Short and Long Term Follow-up Results After Percutaneous Balloon Pulmonary Valvuloplasty

Thesis

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AIM OF THE WORK

Introduction And Aim of The Work

Medical dilatation is not new. References to crude instruments date back to the Egyptians and Romans who used reeds for dilating the urethra. The first use of a balloon catheter was reported in the early 1800s when a catgut balloon was used to dilate the urethra [1].

Numerous mechanical devices for dilatation of the cervix, oesophogus, urologic tract and blood vessels have existed for centuries. Except for materials used, they have remained relatively unchanged in design. Hundreds of bougies, olives and rod-like instruments with various curves and tapers have been designed to fit particular anatomic narrowings. Most bear the name of the physician who originated the specific design. Moving-action leverage, type devices have also been in existence for a long time. However, the smaller ones can not be used in applying great force. In addition, they are quite fragile and because of the friction involved, do not work very well around curves. Recently a number of transcatheter techniques for opening clogged arteries have been advanced including ultrasonic emulsifiers and Roto-Rooter type devices that can eat into clot and withdraw it through the catheter [2].

The first clinical dilatation of blood vessels was described by ***Dotter and Judkins*** in 1964 [3]. Their coaxial catheter design was applied to the femoral artery with mixed success [4]. As the Dotter technique began to be used (primarily in Europe), some of its users found that a coaxial catheter system was not necessary in every case.

The coaxial catheter technique of angioplasty was criticized because of local complications at the puncture site when such large catheters (12F) were introduced percutaneously. In addition, objections were raised to the potential damage caused by the shearing force applied as the large catheter is advanced through the lesion. Moreover, technical limitations at the puncture site precluded dilatations to greater than 4 mm which was usually inadequate for large diameter iliac vessels and generally limited the application of the technique to femoral dilatations [5].

Variations on this approach included that first described by ***Staple*** [6] and later by ***Van Andel*** [4] of Holland who used gradually tapered catheters made to specification. Later balloons were tried, but met with little success because of their tendency to inflate in the direction of least resistance. Only soft lesions could be dilated with these. In 1973, ***Portsmann*** [7] described a "caged balloon" catheter to get around the problem. Unfortunately, although it applied more force, it produced a lot of debris and a rough surface.

In 1974, ***Gruntzig and Hopff*** [8] described a non-elastic balloon catheter which interestingly was very similar in concept to the catgut device of the early 1800's. Balloon dilatation of stenotic lesions became popular only after ***Gruntzig*** applied similar techniques for dilatation of coronary arteries in the mid 1970's [9]. Three to four years later, "balloon fever" started to spread, not only among angiographers but also among surgeons [10]. Later, this "fever" started to spread to the U.S.A. It is interesting to note that percutaneous transluminal angioplasty became popular in the U.S.A. at a time when the number of diagnostic procedures was decreasing as a result of wide spread use of sonography and computer tomography [11].

The Gruntzig balloon [8] dilatation catheter was introduced for use in percutaneous transluminal angioplasty of the iliac and femoropopliteal arteries. Since then, its uses have expanded to include angioplasty of the renal [12], coronary [13], axillary, carotid, subclavian, coeliac, superior mesenteric and hypogastric arteries [14-16] and of the abdominal aorta [17] as well as dialatation of vein graft stenosis [18], stenosis angioaccess dialysis fistulas and shunts, postoperative arterial anastomotic stenosis in renal transplant patients [19], portosystemic venous shunts [20], and Blalock Taussig anastomoses. The catheter has also been used to dilate strictures of the biliary systems, including biliary enteric anastomoses [21], ureteral strictures [22], gastro-enterostomy stones, and aquired stricture of a main bronchus [23].

Recently, transluminal balloon angioplasty has been applied in pediatric cardiology to treat pulmonary valve stenosis [24], peripheral pulmonary artery stenosis [25], coarctation of the aorta [26], coarctation restenosis [27], aortic valve stenosis [28], mitral stenosis [29], discrete membranous subaortic stenosis [30], caval stenosis [31], ductus arteriosus [32], and stenotic pulmonary veins [33].

El-Tobgy deserves the credit of introducing balloon valvuloplasty in Egypt. He applied the technique on the pulmonary valve in 1986 [34]. ***El-Sherbini*** introduced balloon angioplasty of coronary arteries at the same year [35]. Later aortic and mitral valvuloplasties were reported in 1988 [36-37].

Percutaneous balloon valvuloplasty and angioplasty not only allows young children to grow to an age when surgical repair is less risky without the intrathoracic adhesions that complicate future thoracotomies [28] but it also may result in permanent relief of congenital stenosis.

Aim of The Work:

The aim of this work is to evaluate short and long term results after balloon pulmonary valvuloplasty.

REVIEW OF LITERATURE

Balloon Dilatation Catheters

Objectives [38]:

The objectives of dilatation are numerous and not easy to acheive. They are:

* To open the vessel lumen. The underlying objective is to improve flow and it is assumed that opening the lumen will do this.

* To perform the opening in such a manner that the vessel stays open.

* To create a smooth inner surface without rough transition.

* To produce no distal debris.

* To create minimum interference or disruption of the arterial wall structure.

The Gruntzig-style balloon dilating catheter seems to acheive many of these objectives.

Description:

The balloon dilatation catheter, styled after the ***Gruntzig*** technique was a special inelastic balloon which is filled with dilute contrast media to exert radial force on a narrow vessel segment [39].

Balloon Construction:

1- The balloon is size limited. Excess pressure does not cause greater expansion (as with a latex balloon).

2- The minimum axial force required to dilate should be applied.

Catheter Construction:

1- The catheter body has two lumens. The lumen marked "distal" is the central lumen of the catheter, which terminates at the distal tip.

The lumen marked "balloon" is the balloon inflation lumen.

2- The material offers good torque control and retains pre-set curves at body temperatures.

3- Radio-opaque markers provide radio-opaque reference points for positioning the uninflated balloon within a lesion or a valve [39].

Advantages [38]:

* Once in the lesion it applies radial force only. There is no axial component.

* It has smooth outer shape and surface.

* It has a controlled diameter; excess inflation pressure will not significantly increase the diameter. This allows the application of a very strong force in a controlled manner.

* It can be introduced percutaneously and manipulated like an angiographic catheter.

* It can operate next to obstructions and around curves.

* It can be made in many different sizes and shapes.

The ideal hydraulic dilating catheter should have a large expansion ratio and be capable of being manouvered into small and remote vessel segments. No one catheter is sufficient to handle all lesions. A wide variety of sizes, shapes, and designs is required.

Types of Balloons [39]:

We have three types of balloons:

1- **Valvuloplasty (VP) Trefoil Meier:** is a four lumen catheter with three balloons mounted on the distal tip. Three lumen (BAL) are for inflation of the balloon.

2- **Valvuloplasty (VP) Bifoil:** is a three lumen catheter with two balloons mounted on the distal tip. Two lumen (BAL) are for inflation of the balloon.

3- Valvuloplasty (VP) Single Balloon: is a double lumen catheter with a balloon mounted on the distal tip. One lumen (BAL) is for inflation of the balloon.

The additional lumen in each balloon is for guide wire introduction and monitoring of pressure or the infusion of medication and/or contrast media through the distal tip. The balloon is designed to provide a distensible segment which inflates to a known diameter and length at a specific pressure.

Basic Principles:

Successful application of Gruntzig-style balloon dilating catheters requires an understanding of a number of principles of physics.

The dilating force:

"This is the tendency for a balloon to stretch or separate at its circumference when pressure is applied inside [38] ".

Since the inside surface area increases with the diameter of the balloon, the same pressure will produce more force in a large balloon than in a smaller balloon. For the same pressure, the force is proportional to the radius [38].

The dilating force depends upon some parameters:

1- Dilating force versus Balloon pressure:

For the same size balloon, an increase in pressure will increase the dilating force in a linear fashion, providing there is no changes in the size of the lesion [38].

2- Dilating force versus stenosis size:

For the same pressure, a dilating balloon will produce more force on a large area lesion than a small one [38].

3- Dilating force versus degree of stenosis:

At the same pressure, a dilating balloon will produce more force in a tight or narrow stenosis than in a shallow or open one [38].

4- Dilating force versus material:

Balloons of the same dimension will produce considerably greater dilating force at the same pressure if the balloon material does not stretch. When a material stretches or deforms under pressure, it prevents concentration of force at the stenosis. The balloon stretches around the lesion rather than exerting force on it [38].

5- Dilating force versus balloon length:

Surprisingly enough, the length of the balloon also has an effect on dilating force, but that effect depends on the material out of which the balloon is made. Balloons made of polyvinyl chloride, will stretch or yield somewhat under pressure and, as a result, a balloon with less area (shorter) will exert more dilating force than a larger one. A balloon 1 cm long may exert 50% more force than a balloon 4 cm long, with a material that does not stretch as much as such specially heated polyethylene, the dilating force does not decrease with balloon length. Surprisingly, it may actually increase [38].

The material of the balloon:

The balloons are made of polyvinyl chloride, polyethylene polytetraflorethelene [40]. The polyethylene balloon has higher tensile strength when compared to the polyvinyl one. This is a distinct advantage which provides wider safety margins. The polyethylene balloon ruptures at consistent higher pressures than