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TO ASSESS THE ADEQUACY OF CORONARY STENTS DEPLOYMENT (APPOSITION)WITH INTRAVASCULAR ULTRASOUND IN COMPARISON WITH CORONARY ANGIOGRAPHY

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All the authors contributed significantly to the research that resulted in the submitted manuscript.

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ABSTRACT

Objective: To determine the adequacy of stent deployment (apposition) as assessed by IVUS and its comparison with quantitative coronary angiography (QCA).

Methodology: In this comparative study we analyzed the stents for adequate deployment in 100 patients who were randomly selected from the patients who underwent PCI either with bare metal or drug eluting stent comparing QCA with IVUS at our catheterization laboratory, Cardiology department. The study was conducted from August 2010 to February 2011. We used Volcano therapeutic IVUS system employing Volcano - eagle eye Gold catheter. Stents were said to be adequately deployed when there was (1) complete apposition of the stent struts over the entire length of stent. A performa was used to collect patient's details and record the IVUS analysis. SPSS version 15 was used to analyze the data.

Results: A total of 100 study subjects were included in the study, mean age was 54.38 ± 9.97 years and 85% (85) were male. Diabetics were 40 %(40), 47%(47) were hypertensives, 46%(46) were dylipidemic and 36%(36) were smokers and 40%(40) had a previous myocardial infarction. It was observed that 85% (34) of the cases had their struts adequately apposed while in 15%(06) stent apposition was inadequate and needed to be further dilated .Most of the stents (52.5%) used were Endeavor. LAD was stented in 72.5 % (72) followed Circumflex12.5 %(12), RCA 10 %(10) while Ramus and OM1 in5 %(6).

Conclusion: In significant number of patients stents were not adequately deployed requiring re-ballooning to optimize the results as assessed by IVUS.

Key Words: IVUS, QCA, PCI, RCA, LAD

INTRODUCTION

Percutaneous coronary intervention (PCI) is of the established treatment for symptomatic coronary artery disease (CAD).[1] But PTCA results in the recurrence of restenosis and requires re-intervention.[2] Because of high restenosis rate with PTCA, the rate of PCI (stent insertion) has increased almost 150% from 1996 to 2000 as mentioned in AHA statement.[3] But restenosis is also high with bare metal stents (BMS) and drug eluting stents (DES) have proved to be highly efficacious for reducing the rate of restenosis.[4] Use of drug-eluting stents (DES) has reduced the incidence of restenosis rate and the need for repeat revascularization compared with the use of bare-metal stents.[5] But recent reports evaluating follow-up outcomes across various clinical and angiographic subgroups, however, showed that several factors conferred a higher risk of restenosis even after DES use.[6,7] Intravascular ultrasound (IVUS) studies have suggested that suboptimal stent deployment is a major aetiology underlying both DES restenosis [8-10] and stent thrombosis.[11,12]

The rational of conducting this study was to determine the adequacy of stents deployment (apposition) as assessed by IVUS in comparison with coronary angiography in Peshawar. Objective of the study was to determine the adequacy of stent deployment (apposition) as assessed by IVUS and its comparison with quantitative coronary angiography (QCA).

METHODOLOGY

The study was conducted in Catherization laboratory Cardiology Unit LRH Peshawar, from 1st August 2010 till 28 February 2011.This was Cross-sectional Comparative study and the sampling technique was purposive non probability sampling. A total of 100 patients were inducted in this study. (Sample size was 100 patients, using 80% proportion of adequate deployment by QCA and 57% proportion of adequate deployment by IVUS, 95% CI and 80% power of the study under the WHO software for sample size determination). In this study those patients were included who were more than 18 years of age of either gender and undergoing elective PCI in Cardiology Unit PGMI, LRH, Peshawar. Patients were excluded if there was coronary artery dissection not covered by a stent, TIMI flow grade <3 post-stent placement, stent placement in sole remaining circulation or left main equivalent, stent placement within an aneurysmal portion of a vessel such that complete stent-vessel wall contact could not be achieved, a bypass graft supplying a native vessel and performance of IVUS during the index procedure before stent placement.

Permission to perform the study was obtained from the hospital and PGMI ethical committee. A written informed consent was obtained. Patients detail history was taken and preliminary serological screening as per hospital protocol for Hepatitis and HIV. A 12 lead ECG was obtained. Patients had already undergone diagnostic coronary angiography and were admitted for planned PCI. Post PCI, IVUS study was done in every patient employing the Volcano therapeutic IVUS system using Eagle eye Gold Catheter. QCA was performed in the same subset of patients employing Siemen angiography software. Patients were labeled as having adequate deployed or not adequate deployed stent as per operational definition. IVUS and QCA visuals were stored on a DVD disk for later analysis to calculate minimal luminal diameter and maximal luminal diameter, in-stent and reference cross-sectional areas and percent diameter stenosis and residual diameter stenosis. Data was recorded into the study proforma. A stent would be defined as adequately deployed if its struts are properly apposed against the vessel wall i.e. when no space is seen behind the stent struts and when you apply chromo mode you don't see any blood speckle behind the stent struts. adequacy of stent deployment using is defined as stent adequately deployed if the residual diameter stenosis is less than 10% post PCI. Minimal and maximal lumen diameter is defined as major and minor axes of elliptical cross section. intravascular ultrasound uses high frequency sound waves that are emitted from ultrasound filaments mounted on a IVUS catheter tip and recollected after striking the vessel inner dimension to reconstruct a three dimensional and longitudinal image of the vessel wall for analysis by an IVUS software. IVUS catheter are passed through the area of interest and pulled back at a steady speed using motorized pull back system to obtain the images of the desired segment. Quantitative coronary angiography (QCA) uses the conventional fluoroscopic angiographic images to calculate the minimal and maximal diameter and percent stenosis using the QCA software that is built in the angiographic machine for offline analysis.

The statistical analysis was performed using the statistical program for social sciences (SPSS version 15). Descriptive variables like gender, stent apposition and symmetry index are presented in the form of frequencies and percentages. Numerical variables like age, stent size, amount of stenosis, as means ±SD. Chi-square test was applied for adequacy of stent deployment by IVUS and QCA. Data is presented in the form of graphs and tables. P value of < 0.05 will be considered significant.

RESULTS

A total of 100 study subjects were included in the study, mean age was 54.38 ± 9.97 years and 85 %(85) were male. Diabetics were 40 %(40), 47%(47) were hypertensive's, 46%(46) were dylipidemic and 36%(36) were smokers and 40%(40) had a previous myocardial infarction Table 1 showing baseline characteristic. Both drug eluting and bare metal stents were used with the main

drug eluting stent being endeavor (Zatrolimus eluting stent) follow by driver which is a stainless steel bare metal stent.

Left anterior descending artery (LAD) was the main artery that was stented followed by circumflex and right coronary artery. Both drug eluting and bare metal stents were used with the main drug eluting stent being endeavor (Zatrolimus eluting stent) follow by driver which is a stainless steel bare metal stent shown in Table 2.

Complete stent apposition of the stent struts was seen in 85% of the cases and only 15% were not adequately deployed shown in Table 3.

According QCA criteria only 5% of the stented lesion were having greater than 10% residual stenosis. Rest of the 95% was adequately deployed as shown in Table 4.

When adequacy of stent deployment assessed by IVUS was compared with that of QCA, we found significant difference p valve of 0.00312 as shown in Table 5.

DISCUSSION

IVUS insights into vessel and stent geometry have played a major role in developing the concept of optimized stent deployment using high pressure balloon inflations.[13,14] Small observational studies in the BMS era suggested the benefits of a larger stent cross-sectional area (CSA) and higher postdilation pressures with IVUS guidance, on better stent apposition and restenosis rates.[15,16] In our study we found that a significant amount 15(15%) were not adequately opposed to vessel wall, that is in accordance with other

Table 1: Showing Baseline Characteristics

Characteristics	(n= 100)
Age (years)	54.38±9.97
Males	85(85)
Diabetes	40%(40)
Hypertensive	47(47)
Dyslipidemia	46%(46)
Smoking	36%(36)
SP/MI	40%(40)

Table 2: Type of Stents Used

Drug Eluting Stents	57.5% (58)
Endeavor stents	52.5%(52)
Taxus stents	2.5%(2)
Cypher stents	2.5%(2)
Bare Metal Stents	**42.5%(42)**
Drivers stents	35%(35)
Bx sonic stents	5%(5)
Coroflex stents	2.5%(2)

Table 3: Apposition of Stent Struts Against the Vessel Wall When Assessed by IVUS

ADEQUATELY APPOSED	85% (15)
INADEQUATELY APPOSED	15% (15)

Table 4: Quantitative Coronary Angiography Results

Mean prestent stenosis	75%
Mean post stent stenosis	12%
Adequately deployed <10% residual STENOSIS	95%
Inadequately deployed > 10% residual STENOSIS	5%

Table 5: Comparison of Adequacy of Stent Deployment by IVUS and QCA

Adequacy	IVUS	QCA	
Yes	85 (85%)	95(95%)	P-value
No	15(15%)	05 (5%)	0.00312
Total	100	100	

study determining the frequency of adequate stent deployment using IVUS, 32 patients (20·4%) stents were not adequately deployed.[17] In present study 95%(95) of stents were adequately deployed using QCA criteria, but IVUS studies have demonstrated that visual estimation or quantitative angiographic analyses of vessel dimension for stent deployment appear inaccurate.[18,19] In one of the study with early generation DES using IVUS for adequate stent deployment it was found that DES obtained only 75% of predicted minimal stent diameter and 66% of the predicted minimal stent area (MSA).[20] Since Apposition of stent struts to the vessel wall is also an important facet of stent optimization. Adequate stent expansion and adequate stent strut apposition have been reported to be important factors in reducing repeated revascularization due to stent restenosis or stent thrombosis.[14,21] In the DES era, incomplete stent apposition has been regarded as an important local factor in DES failure, probably due to reduced drug delivery to the vessel wall.[22,23] Thus, the risk of stent under-expansion, incomplete stent apposition, and incomplete lesion coverage increases and these suboptimal stent deployment conditions have been reported to be potent IVUS predictors of stent restenosis and stent thrombosis suggesting that stent implantation under IVUS guidance still has a pivotal role even in the DES era.[14,24,25]

CONCLUSION

In significant number of patients stents were not adequately deployed requiring re-ballooning to optimize the results as assessed by IVUS.

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