The Evolution of the Treatment of Isolated Pulmonary Valve Stenosis

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In the course of studies covering 40 years, 1913 to 1953, leading to the development of cardiopulmonary bypass, many ingenious blind instrumental or digital intrusions were made into the heart chambers to treat lesions therein. Limits were defined for the arrest of circulation through part or all of the heart to permit a brief glimpse of the lesion and effect at least a partial correction. The often remarkably good results of operations performed under less than ideal operating conditions for lesions such as isolated pulmonary stenosis encouraged the interventional cardiologist and radiologist, working together, to adapt the cardiac catheter, used previously for exploration of the vascular system and diagnosing intravascular lesions, to therapeutic purposes. They positioned a catheter with uninflated balloon attached in the pulmonary artery, then either by inflating the balloon beyond the constricted orifice and pulling it through or by rapidly and precisely inflating the balloon lying across the orifice were able to disrupt the stricture and relieve the stenosis. Results matched those of early non-visual operations. Recently the cardiologist has expanded the approach to relieve other constricted orifices in the heart and great vessels and to close abnormal openings.

In isolated pulmonary stenosis, the nearly complete relief of obstruction and the tolerance of the circulation to blunt disruption of valvular stenosis bodes well for the long-term success of balloon valvuloplasty in this congenital malformation of the heart.

The successful treatment of isolated, or "pure," pulmonary valve stenosis, a congenital anomaly, is a remarkable example of how the developments in diagnostic and surgical technique that occurred during the twentieth century contributed to the resolution of heretofore incurable cardiac disorders. Pure pulmonary stenosis is taken to illustrate this for two reasons: One, it was this disorder for which the first deliberate intracardiac operation to correct an innate cardiac lesion was performed and, second, the evolution of treatment appears to have ended in intervention that no longer requires a surgical operation. An account of the surgical procedures applied to relieve isolated pulmonary stenosis and the development of the equally successful treatment by simple balloon disruption of the stenotic valve is the subject of this paper. The progression of mechanical maneuvers for treating isolated pulmonary stenosis, which took place between 1913 [1] and 1982 [2], is also evident in the evolution of the treatment of several other cardiac lesions.

Maude Abbott, in an autopsy review of 1,000 cases of congenitally deformed hearts, found only six cases of pulmonary stenosis with an intact cardiac septum. In nine other cases, the foramen ovale was patent, allowing venous blood to pass unoxgenated to the left side and into the systemic circulation [3]. In a more recent study of nearly 20,000 live births, pulmonary stenosis accounted for about 7 percent of cases of congenital heart disease.

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heart disease [4]. Typically, the valve leaflets, though well formed, are incompletely fused. In severe cases, the valve orifice is of pinhole size, and in such cases death may occur suddenly. With less severe stenosis, patients may remain asymptomatic for years; if untreated, most eventually succumb to failure of the right ventricle or to infection.

In 1913, Doyen of Paris (Fig. 1), a dextrous and innovative surgeon, though one with a flamboyant style unappealing to his colleagues, made the first attempt to relieve what he believed to be pulmonary valvular stenosis in a 20-year-old cyanotic patient. The account of Doyen’s landmark, though unsuccessful, operation, was recorded by J. Dumont, as follows [1]:

Last January during his clinic, M. Doyen made the diagnosis of pulmonary infundibular stenosis in a 20-year-old girl with “blue disease” or cyanosis and who had experienced several syncopes a day. The good results of sutting the wounds of the heart led him to think it was not impossible to perforate the heart and to attempt the section of a shrunken orifice.

M. Doyen built a special tenotome and he decided which surgical technique to use for this procedure. This young patient was a minor and he had to wait for the approval of her family. During the day, the patient became worse and in the next morning, before the surgery, she had several syncopal episodes. The heart was exposed, the tenotome introduced in the right ventricle but the attempt to cut the shrunken point did not succeed in increasing the blood to the lung and the cyanosis persisted, even with 100 percent oxygen. The patient survived the immediate procedure but died the next morning. The examination of the heart showed the stenosis was situated in a completely different way than they
thought: The right ventricle was in communication with the left ventricle and a wall, on the contrary, interrupted the communication between the right ventricle and the pulmonary artery. This wall presented in its middle a small hole (4 mm) with inflammatory edges which could have been decreasing in the last few weeks. The picture of the organs showed that each lung was just a little bigger than the heart. Thus they did not receive 1/20th of the blood flow they should have received. Examination of the specimen permitted M. Doyen to recognize that in such a case one could correct the malformation not with a tenotome but by making a small incision under the pulmonary artery and rapidly removing a small crown of tissue all around the small orifice, then immediately suturing the heart, and all is finished.

M. Doyen studied at the same time the surgical technique which could be an appropriate technique for mitral stenosis, a quite frequent disease often the result of rheumatism, and he determined the precise technique for using the tenotome in mitral valve stenosis.

An interesting detail: that is, one cannot attempt a similar operation without wearing rubber gloves and above these rubber gloves, cotton gloves to be able to gently handle the heart in the left hand without interrupting its pulsations.¹

Obviously, Doyen's patient did not have an isolated pulmonary stenosis but a tetralogy of Fallot, a condition not amenable to simple pulmonary valvulotomy. Many years later, in 1945, Blalock and Taussig [5] were to devise an operation to bypass the obstructed right ventricular outflow tract and increase the flow of unoxygenated blood to the lungs by anastomosis of a systemic artery to the pulmonary artery. The success of their operation was to have a galvanizing effect on the further development of cardiac surgery for congenital malformations of the heart [6].

Except for some remarkable experiments in dogs during 1914 by Carrel, who exposed and manipulated the pulmonary valve and other intracardiac structures during short periods of circulatory occlusion [7], the enthusiasm for intracardiac surgery languished until the early 1920s, when there was a flurry of activity directed principally toward the surgical relief of mitral stenosis. The invention of a cardioscope by Allen and Graham in 1922 [8] made it possible to operate on the valves of the heart (including the pulmonary valve) with the heart beating, which appeared at first would enhance intracardiac operations. The instrument consisted of a closed tube with at its tip a light covered with a glass lens, and, held by a groove in the center of the lens, a knife blade which could be advanced to cut the constricting valve ring by a handle attached to it at a right angle and positioned parallel to the tube (Fig. 2). The safest approach to the pulmonary valve with the cardioscope was found to be through the left pulmonary artery. Using the cardioscope, they also visualized the mitral valve through the left atrial appendage. Allen and Graham are said to have used their instrument in one patient, though without success [9].

In 1948, Brock [10], using a cardioscope of his own design, attempted to visualize the pulmonary valve and relieve pulmonary stenosis by way of the left pulmonary artery. After three unsuccessful attempts he abandoned the technique. Brock concluded that visualization of the pulmonary valve from the pulmonary artery before surgically relieving the stenosis carried too high a risk. He then turned to Doyen's

¹I am grateful to Dr. Bernard Vasseur for this translation from the original article.
transventricular approach, using a specially designed spade-shaped knife. Subsequently, an expandable metal dilator was added to split the valve leaflets further after passage of the valvulotome. Using this technique of pulmonary valvulotomy, he and others achieved good results with low risk to the patient. Sellors [11], another prominent English thoracic surgeon, had, shortly before Brock’s first successful case, also relieved pure pulmonary stenosis using the transventricular approach; he used a tenotomy knife to cut open the stenosed valve in two places. Potts in 1950 [12] (Fig. 3) designed an elegantly crafted forward-cutting valvulotome with retractable blades, and Himmelstein designed an instrument with backward-cutting retractable blades with which to excise a portion of the valve [14].

Just as the surgical techniques for the relief of pulmonary stenosis as well as other intracardiac lesions were improved, so were diagnostic techniques. Cardiologists had become adept at locating precisely the site of the pulmonary stenosis and detecting and assessing associated lesions. Now, armed with factual physiologic and clinical information, cardiac surgeons could perform operations which were more therapeutic than exploratory. But, dissatisfied with the incomplete relief of pulmonary stenosis obtained by blindly cutting the valve leaflets from below the valve and disenchanted with the cardioscope, they strove to develop techniques for the complete relief of valve stenosis through intra-arterial control of the valvulotomy and through direct exposure of the valve.

In the early 1950s, new surgical techniques to correct pulmonary stenosis through the pulmonary artery were introduced. Søndergaard employed a supravalvular approach without interrupting the circulation [15]. Having applied to the wall of the
pulmonary artery a clamp of a design he evolved from an earlier clamp to isolate and thus expose a portion of the atrial septum, Søndergaard attached to this clamp a rubber sleeve and through this sleeve passed scissors which engaged and incised the valve leaflets. A technique developed elsewhere also involved attaching an entry sleeve, but in this case a rubber or fabric diverticulum was sutured directly to the wall of the right ventricle [16] or main pulmonary artery [17]. This procedure made it possible to introduce the finger along with the scissors to enable a digital assessment and control of the procedure (Fig. 4). Digital examination and, if necessary, incision into and spreading of the hypertrophied subvalvular muscle in the infundibular area was also possible with this diverticulum approach. Soutter et al., and others [18,19], performed pulmonary valvulotomy through the central end of a branch of the pulmonary artery after lung resection for tuberculosis.

During this period, Varco and others [19] returned to the experimental technique
for valve exposure introduced by Carrel in 1914 [7], employing temporary interruption of the circulation by venous inflow occlusion at normothermia. They expeditiously, under direct vision, opened the pulmonary artery above the valve and made several quick incisions in the leaflets. The operation was a stressful experience for the surgical team and, at best, achieved a technically perfect valvulotomy only some of the time. Nevertheless, Lam subsequently used this technique in 48 consecutive pulmonary valvulotomies with but one death [20].

The results of pulmonary valvulotomy done with either brief visual or more deliberate digital guidance to the stenotic valve from the pulmonary artery were superior to the results with the blind techniques used earlier and were more consistent, but the surgeons were still not satisfied with the available operative techniques. They continued to seek a method that would allow them to enter either above or below the valve and provide time to operate in a bloodless field with deliberation and also to correct any other intracardiac anomalies.

In the late 1940s and early 1950s, on the basis of the fundamental work of Bigelow on induced hypothermia in animals [21], it was appreciated that cooling of the body could be used as an adjunct to intracardiac surgery. With its metabolic needs reduced, the heart could tolerate a longer period of arrested circulation. The first intracardiac operation employing inflow occlusion and body cooling was that of Lewis and Taufic [22] who, in 1952, closed an atrial septal defect in a patient who had been cooled in an ice bath after being anesthetized. Swan, in 1954 [23], performed many pulmonary valvulotomies through the pulmonary artery under the protection of hypothermia. Earlier observers had noted that, unlike the consequences of incompetence following aortic valvulotomy, incompetence from pulmonary valvulotomy was inconsequential. On this basis Swan made no attempt to create a competent pulmonary valve but strove for the widest possible valve orifice by completely relieving the stenosis (Fig. 5). Different from the results with blind transventricular valvulotomy or with a hastily performed pulmonary valvulotomy under normothermia, the results with the more deliberately performed procedures under hypothermia were consistently excellent.

Although many successful pulmonary valvulotomies were then performed, either by digital control through a diverticulum or under direct vision, for operations on the more complex lesions of the heart longer periods of exposure of the intracardiac lesion for
surgical repair of the defect were necessary. Such operations required temporary isolation of the heart.

The history of extracorporeal oxygenation of the blood, which has enabled the surgeon to isolate the heart from the circulation, dates from the mid-nineteenth century. Development of a heart-lung machine suitable for clinical application was begun in the 1930s by Gibbon [24]. As the tempo of cardiac surgery picked up in the early 1950s, several groups developed ingenious extracorporeal oxygenators, and it was inevitable that one or more of these would soon be applied in situations where the cardiac disease was amenable to surgical correction.

Another method of isolating the heart from the systemic circulation, which obviated the need for an extracorporeal oxygenator, was to use the patient's own lungs, or the lungs of another individual, substituting a simple mechanical pump for the heart.

To test the latter hypothesis, in the late 1940s a third-year medical student, William H. Sewell, Jr., constructed a small pneumatic pump, similar in principle to the present-day artificial heart, to bypass one side of the heart (Fig. 6). Venous blood was withdrawn from the venae cavae of an experimental animal into the rubber pumping chamber. Compression of the chamber ejected the blood into the cannulated right pulmonary artery and mechanically ventilated right lung. This method was applied to bypass the right ventricular chamber which, empty of blood except for the coronary venous return, afforded wide exposure of the operative field. In two consecutive experiments done with aseptic techniques, the ventricle was maintained open for one to two hours, then closed and the pump disconnected, the animals recovering completely [25]. Several years later, in 1952, Dodrill (Fig. 7), using this technique in a patient, performed a pulmonary valvulotomy, the first successful clinical open-heart operation aided by a mechanical pump.

Several months after Dodrill's report [26], the first successful operation (closure of atrial septal defect) using an extracorporeal oxygenator and a mechanical pump to permit total cardiopulmonary bypass was performed by Gibbon, in May 1953 [27].

Thus, with the heart isolated from the circulation, deliberate, unhurried intracardiac operations were now possible. The addition of body hypothermia to reduce metabolic demands during operation, as reported by Sealy et al. [28], provided the surgeon with even greater latitude and more favorable operating conditions, including periods of complete circulatory arrest. The surgeon had every reason to be proud of
these hard-won achievements, the result of many years of diligent research. Ingenious operations to treat previously incurable cardiac anomalies and disease rapidly followed. The demand for cardiac surgical facilities grew, and soon no major medical center was without them. The day of the cardiac surgeon had arrived.

As the years passed, barely noticed by the busy cardiac surgeon, the cardiologist and the interventional radiologist were becoming increasingly imaginative in their use of the cardiac catheter as an extended finger to explore intraluminally the cardiovascular system. By angiography and sophisticated echo and radionuclear imaging in the unanesthetized patient with circulation uninterrupted, the structure of the functioning cardiovascular system was clearly defined.

The first indication that the catheter might be adapted for the treatment of cardiovascular diseases was its application to the non-surgical attack on obstruction of the arteries. In 1964, transluminal dilatation of atherosclerotic lesions of the lower extremity, or angioplasty, was reported by Dotter and Judkins [29]. Fifteen years later, in 1979, the method was applied to coronary artery disease by Gruntzig using a small flexible catheter with an inflatable balloon attached to the tip [30]. Angioplasty is now recognized as an effective procedure for selected cases of occlusive vascular disease, replacing surgical correction in many instances.

The cardiologist, aware of the success of the blunt force applied by finger or instrument in relieving stenotic valves or orifices, moved to apply force to stenotic orifices using balloons attached to the cardiac catheter. Rashkind, a pediatric cardiologist, in 1966 was the first to conceive of using the balloon as a surgical tool inside the heart [31]. Unhappy with the high mortality associated with surgical operations to improve arteriovenous mixing in infants with transposition of the great arteries, he passed a catheter with balloon attached into the left atrium from the right atrium through the patent foramen ovale. The balloon was inflated and forcibly pulled back into the right atrium through the foramen, tearing the thin, valve-like endocardium that partially closes the foramen at birth, creating a large communication...
between the two chambers. Now unoxygenated blood could pass to the lungs and return again to the heart and be delivered to the systemic circulation. The best results of the procedure were obtained in the first three months of life when the valve-like membrane guarding the foramen ovale was thin and susceptible to disruption by the balloon. There were complications and disappointments, but the results were better and the mortality lower than the surgeon could expect in such sick infants. Emboldened by their success with the balloon catheter, the cardiologists moved on to dilatation of other stenotic structures within the heart and great vessels.

Since the earlier fear of serious consequences from the creation of pulmonary insufficiency was almost entirely dispelled by the long-term follow-up of many patients withstanding varying degrees of this condition, it was not surprising that balloon dilatation would be applied for relief of pulmonary valve stenosis. In 1979, Semb [32] carried out “balloon valvulotomy” of a stenotic pulmonary valve in a critically ill infant with an associated massive tricuspid insufficiency. A balloon catheter was passed into the pulmonary artery beyond the stenosed valve. The balloon was inflated with carbon dioxide and withdrawn into the ventricle. The valvular stenosis was relieved, and the patient rapidly improved. Kan and White developed a balloon catheter [33] specifically designed to be inflated with fluid injected by hand. With the balloon positioned across the stenotic orifice, they could precisely control the extent of the valvuloplasty. After several trials in the animal laboratory, where the balloon catheter design was finalized, chance dropped into their hands an unusual opportunity to test the therapeutic effectiveness of their balloon technique. A bulldog with congenital pulmonary valve stenosis, a condition that is breed-specific [34], was referred to them for treatment. “Rumbo” became the first patient to experience successful “intraluminal balloon valvuloplasty.” A catheter, to which a specially designed balloon was attached, was placed in his stenotic valve under fluoroscopic control (Fig. 8). The balloon was inflated, the valve split, and the stenosis was relieved instantly, thus proving the effectiveness of the procedure.

Not long afterward, an eight-year-old asymptomatic girl with pulmonary stenosis was referred to the Johns Hopkins Clinic for treatment. Her father did not wish her to have a major operation for correction of the deformed valve and wondered if there were not some simpler way to relieve the valvular stenosis. The new balloon technique was
explained carefully to the father and daughter and they readily accepted being the first human patient for its use. The catheter was positioned across the stenotic valve and inflated by hand to a pressure of 45 psi [2]. As predicted, from the result obtained in Rumbo, the valve split widely and the stenosis was relieved. Thus congenital pulmonary stenosis was cured without thoracotomy or cardiotomy, with no need for a heart-lung machine, or even a transfusion, and without prolonged hospitalization (Fig. 9). The results of many additional pulmonary valvulotomies have been equally successful. Surgical pulmonary valvulotomy, its perfection a triumph so hard-won, would now rarely be required.

It will be recalled that in Maude Abbott’s series of congenital anomalies, in about 60 percent of cases of pulmonary valve stenosis the foramen ovale in the atrial septum, referred to in the discussion of Rashkind’s procedure, closed at birth. The foramen may remain open if there is obstruction to forward flow of blood through the right side of the heart. In some cases, an anatomical defect in the atrial septum co-exists with pulmonary stenosis. When the stenosis is relieved, the right-sided pressures fall and the foramen usually closes, but, where there is a deficiency of atrial septal tissue, an operation may be required for closure of the defect to prevent paradoxical embolization from the venous to the arterial circulation, which could cause mischief by blocking arterial flow to vital organs.

Thus, in cases of pulmonary valve stenosis with an atrial septal defect there would still appear to be something for the surgeon to do. But alas, the resolution of this problem too may fall into the purview of the cardiologist. Recently it was reported that an opening in the atrial septum had been closed without operation. William E. Hellenbrand, a pediatric cardiologist, using a technique suggested by Rashkind, accomplished this feat by inserting from a peripheral vein a catheter carrying a detachable patch and securing the patch to the rim of an opening in the atrial septum, effectively barring the passage of blood and material between the two upper chambers of the heart [35]. It is doubtful, however, if the closed-heart technique will be appropriate for application to all cases of closure of atrial septal defects because of their considerable variation in anatomic structure and form. It is reasonable to expect
that the selection of open or intraluminal closure of the defect will depend on direct observation of the defect before closure, using an improved fiberoptic intraluminal cardioscope.

The evolution from intracardiac surgery for isolated pulmonary stenosis to its replacement by non-operative techniques is accepted for now. We have come full circle in the development of techniques to relieve pulmonary stenosis: from blind to visual and back to blind again. More recently, balloon valvuloplasty, refined to suit the problem, has had good results in mitral and aortic stenosis and other stenotic lesions of the cardiovascular system. What place these non-operative techniques will ultimately have in the treatment of cardiovascular lesions cannot be judged at present. It has been only a few years since balloon dilatation of stenotic lesions of the cardiovascular system was introduced, and stenosis has recurred in some cases. These cases have been managed by watchful waiting, redilatation, or surgical correction. It would not be surprising, however, because of the anatomic and functional features peculiar to the pulmonary valve and the pulmonary circulation that permit near total disruption of the valve structure without dire effects on the circulation, if pulmonary valvuloplasty by the balloon technique turns out to be the most successful of the intracardiac balloon dilatation procedures.

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