columbia also offers hybrid procedures for neurology patients.

"Hybrid procedures are an emerging trend. This is good news for our patients, especially as more physicians receive dual training in surgery and interventional techniques," says Dr. Craig Smith, Surgeon-in-Chief at New York-Presbyterian Hospital/Columbia University Medical Center and chairman of the Department of Surgery at Columbia University College of Physicians and Surgeons.

"The hybrid approach shows how multidisciplinary collaboration can directly benefit the patient," says Dr. Allan Schwartz, Cardiologist-in-Chief at New York-Presbyterian Hospital/Columbia University Medical Center and the Harold Ames Hatch Professor of Medicine Columbia University College of Physicians and Surgeons at Columbia University College of Physicians and Surgeons.

Dr. Mathew Williams received more than 14 years of medical training, beginning with his medical school training at Columbia University College of Physicians and Surgeons, followed by a residency in general surgery at UCLA. He returned to Columbia for a research fellowship in cardiothoracic surgery. At New York-Presbyterian/Columbia, he completed a residency in general surgery, followed by fellowships in cardiothoracic surgery and interventional cardiology.

Big Breakthrough for the Tiniest Hearts

A novel feeding device developed at the University of Pennsylvania School of Nursing may decrease the risk of failure to thrive (FTT), which currently affects half of all newborns with congenital heart defects even after their surgical lesions are corrected.

Professor and nurse practitioner Barbara Medoff-Cooper, PhD, CRNP, of Penn Nursing invented a device that analyzes an infant's ability to organize feeding by sucking, swallowing, and breathing effectively. This device, developed in collaboration with Penn bioengineers, allows healthcare professionals to assess infants at risk for dysfunctional feeding and poor weight gain as often seen in both premature infants and infants with complex congenital heart disease. The data also can be correlated with growth or developmental problems that may occur during the first year of life.

"Feeding actually speaks loudly to us about the brain," says Dr. Medoff-Cooper. "If a child is feeding well, it gives us one fewer major issue to worry about. Conversely, even a full-term infant who is not feeding well is at high risk for developmental problems."

Dr. Medoff-Cooper conducted the first comprehensive evaluation of feeding difficulties in infants with complex congenital heart defects. Her work has demonstrated that feeding behaviors can predict developmental outcomes in high-risk infants because of the complicated interplay of movements and physiologic responses needed in the feeding process. The premise of her work is that feeding effectiveness corresponds to how well infants will achieve other developmental milestones.

The University of Pennsylvania School of Nursing is one of the premier research institutions in nursing, producing new knowledge in geriatrics, pediatrics, oncology, quality-of-life choices, and other areas. Researchers here consistently receive more research funding from the National Institutes of Health than any other private nursing school, and many Master's programs are ranked first in the country. This year, faculty, students, alumni, and staff celebrate 125 years of nursing at Penn.

JUNE MEDICAL MEETING FOCUS

Cardiostim 2012 - 18th World Congress Cardiac Electrophysiology & Cardiac Techniques

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