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Original Article

Evaluation of Quantitative Coronary Angiography for Assessment of Adequacy of Stent Deployment

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Objective: To determine the adequacy of stent symmetry (deployment) as assessed by intravascular ultrasound (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 were undergoing percutaneous coronary angiography (PCI) either with bare metal or drug eluting stent at our catheterization laboratory, Cardiology department Postgraduate Medical Institute (PGMI) Lady Reading Hospital Peshawar. The study was conducted from August 2010 to February 2011. We used Volcano therapeutic intravascular ultrasound (IVUS) system employing Volcano – eagle eye Gold catheter. Stents was supposed to be symmetrical (adequately deployed) if the ratio of minimum luminal diameter to maximum luminal diameter was 0.7.Performa was used to collect patient's details and record the IVUS analysis. Statistical Package for the Social Sciences SPSS version 15 was used to analyze the data.

Results: A total of 100 subjects were included in the study, their mean age was 54.38 ± 9.97 years and 85 %(85) were male. Diabetics were 40 %(40), hypertensive's were 47%(47), dylipidemic were 46%(46) smokers were 36%(36) and 40%(40) had a previous myocardial infarction. Both drug eluting and bare metal stents were used and the main drug eluting stent was endeavor (Zatrolimus eluting stent) and the main bare metal stent was integrity.

Left anterior descending artery (LAD) was most commonly stented artery, followed by circumflex and right coronary artery respectively.

Mean ratio of the minimum to maximal luminal diameter was 0.8205 ± 0.084. A ratio of greater than 0.7 was achieved in 77.5% patients so that they had a better symmetry.

By quantitative coronary angiography (QCA) only 5% of the stented lesions were having greater than 10% residual stenosis not properly deployed while 95% of the stents were adequately deployed. When we compared our finding of IVUS with that of quantitative coronary angiography(QCA)by applying chi-square test, we found that there were significant stents that were not properly deployed (p valve of 0.00312) and need further dilatation.

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

Key wards: Intravascular ultrasound (IVUS), quantitative coronary angiography (QCA), percutaneous coronary intervention (PCI), right coronary artery (RCA), left anterior descending artery (LAD), left circumflex coronary artery (Circ)

Introduction

Percutaneous transluminal coronary angioplasty (PTCA) is one of the established treatment for symptomatic coronary artery disease (CAD).[1] But PTCA results in the recurrence of restenosis (recurrence of stenosis) that requires re-intervention.[2]

Because of high restenosis rate with PTCA, the rate of percutaneous coronary intervention (PCI) 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 eti-

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ology underlying both DES restenosis [8,9,10] and thrombo-sis.[11,12]

The rational of conducting this study was to determine stents apposition as assessed by IVUS in comparison with coronary angiography in Peshawar.

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

OPERATIONAL DEFINITION:

Adequacy of Stent deployment using IVUS: 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 u apply chromo mode you do not see any blood speckle behind the stent struts (this already analyzed and published) and **s**tents was supposed to be symmetrical (adequately deployed) if the ratio of minimum luminal diameter to maximum luminal diameter was 0.7 (minimum Luminal diameter LD/ maximum Luminal diameter LD > 0.7).

Adequacy of stent deployment using QCA: A stent is said to be adequately deployed if the residual diameter stenosis is less than 10% post PCI.

Reference cross-sectional area: It was defined as the most normal looking area 10mm proximal or distal to the stent).

Methodology

The study was conducted in Catherization Laboratory Cardiology Unit, Postgraduate Medical Institute (PGMI), Lady Reading Hospital Peshawar (LRH) from 1st August 2010 till 28 February 2011. This was Cross-sectional Comparative study and the sampling technique was purposive non probability. 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, Thrombolysis In Myocardial Infarction (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 were obtained. 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 Siemens angiography software. Patients were labeled as having adequate deployed or not 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 Performa.

Data 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 was considered to be significant.

Results

A total of 100 subjects were included in the study, their mean age was 54.38 ± 9.97 years and 85 %(85) were male. Diabetics were 40 %(40), hypertensive were 47%(47), dyslipidemic were 46%(46) smokers were 36%(36) and 40%(40) had a previous myocardial infarction. **Table 1** shows baseline characteristic. Both drug eluting and bare metal stents were used and the main drug eluting stent were endeavor (Zatrolimus eluting stent) and the main bare metal stent was integrity as shown in **Table 2**

Left anterior descending artery (LAD) was the commonly stented artery, followed by circumflex and right coronary artery respectively.

Overall mean stent diameter was 3.055 ± 0.298, mean stents length was 21.08 ± 6.907, mean minimal luminal diameter was 2.75 ± 0.355(range 2.1 to 3.6) and mean maximal luminal diameter was 3.018 ± 0.32 (range 2.5

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 Ratio of minimum Luminal Diameter & maximum Luminal Diameter.

Variables	Mean ± SD	Minimum -	Maximum Values.
Length of the stents	21.08±6.907	12 –	30
Diameter of the stents	3.055±0.298	2.5 –	3.5
Minimal lumen diameter(LD)	2.75±0.355	2.1 –	3.6
Maximal lumen diameter(LD)	3.018±0.3289	2.5 –	3.8
Ratio of min LD/max LD	0.8205±0.084	0.6 –	0.94

to 3.8). Mean ratio of the minimum to maximal luminal diameter was 0.8205 ± 0.084. A ratio of greater than 0.7 was achieved in 77.5% patients so that they had a better symmetry. These finding are shown in **Table** 3.

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 between IVUS and QCA.

adequacy	IVUS	QCA	P-value 0.00412
Yes	78 (77%)	95(95%)	
No	23 (23%)	5 (05%)	
Total	100	100	

By QCA only 5% of the stented lesions were having greater than 10% residual stenosis not properly deployed while 95% of the stents were adequately deployed as shown in **Table 4.**

When we compared our finding of IVUS with that of QCA by applying chi-square test, we found that there were significant stents that were not properly deployed(p valve of 0.00312) as shown in **Table 5** and need further dilatation.

Discussion

In this study we assessed the stents whether properly deployed i.e. symmetrical, using IVUS and to the best of our knowledge this is first study in Pakistan. In our study we found that significant amount of stents were not properly deployed i.e. under-deployed or, malapposed when assed by IVUS although QCA showed that it were properly deployed. One of the initials problem with BMS was sub-acute stent thrombosis but with combination of thienopyridine along with high-pressure stent deployment, has significantly reduced this problem.[13] In modern era of BMS the incidence of stents thrombosis was reported to be 0.9%. Critical insights into the pathophysiology of sub-acute stent thrombosis in the BMS era were gained from IVUS, it was found that features associated with subacute stent thrombosis were stent under-expansion, malapposition, inflow/outflow disease, dissection, thrombus, and tissue prolapse. [14]

After DES implantation it was found that reduced minimal stent area and stent expansion along with greater residual disease were associated with stents thrombosis .[11, 12] Correlation between post-procedural minimal stent area on IVUS examination and restenosis in patients undergoing sirulimus eluting stent (SES) implantation has been made from a number of IVUS studie.[8,9,10] Inadequate lesion coverage has also been identified to be associated with edge restenosis with DES.[17] In BMS era IVUS guided PCI has resulted in reduced rate of restenosis.[18,19] Though only a trend,

our findings suggest a benefit of IVUS guidance in the prevention of DES restenosis. This may have important implications in complex patient and lesion subsets.[13] In our study we found that significant number of stent were suboptimal deployed and need further intervention. The hypothesis that IVUS guided stent implantation is an effective tool in adequate stent expansion was confirmed in CRUIS trial although the most important limitation of this study was that it lacked of clear criteria for IVUS optimization.[18] Several IVUS characteristics have been found to be associated with increase adverse events after PCI with bare-metal stent (BMS), including smaller minimal stent area (MSA), stent underexpansion, persistent edge dissections, incomplete stent apposition (ISA), and incomplete lesion coverage.[20,21] Of these, smaller minimal stent area (MSA) is most commonly associated with target vessel failure at follow-up[20,22] and in registry of 1,706 patients, the risk of restenosis with BMS decreased 19% for every 1-mm^2 increase in MSA.[23] The clinical benefit of an IVUS-guided BMS PCI strategy is largely driven by reductions in restenosis and target vessel revascularization (TVR), without significant benefits in death or myocardial infarction[24] and this was illustrated in a recent meta-analysis of 2,193 patients from 7 randomized trials, where an IVUS-guided PCI strategy with BMS reduced TVR (13% vs. 18%, p0.001) compared with angiography-guided PCI strategy with similar rates of death (2.4% vs. 1.6%, p =0.18) and myocardial infarction (3.6% vs. 4.4%, p=0.51).[25] Thus IVUS guided PCI should be performed both for DES and BMS for better results especially high risk for adverse events.

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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