ROLE OF INTRAVASCULAR ULTRASOUND (IVUS) IN EVALUATING OPTIMAL INFLATION AND SIZE OF STENTS AND BALLOON IN PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTIONS (PCI)

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SUMMARY

Objective: To evaluate the size of balloon and stent and inflations given to patients undergoing PCI before and after IVUS.

Design: A retrospective study.

Place and duration of study: This retrospective study was conducted at department of catheterization laboratory National Institute of Cardiovascular Diseases (NICVD) Karachi from 1998 to 2001.

Subjects and Methods: All patients who have undergone PCI in catheterization laboratory NICVD from 1998 to 2001 were included. These patients include those who have undergone IVUS in between year 2000 & 2001.

Results: IVUS study and use of stents & balloon in four years showed that mean diameter of stent in males used increased from 3.05 mm to 3.13 mm and mean length reduced from 18.32 mm to 15.22 mm with inflations ranged from 9.30 atm to 13.4 atm. For Balloons mean diameter decreased from 2.7 mm to 2.6 mm and mean length reduced from 20.9 mm to 19.24 mm with inflations that increased from 5.04 atm to 6.4 atm.

In females stent used with mean diameter that increased from 2.96 mm to 3.08 mm and mean mean length decreased from 18.33 mm to 15.47 mm and inflation increased from 9.33 atm to 12.69 atm. Balloon used with mean diameter that decreased from 2.9 mm to 2.6 mm with length that decreased from 20.8 mm to 19.04 mm and with inflations 6.20 atm to 5.80 atm.

Conclusion: This study showed that IVUS demonstrated a significant increase in stent expansion after IVUS. Mean length of stent and balloon used decreased yearly. Mean diameter of stent used were increased while that of balloon decreased after IVUS.

Keywords: Intravascular ultrasound (IVUS), Stents, Balloon.

INTRODUCTION

Contrast angiography is still the most important imaging method used to guide therapy for coronary disease. Many studies have challenged the accuracy and reproducibility of this technique.1-7

In recent years, intravascular ultrasound (IVUS) has evolved as a valuable adjunct to angiography providing insights that are significantly altering conventional paradigms in diagnosis and therapy8-10. The contributions of ultrasound originate principally from two key features, its tomographic perspective and its ability to direct image the vessel wall, whereas angiography depicts only a 2D silhouette of the lumen. Ultrasound allows

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precise tomographic measurement of lumen area and plaque size, distribution and to some extent composition.11 IVUS imaging has played a pivotal role in understanding and optimizing the benefits of stent therapy.11-12

The study was oriented to see the impact of IVUS in sizing of stents and balloons and in inflations.

PATIENTS AND METHODS:

The study was carried out at the National Institute of Cardiovascular Diseases (NICVD) Karachi from January 1998 to December 2001. All patients who have undergone Percutaneous Coronary interventions were taken. A record of patients of diameter, length and inflations of balloon and stent from Cath Lab was noted. Patients undergoing IVUS, in between 2000 & 2001 were also taken in this study. Coronary imaging Catheter (Atlantes TMSR, Boston Scientific SCIMED) 40MHZ with ultrasound system and guide wire 0.014 in (0.36mm) were used.

Statistical analysis was done by using student t-test.

RESULTS:

The total number of patients from 1998 to 2001were 851 out of which 716 patients were male and 135 patients was female. Yearly evaluation of stents and balloon was undertaken which is as follows. (Table I & II)

STENTS:

Diameter:
In males yearly (from 1998 to 2001) maximum diameter used was 3.5mm, 3.7mm, 4mm, 4mm with minimum dimensions of 2mm, 1.5mm, 2.5mm, 2.5mm with mean diameter of 3.05mm, 3.04mm, 3.12mm & 3.13mm with P=NS. (Table I).

Similarly in females maximum diameter evaluated was 3.5mm, 4mm & 3.5mm with minimum diameter of 3mm, 2.5mm, 2mm & 2.5mm with mean diameter of 3.08mm, 2.96mm, 3.07mm & 3.08mm with P=NS. (Table II)

Length:
In males, maximum length of stent used yearly was 25mm, 30mm, 30mm & 28mm while minimum length used was 15mm, 8mm, 8mm & 7mm with mean length of 18.32mm, 15.60mm, 14.88mm, 15.22mm with P=0.0005 & 0.0031 in 2000 & 2001. (Table I)

In females, maximum length of stent used was 25mm, 30mm, 28mm & 28mm with minimum length of 15mm, 8mm, & 10mm with mean of 18.33mm, 14.43mm, 14.48mm, 15.47mm with P=NS. (Table II)

Inflations:
In males, the maximum inflation in stent each year was 14atm, 14atm, 22atm & 24atm with minimum of 4atm, 2atm & 2atm with mean of 9.30atm, 10atm, 10.8atm & 13.4atm with P=NS. (Table I)

In females, the maximum inflation given in stent was 12atm, 12atm, 20atm & 18atm with minimum of 4atm, 2atm & 2atm with mean of 9.33atm, 9.56atm, 13atm & 12.69atm with P=NS. (Table II)

BALLOON:

Diameter:
In males, the maximum diameter used each year was 3.5mm, 3.5mm, 4mm & 4mm with minimum dimensions of 1.5mm, 1.5mm, 1.5mm & 2mm with mean of 2.7mm, 2.7mm, 2.6mm, 2.6mm with P=0.021. (Table II).

In females, the maximum diameter used was 3mm, 3.5mm, 3.5mm & 3.5mm with minimum dimensions of 2.5mm, 2mm, 2mm & 1.5mm with mean of 2.9mm, 2.5mm, 2.5mm & 2.6mm with P=0.043, 0.042 & 0.03. (Table II)

Length:
In males, the maximum length used was 30mm each year with minimum length of 15mm, 10mm, 8mm & 9mm with mean of 20.9mm, 20mm, 19.14mm & 19.24mm with P=0.03 & 0.01. (Table I)

In females, the maximum length of balloon used was 30mm, 40mm, 30mm & 30mm with minimum length of 15mm, 10mm, 10mm & 10mm with mean length of 20.8mm, 21.5mm, 19.20mm & 19.04mm with P=NS. (Table II)

Inflations:

In males, the maximum inflation given was 12atm, 14atm, 14atm & 20atm with minimum inflation of 2atm, 1atm, 1atm & 2atm with mean inflation of 5.04atim, 5.10atm, 6.08atm & 6.4atm with P=NS. (Table I)

In females, the maximum inflation given was 10atm, 15atm, 16atm & 10atm with minimum inflation of 4atm, 2atm & 2atm with mean of 6.2atm, 5.85atm, 6.24atm & 5.80atm with P=NS. (Table II)

Table I

	MALES			
STENTS	**1998 (N)**	**1999 (N)**	**2000 (N)**	**2001 (N)**
Diameter				
Maximum (mm)	3.5 (26)	3.7 (97)	4 (268)	4 (227)
Minimum (mm)	2	1.5	2.5	2.5
Mean (mm)	3.05	3.04	3.12	3.13
P-Value	-	0.849	0.356	0.224
Length				
Maximum (mm)	25 (26)	30 (97)	30 (268)	28 (227)
Minimum (mm)	15	8	8	7
Mean (mm)	18.32	15.60	14.88	15.22
P-Value	-	0.021	0.0005	0.0031
Inflations				
Maximum (atm)	4 (33)	14 (112)	22 (325)	24 (259)
Minimum (atm)	4	2	2	2
Mean (atm)	9.30	10	10.8	13.4
P-Value	-	0.20	0.94	0.34
BALLOON				
Diameter				
Maximum (mm)	3.5 (34)	3.5 (117)	4 (240)	4 (183)
Minimum (mm)	1.5	1.5	1.5	2
Mean (mm)	2.7	2.7	2.6	2.6
P-Value	-	0.701	0.158	0.021
Length				
Maximum (mm)	30 (34)	30 (117)	30 (240)	30 (183)
Minimum (mm)	15	10	8	9
Mean (mm)	20.9	20	19.14	19.24
P-Value	-	0.87	0.003	0.01
Inflations				
Maximum (atm)	12 (48)	14 (117)	14 (241)	20 (169)
Minimum (atm)	2	1	1	2
Mean (atm)	5.04	5.10	6.08	6.4
P-Value	-	0.63	0.91	0.5

Key = P<0.05
P value compared with 1998 as base line

Table II

	FEMALES			
STENTS	**1998 (N)**	**1999 (N)**	**2000 (N)**	**2001 (N)**
Diameter				
Maximum (mm)	3.5 (6)	3 (16)	4 (50)	3.5 (42)
Minimum (mm)	3	2.5	2	2.5
Mean (mm)	3.08	2.96	3.07	3.08
P-Value	-	0.283	0.925	0.968
Length				
Maximum (mm)	25 (6)	30 (16)	28 (50)	28 (42)
Minimum (mm)	15	8	8	10
Mean (mm)	18.33	14.43	14.48	15.47
P-Value	-	0.132	0.069	0.126
Inflations				
Maximum (atm)	12 (6)	12 (16)	20 (53)	18 (43)
Minimum (atm)	4	4	2	2
Mean (atm)	9.33	9.56	13	12.69
P-Value	-	0.20	0.94	0.34
BALLOON				
Diameter				
Maximum (mm)	3 (6)	3.5 (20)	3.5 (48)	3.5 (41)
Minimum (mm)	2.5	2	2	1.5
Mean (mm)	2.9	2.5	2.5	2.6
P-Value	-	0.043	0.042	0.03
Length				
Maximum (mm)	30 (6)	40 (20)	30 (48)	30 (41)
Minimum (mm)	15	10	10	10
Mean (mm)	20.8	21.5	19.20	19.04
P-Value	-	0.803	0.374	0.238
Inflations				
Maximum (atm)	10 (7)	15 (20)	16 (49)	10 (35)
Minimum (atm)	4	2	2	2
Mean (atm)	6.2	5.85	6.24	5.80
P-Value	-	0.13	0.48	0.55

Key = P<0.05
P value compared with 1998 as base line

DISCUSSION:

These data shows that the mean diameter of stents in both males and females before and after IVUS is not significant except for the maximum diameter in males which increased from 3.5mm to 4mm. For length of stents there is progressive decrease in length with a mean of 18.33mm to 15.22mm in males and 18.33mm to 15.47mm in females.

For inflations in stent mean inflation is increased from 9.30atm to 13.4atm in males and 9.33atm to 12.69atim in females.

For balloons mean diameter decreased from 2.7mm to 2.6mm in males and 2.9mm to 2.6mm in females. Similarly, the length of the balloon decreased from 20.9mm to 19.24mm in males and 20.8mm to 19.04mm in females. This shows a decrease in the size and length of the balloon used. Balloon inflated in males with mean of 5.04atm to 6.4atm and 6.2atm to 5.80atm in females, an increase inflation in males while decrease inflation in females.

Single Center studies have reported that ultrasound imaging frequently influences the operator's appreciation of target lesion seventy, morphology and optimal approach to therapy.13

The pioneering observations of Columbus et al based on IVUS, demonstrated that deployment with conventional balloon pressures resulted in a high incidence of incomplete expansion and opposition. The investigators used IVUS to guide high-pressure dilatation achieving full expansion and complete stent opposition in 96% of 359 consecutive but nonrandomized patients.14 In our study mean pressures were increased from 9.3atm to 13.4atm in males and 9.30atm to 13.6atm in females (Table I & II) for optimal expansion of stents.
The outcome of ultrasound guidance of balloon angioplasty was Clinical Outcomes with Ultrasound Trial (CLOUT) in which IVUS imaging was performed after obtaining a satisfactory angiography result. After IVUS balloon to artery ratio increased from 1.12 to 1.30 with an increase in angiographic minimal luminal diameter from 1.95 to 2.21mm2.15 In our study with balloons the inflation in males were 5.04atm to 6.4atm and in females 6.20atm to 5.80atm. The decrease pressure in our study was probably due to increase use of stents and its optimal expansion.

CONCLUSION:

IVUS evaluation and use of stents and balloons demonstrates a significant degree of under expansion compared with estimation by Coronary angiography. Using ultrasound imaging our cases underwent optimal stent dilatation. This preliminary experience demonstrates that IVUS assessment is an important adjunct to assist proper stent and balloon size and inflation. Further studies are necessary to evaluate the effectiveness of the approach.

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