Original Article

Intravascular Ultrasound-Guided Coronary Stent Optimization By High Inflation Pressure Stent Deployment Versus Additional Routine Post Stenting Non- Complaint Balloon Dilatation

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Abstract

Background Optimization of stent deployment during percutaneous coronary intervention (PCI) is a key element for improving clinical outcomes but even in the DES era, optimal deployment of stents remains a challenging issue **Objective** to investigate whether the high inflation pressure stent deployment is enough for optimal deployment or routine post stenting noncompliant balloon dilation will be required **Methods** We included 60 patients with coronary artery disease who were subjected to elective stenting. Patients were divided into two groups: group A, high inflation pressure stent deployment (at 16-20 atm) followed by stent boost subtract imaging (SBS) assessment and if showing stent under-deployment, we added non-compliant balloon (NC) inflation at high pressure and group B, stent deployment was done at high pressure followed by routine NC balloon postdilatation at 18–20 atm. All stents were 2nd generation DES. Then both groups were assessed by IVUS MUSIC criteria & SBS optimal deployment criteria to determine the optimal deployment. **Results** The mean stent deployment pressure in group A (16.33±1.29) and mean duration of stent deployment in group A (29.07±4.25). There was no statistically significant difference between groups A and B regarding optimal stent deployment (P=1.000) and the occurrence of complications as spasm, dissection, acute stent thrombosis and no flow (P-value >0.05). The presence of heavy calcification was significantly associated with higher inflation pressure, longer inflation duration and significantly lower MSA/ARLA % (stent expansion) by IVUS in group A (P-value<0.05) and significantly associated with lower symmetry index in group B (P-value<0.05) and in group B the heavy calcification was associated significantly with dissection. **Conclusion** High-pressure stent deployment was associated with optimal stent deployment but heavy coronary calcification in lesion lead to less expansion and less symmetry of stent even after NC balloon dilatation and also heavy coronary calcification was associated with increased risk of complication as dissection, etc .

Keywords: stent deployment pressure, optimal stent deployment, IVUS, SBS

INTRODUCTION

Optimization of stent deployment during percutaneous coronary intervention (PCI) is a key element for improving clinical outcomes **(1)** with the advent of drug-eluting stents (DESs), DESs have become the main strategy for PCI because they have significantly reduced the need for repeat revascularization **(2)**

However, suboptimal stent deployment frequently occurs during DES implantation, which may increase the risk of in-stent restenosis and stent thrombosis **(3)** Therefore, even in the DES era, optimal deployment of stents remains a challenging issue

In bare-metal stent, adjunctive postdilatation using noncompliant balloons after stent implantation provided further stent optimization to reduce the incidence of in-stent restenosis and stent thrombosis**(4)**

Even in the DES, previous studies also support the use of postdilatation with noncompliant balloons after deployment of DES **(5)**

Patients and Methods

This study prospectively recruited 60 patients with coronary artery disease referred to Cardiology Department at Beni-Suef University Hospital for elective PCI. After obtaining written informed consent from the patient or the first-degree relatives. Patients were divided into two groups(equal in number) : group A consists of 30 patients in whom stents deployment were performed by high inflation pressure technique and group B consists of 30 patients in whom stents were deployed at high pressure followed by routine post stenting non complaint balloon dilatation.

Inclusion criteria Patients with coronary artery disease indicated for elective PCI

Exclusion criteria Contraindications to IVUS, extreme vessel tortuosity and angulation that would preclude the ability to deliver an IVUS catheter to the area of interest and patients refusing to participate in our study.
All patients subjected to the following: History taking, Clinical examination, lead electrocardiogram for old myocardial infarction, arrhythmias, etc. and diagnostic coronary angiography, PCI, stent boost and study with IVUS as we will describe later on.

Statistical Analysis

Data were collected then entered and coded into the SPSS version 25 for windows. Numeric variables were expressed as mean and standard deviation while categorical variables were expressed as number and percent.
Comparison between the 2 groups was run by chi-Squared or Fisher exact according to the expected values in the cells while comparison between more than 2 subgroups was run by chi-Squared or exact according to the expected values in the cells.
Comparison between the 2 groups regarding the scale variables was done by T-test for normally distributed ones and Man-Whiteny U test for non-normally distributed variables. More than 3 subgroups were compared regarding the scale variables using One Way ANOVA test or Kruskal Wallis according to their normal distribution then Tukey Post Hoc test was used to compare each 2 groups. Non-parametric Spearman Rho correlation was run between the scale variables.

Results

There was no significant difference between both groups regarding their age and sex distribution (P-value >0.05) as shown in table (1)

Table (1) Age and sex of the studied patients

Items	Group A (no=30)	Group B (no=30)	P-value
Age (mean±SD)	54.13±6.22	54.27±8.33	0.944
Sex Females Males	 9(30.0%) 21(70.0%)	 7(23.3%) 23(76.7%)	0.559

There was no significant difference between both groups regarding the stent length and diameter (P-value >0.05) but there was significant higher inflation pressure and longer inflation duration in group A as shown in (table 2).

Table (2) Distribution of stent size and deployment characteristics among the studied patients

Items	Group A(no=30)	Group B (no=30)	P-value
Size of stent Diameter(mm) Length(mm) Size (diameter x length)	 2.85±0.5 25.83±6.71 73.64±19.83	 3.21±0.9 25.63±9.39 80.27±27.51	 0.060 0.925 0.288
Inflation pressure (Atm)	16.33±1.29	13.30±1.24	0.05
Inflation duration (sec)	29.07±4.25	18.12±3.5	0.044

There was no significant difference between both groups regarding the opposition to the vessel wall, the expansion, MSD by IVUS, and the optimal deployment (P-value >0.05). There was a significant higher symmetry index in group A than group B (P-value<0.001) as shown in table (3).

Table (3) MUSIC criteria among the studied groups

Items	Group A(no=30) %	Group B (no=30) %	P-value
Opposition to vessel wall	30(100%)	30(100%)	NA
Expansion Fully expanded Not fully expanded	 29(96.7%) 1(3.3%)	 30(100%) 0(0%)	1.000
MSD by IVUS(mm)	2.99±0.35	3.19±0.52	0.091
MSA/ARLA (%)	95.07±2.63	94.17±3.28	0.246
Symmetry index	0.89±0.05	0.82±0.07	<0.001*
optimal deployment	28(93.3%)	28(93.3%)	1.000

**P-value is significant*

There was no significant difference between both groups regarding the presence of focal indentation, MSD/RD%, MSD (mm) and adequate deployment by SBS (P-value >0.05) as shown in table (4).

Table (4) Distribution of adequate stent deployment by SBS among the studied groups

Items	Group A (no=30)	Group B (no=30)	P-value
Focal indentation No Yes	 28(93.3%) 2(6.7%)	 28(93.3%) 2(6.7%)	1.000
MSD/RD (%)	96.47±3.18	95.90±4.58	0.580
MSD (mm)	2.99±0.35	3.19±0.53	0.099
Adequate deployment by SBS	28(93.3%)	28(93.3%)	1.000

There was no significant difference between both groups regarding the occurrence of complications as spasm, dissection, acute stent thrombosis and no flow (P-value >0.05) as shown in table (5).

Table (5) Complications among the studied groups

Items	Group A (no=30)	Group B (no=30)	P-value
Spasm	3(10.0%)	5(16.7%)	0.706 (FET)
Dissection	1(3.3%)	2(6.7%)	0.857 (FET)
acute stent thrombosis	0(0%)	0(0%)	NA
no reflow	0(0%)	0(0%)	NA

There was a significant relation between the presence of heavy calcification and the presence of asymmetry in group A only but in group B there was insignificant association between the calcification level and the asymmetry as shown in table (6)

Table (6) Relation of asymmetric stent deployment (symmetry index <0.7) to Calcifications in each group

groups	**Items**	**Symmetry**		**P-value**
		Asymmetrical	Symmetrical	
	calcification	(no=1)	(no=29)	
Group A	heavy	1_a(100.0%)	**2_b(6.9%)**	0.025*
	moderate	0_a(0.0%)	10_a(34.5%)	
	little	0_a(0.0%)	4_a(13.8%)	
	No	0_a(0.0%)	13_a(44.8%)	
Group B	calcification	(no=3)	(no=27)	0.631
	heavy	1_a(33.3%)	3_a(11.1%)	
	moderate	1_a(33.3%)	11_a(40.7%)	
	little	0_a(0.0%)	6_a(22.2%)	
	No	1_a(33.3%)	7_a(25.9%)	

**P-value is significant*

There was no significant relation between the type of lesion and asymmetry in both groups (P-value>0.05) as shown in table (7).

Table (7) Relation between calcification & stent deployment parameters in IVUS and SBS in group A

Group A	**calcifications**	**N**	**Mean±Std. Deviation**	**P-value**
MSD by IVUS (mm)	heavy	3	2.87±0.15	0.667
	moderate	10	3.05±0.28	
	little	4	3.14±0.46	
	no	13	2.93±.042	
MSA/ARLA (expansion) by IVUS (%)	heavy	3	92.33a±5.13	0.024*
	moderate	10	95.40a±2.32	
	little	4	92.75a±1.71	
	no	13	**96.15b±1.62**	
symmetry index by IVUS	heavy	3	0.81±0.14	0.075
	moderate	10	0.89±0.04	
	little	4	0.91±0.01	
	no	13	0.89±0.02	
inflation pressure (Atm)	heavy	3	**18.00a±2.00**	0.002*
	moderate	10	**17.00b±1.33**	

	little	4	15.75b±0.50	
	no	13	15.62bc±0.51	
inflation duration(sec)	heavy	3	**38.00a±1.73**	<0.001*
	moderate	10	30.40c±3.17	
	little	4	25.75b±1.50	
	no	13	27.00b±2.35	
MSD/RD by SBS (%)	heavy	3	**89.33a±6.43**	<0.001*
	moderate	10	97.10b±1.45	
	little	4	97.50b±1.00	
	no	13	97.31b±1.25	
MSD by SBS (mm)	heavy	3	2.87±0.15	0.692
	moderate	10	3.06±0.28	
	little	4	3.12±0.43	
	no	13	2.94±0.41	

**P-value is significant*

The presence of heavy calcification was significantly associated with lower symmetry index only in group B (P-value<0.05) as shown in table (8).

Table (8) Relation between calcification & stent deployment parameters in IVUS and SBS in group B

Group B	calcifications	N	Mean±Std. Deviation	P-value
MSD by IVUS(mm)	heavy	4	3.00±0.08	0.626
	moderate	12	3.14±0.57	
	little	6	3.16±0.41	
	no	8	3.39±0.67	
MSA/ARLA(expansion)By IVUS (%)	heavy	4	94.75±3.30	0.088
	moderate	12	93.75±3.19	
	little	6	96.83±1.72	
	no	8	92.50±3.46	
symmetry index by IVUS	heavy	4	0.79a±0.09	0.038*
	moderate	12	0.80a±0.07	
	little	6	0.89b±0.02	
	no	8	0.81a±0.07	
MSD/RD by SBS (%)	heavy	4	99.00±1.41	0.533
	moderate	12	95.00±6.120	
	little	6	95.83±3.60	
	no	8	95.75±3.33	
MSD by SBS (mm)	heavy	4	3.00±0.08	0.638
	moderate	12	3.15±.58	
	little	6	3.13±0.42	
	no	8	3.39±0.67	

**P-value is significant*

Type B2 and C lesions were significantly associated with higher inflation pressure in group A (P-value<0.05). On the other hand, there was no significant relation between the type of lesion and inflation duration, MSD by IVUS, MSA/ARLA, symmetry index, MSD/RD% in SBS, and MSD in SBS as shown in table (9).

Table (9) Relation between type of lesion & stent deployment parameters in IVUS and SBS in group A

Group A	type of lesion	N	Mean±Std. Deviation	P-value
inflation pressure(Atm)	A	4	15.50a±0.57	0.029*
	B1	8	15.50a±.535	
	B2	8	17.00b±1.41	
	C	10	16.80b±1.39	
inflation duration(sec)	A	4	25.00±0.0	0.085
	B1	8	27.88±2.48	
	B2	8	30.13±3.60	
	C	10	30.80±5.53	
MSD by IVUS (mm)	A	4	3.19±0.52	0.215
	B1	8	2.78±0.36	

	B2	8	3.04±0.30	
	C	10	3.05±0.29	
MSA/ARLA (expansion) By IVUS (%)	A	4	94.25±2.36	0.380
	B1	8	96.25±1.83	
	B2	8	95.38±2.62	
	C	10	94.20±3.19	
symmetry index by IVUS	A	4	0.91±0.01	0.760
	B1	8	0.89±0.02	
	B2	8	0.88±0.09	
	C	10	0.89±0.03	
MSD/RD by SBS (%)	A	4	98.50±1.00	0.532
	B1	8	96.75±1.04	
	B2	8	96.00±2.00	
	C	10	95.80±5.07	
MSD by SBS (mm)	A	4	3.13±0.54	0.359
	B1	8	2.81±0.36	
	B2	8	3.04±0.31	
	C	10	3.05±0.28	

There was no significant relation between the type of lesion and MSD by IVUS, MSA/ARLA, symmetry index, MSD/RD% in SBS, and MSD in SBS in group B as shown in table (10).

Table (10) Relation between type of lesion & stent deployment parameters in IVUS and SBS in group B

Group B	type of lesion	N	Mean±Std. Deviation	P-value
MSD by IVUS (mm)	A	5	3.19±0.40	0.569
	B1	7	3.22±0.63	
	B2	5	3.44±0.44	
	C	13	3.08±0.56	
MSA/ARLA (expansion)by IVUS (%)	A	5	96.00±2.12	0.402
	B1	7	93.28±4.19	
	B2	5	95.20±3.42	
	C	13	93.53±3.02	
symmetry index by IVUS	A	5	0.87±0.06	0.266
	B1	7	0.84±0.05	
	B2	5	0.79±0.08	
	C	13	0.80±0.08	
MSD/RD by SBS (%)	A	5	98.20±2.05	0.562
	B1	7	94.28±3.59	
	B2	5	96.20±3.77	
	C	13	95.76±5.86	
MSD by SBS (mm)	A	5	3.16±0.41	0.708
	B1	7	3.21±0.61	
	B2	5	3.44±0.43	
	C	13	3.10±0.59	

All cases with under-expansion were significantly associated with heavy calcification (P-value<0.05) as shown in table (11)

Table (11) Relation of stent under-expansion (MSA/ARLA <90% by IVUS) to lesion calcification

groups	Calcification	Expansion		P-value
		<90%	**≥90%**	
	total number	1	29	0.035*
Group A	Heavy	1_a(100.0%)	2_b(6.9%)	

	Moderate	0_a(0.0%)	10_a(34.5%)	
	Little	0_a(0.0%)	4_a(13.8%)	
	No	0_a(0.0%)	13_a(44.8%)	

There was a strong significant positive linear correlation between the diameter of the stent and MSD by IVUS and MSD by SBS in group A as shown in table (29) and there was a significant weak linear positive correlation between the length of the stent and inflation duration as shown in table (12)

Table (12) Correlation between stent size (diameter & length) and deployment parameters in IVUS & SBS in group A

Group A		**diameter of the stent**	**length of the stent**	**size (diameter x length)**
MSD by IVUS(mm)	R	.958**	-.132	.244
	P-value	.000	.486	.193
MSA/ARLA (expansion)by IVUS (%)	R	.109	-.163	-.081
	P-value	.565	.390	.672
symmetry index by IVUS	R	-.042	-.156	-.157
	P-value	.827	.410	.406
MSD/RD in SBS (%)	R	.065	-.106	-.086
	P-value	.734	.577	.652
MSD in SBS (mm)	R	.971**	-.092	.285
	P-value	.000	.627	.126
inflation pressure(Atm)	R	.093	.308	.350
	P-value	.624	.098	.058
inflation duration(sec)	R	-.078	.389*	.342
	P-value	.681	.034	.064

There was a strong significant positive linear correlation between the diameter of the stent and MSD by IVUS and MSD measured by SBS in group B as shown in table (13).

Table (13) Correlation between stent size (diameter & length) and deployment parameters in IVUS & SBS in group B

Group B		**diameter of the stent**	**length of the stent**	**size (diameter x length)**
MSD by IVUS (mm)	R	.981**	-.332	.213
	P-value	0.001	.073	.259
MSA/ARLA (expansion) by IVUS (%)	R	-.056	.036	.002
	P-value	.768	.852	.991
symmetry index by IVUS	R	.069	-.185	-.136
	P-value	.718	.327	.473
MSD/RD in SBS(%)	R	.014	-.044	-.004
	P-value	.943	.817	.983
MSD in SBS (mm)	R	.980**	-.315	.235
	P-value	0.001	.090	.211

There was no significant relation between stent size (diameter & length) and occurrence of dissection but longer inflation duration in group A was associated with occurrence of dissection as shown in table (14).

Table (14) Relation between stent size (diameter & length and inflation pressure) and occurrence of dissection

Groups		**dissection**	**N**	**Mean±Std. Deviation(S)**	**P-value**
Group A	diameter of the stent (mm)	no	29	2.86±0.33	0.787
		YES	1	2.75	
	length of the stent(mm)	no	29	25.76±6.82	0.749

		YES	1	28.00	
	size (diameter x length)	no	29	73.52±20.17	0.867
		YES	1	77.00	
	inflation pressure(Atm)	no	29	16.28±1.27	0.196
		YES	1	18.00	
	inflation duration(sec)	no	29	28.69±3.79	0.007*
		YES	1	40.00	
Group B	diameter of the stent(mm)	no	28	3.23±0.63	0.438
		YES	2	2.88±0.18	
	length of the stent (mm)	no	28	24.89±9.29	0.107
		YES	2	36.00±0.00	
	size (diameter x length)	no	28	78.61±27.72	0.222
		YES	2	103.50±6.41	

Discussion

Stent deployment by stent delivery balloon at high pressure (16-20 Atm) showed no significant difference in comparison to stent deployment at high pressure and routine post-stenting non-compliant balloon dilatation at 18-20 Atm when both are assessed by IVUS (MUSIC criteria) & stent boost subtract imaging regarding optimal stent deployment and incidence of complications (spasm, dissection and no reflow)

Our results agreed with **Cheneau et al (6)** found that Stent underexpansion was common with Cypher stents when expanded with 14 atm balloon inflation pressure, although this pressure was higher than the nominal pressure (11 atm). However, increasing the deployment pressure to 20 atm considerably reduced the incidence of stent underexpansion. Therefore, deploying Cypher stents at very high pressures might improve early and late outcomes.

Our study showed that increased stent length in group (A) was associated with longer inflation time for better stent deployment which go hand in hand with **Vallurupalli et al(7)** that found that stent length was the only significant predictor of the need for prolonged stent inflation.

Our study showed that heavy calcifications were associated with need for higher inflation pressure as agreed with **Ozdemir et al (8)** that found that calcification on the culprit vessel is one of the risk factors for high inflation pressures in PCI.

In our study group (A) ,(high inflation pressure group) there were two cases sub-optimally deployed according to MUSIC criteria , one case under expanded (MSA/ARLA <90%) and other is asymmetrically deployed (symmetry index <0.7) and the explanation in our study was the presence of heavy calcifications which proved in our study to be associated with lower degree of expansion and symmetry of stent .

This go in accordance with **Vavuranakis et al (9)** that found that the rigid and calcified segment of the arterial wall that is present within the lesion can affect final stent diameter and symmetry even if balloon inflations are performed at high pressure.

In our study group B there were three stents remained asymmetrically expanded despite full expansion and well opposition according to MUSIC criteria which can be explained in two cases by the presence of heavy calcification in one and moderate calcification in other case in accordance to the previously mentioned study **(Vavuranakis et al)** but according to **NAKANO et al (10)**, Highly asymmetric stent expansion after sirolimus-eluting stent (SES) implantation may not have a negative impact on clinical outcomes at 12 months if a minimal lumen-CSA is achieved(5.5 mm2 or more) after the procedure and if the total length of the stent is not excessive(stent length of 40 mm or less) which is the same in our study (minimal CSA >5.5mm2 and stent length <40 mm(

In group B in our study there were two cases complicated by dissection that were covered by stenting and our explanation for dissection in these two cases is the presence of heavy calcification as also supported by **Abazid et al (11)** that showed that increased coronary calcification measured by Multidetector computed tomography (MDCT) is associated with an increase in immediate PCI complications.

In our study we found that MSD measured by SBS has significant positive linear correlation to MSD measured by IVUS that agreed with **Laimoud et al (12)** that found that Stent Boost enhancement has superior correlations for stent expansion measured by IVUS when compared with QCA. SB enhancement improved stent visualization and identification of stent underexpansion to guide stent postdilatation.

Conclusion

High inflation pressure deployment of 2nd generation DES is associated with optimal stent deployment (according to MUSIC criteria) as effective as routine post stenting NC balloon dilatation but heavy coronary calcification in lesion lead to less expansion and less symmetry of stent even after NC balloon dilatation and needs higher inflation pressure and longer inflation duration so if stent deployment is performed in calcified lesions, higher balloon pressures should be applied with IVUS guidance. Heavy coronary calcifications were associated with increased risk of complications as dissection.

We can use stent boost method for detection of stent insufficient deployment in centers where IVUS is not available.

References

1. Romagnoli E, Sangiorgi GM, Cosgrave J, Guillet E, Colombo A. Drug-Eluting Stenting. The Case for Post-Dilation. JACC Cardiovasc Interv. 2008;1(1):22–31.
2. Morice MM. Numb Er 23 With a Standard Stent for Coronary Revascularization. N Engl J Med [Internet]. 2002;346(23):1773–80. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12050336
3. Sonoda S, Morino Y, Ako J, Terashima M, Hassan AHM, Bonneau HN, et al. Impact of final stent dimensions on long-term results following sirolimus-eluting stent implantation: Serial intravascular ultrasound analysis from the SIRIUS trial. J Am Coll Cardiol. 2004;43(11):1959–63.
4. Fitzgerald PJ, Oshima A, Hayase M, Metz JA, Bailey SR, Baim DS, et al. Final results of the Can Routine Ultrasound Influence Stent Expansion (CRUISE) study. Circulation. 2000;102(5):523–30.
5. Pasceri V, Pelliccia F, Pristipino C, Roncella A, Irini D, Varveri A, et al. Clinical effects of routine postdilatation of drug-eluting stents. Catheter Cardiovasc Interv. 2014;83(6):898–904.
6. Cheneau E, Satler LF, Escolar E, Suddath WO, Kent KM, Weissman NJ, et al. Underexpansion of sirolimus-eluting stents: Incidence and relationship to delivery pressure. Catheter Cardiovasc Interv. 2005;65(2):222–6.
7. Vallurupalli S, Bahia A, Ruiz-Rodriguez E, Ahmed Z, Hakeem A, Uretsky BF. Optimization of stent implantation using a high pressure inflation protocol. Catheter Cardiovasc Interv. 2016;87(1):65–72.
8. Ozdemir L. Pp-251 the Association Between Inflation Pressure and Patient'S Characteristics, Biochemical Tests and Lesion Localization in Patients Who Undergo Elective Pci. Int J Cardiol [Internet]. 2012;155:S187. Available from: http://dx.doi.org/10.1016/S0167-5273(12)70451-5
9. Vavuranakis M, Toutouzas K, Stefanadis C, Chrisohou C, Markou D, Toutouzas P. Stent deployment in calcified lesions: Can we overcome calcific restraint with high-pressure balloon inflations? Catheter Cardiovasc Interv. 2001;52(2):164–72.
10. Nakano M, Wagatsuma K, Iga A, Nil H, Amano H, Toda M, et al. Impact of highly asymmetric stent expansion after sirolimus-eluting stent implantation on twelve-month clinical outcomes. J Cardiol. 2007;49(6):313–21.
11. Abazid RM, Obadah Kattea M, Smettei OA, Beshir Y, Sakr H. Impact of coronary artery calcification on percutaneous coronary intervention and postprocedural complications. J Saudi Hear Assoc [Internet]. 2017;29(1):15–22. Available from: http://dx.doi.org/10.1016/j.jsha.2016.05.002
12. Laimoud M, Nassar Y, Omar W, Abdelbarry A, Elghawaby H. Stent boost enhancement compared to intravascular ultrasound in the evaluation of stent expansion in elective percutaneous coronary interventions. Egypt Hear J [Internet]. 2018;70(1):21–6. Available from: https://doi.org/10.1016/j.ehj.2017.09.001