Influence of Diabetes Mellitus on Immediate Results of Coronary Stent: National Center for Cardiovascular Interventions (CENIC) Data Analysis

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Objective

This study sought to investigate the influence of Diabetes Mellitus (DM) on immediate results after coronary stenting implantation (CSI) according to clinical presentation.

Methods

Between January, 1997 and December, 2003, 11,874 diabetic patients underwent CSI, as recorded by CENIC database: 7,386 (62.3%) had chronic coronary disease (CCD); 3,142 (26.4%) acute coronary syndrome with non-ST segment elevation (ACSNST); and 1,346 (11.3%), reported acute myocardial infarction (AMI), with ST Segment elevation. Those groups were compared with 48,103 non-diabetics: 30,980 (64.5%) with CCD; 10,938 (22.7%), with non-elevated ST segments and unstable angina; and 6,185 (12.8%), with AMI.

Results

Diabetic patients presented worse clinical and angiographic characteristics. Diabetics with CCD showed similar incidence of MACE as compared to non-diabetics (0.98% x 0.91%, p=0.5971); however, diabetics with ACSNST and AMI reported higher incidence of events: 2.76% x 1.46% (p<0.0001) and 7.87% x 4.1% (p<0.0001), respectively. Multivariate analysis showed DM to act as independent risk predictor for larger adverse events under non-elevated ST segment and unstable angina (ACSNST) (OR: 1.92 CI: 1.46-2.52 p<0.0001) and with AMI (OR: 2.0 CI: 1.57-2.54 p<=0.0001) and no influence for CCD (OR: 1.08 CI: 0.83-1.42 p=0.5470

Conclusion

Diabetic patients with CCD reported similar outcome as compared to the non-diabetics; however, those with ACSNST and AMI presented higher incidence of major adverse cardiac events during hospital stay.

Key words

Diabetes Mellitus, stenting, coronary atherosclerosis.

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DM prevalence has increased progressively in the last 20 years. One hundred million people worldwide are estimated to be DM carriers in our days[1]. DM is an important risk factor for general atherosclerosis. Therefore, cardiovascular complications are the major causes for death and impairment in those patients[2]. Additionally, diabetics exhibit a more aggressive course for coronary diseases, which results in 45% death incidence within 7 years, and 75% within 10 years after the onset of symptoms[3].

In diabetics, immediate and long-term results following percutaneous coronary intervention (PCI) used to be unfavorable when compared to non-diabetics[4,5]. However, results have improved after the use of coronary stenting[6] associated to aspirin anti-platelet-aggregation therapy, thienopyridine derivates, and glycoprotein IIb/IIIa receptor inhibitors[7,8]. However, the benefit of such association for the diabetic population is still controversial[9].

The clinical presentation of coronary disease is important for short and long term prognostics in diabetic patients. Those reporting acute conditions are exposed to higher risk of death and non-fatal infarction[10] during hospital stay; and those with stable angina have reported shorter survival time during long-term outcome[11] when compared to the non-diabetics. Age and gender have been the basis for comparison between those two populations for most studies using PCI as treatment procedure; however, few studies have analyzed the clinical presentations. Except for AMI, most series publications on percutaneous treatment in diabetics have associated presentation clinical condition (stable and unstable angina); few studies have analyzed whether clinical presentation of coronary diseases influence immediate results for percutaneous treatment in diabetics.

The purpose of this study was to compare the immediate results of *coronary stenting* between diabetic and non-diabetic patients based on clinical condition.

Methods

Records of patients submitted to *coronary stenting* between January, 1997, and December, 2003 at CENIC – which belongs to the Brazilian Society of Hemodynamic and Interventional Cardiology (SBHCI) – were analyzed. Data collection stored in a database was the spontaneous contribution of permanent members. Patients submitted to balloon angioplasty only were excluded from the analysis, since results are suboptimal when compared to stenting, in addition to being a procedure not widely used in the most recent years.

In the first analysis, patients were divided into diabetics (DM) and non-diabetics (N-DM): clinical and angiographic data, as well as immediate post-procedure results were compared. Patients were later divided into three groups according to clinical presentation: chronic coronary disease (CCD), defined as stable angina, silent ischemia, recent onset and progressive angina; moderate and high risk non-elevated ST segment, following TIMI Risk Score[12] and non-Q-wave AMI (ACSNST); and acute myocardial infarction (AMI), defined as AMI with supra-unlevelling of ST segment, submitted to primary angioplasty. Results from diabetics and non-diabetics were compared in the groups.

Study primary outcome was to investigate the incidence of a combined event: death, AMI, and the need for surgical or percutaneous revascularization during hospital stay. Death was defined as the outcome from any etiology; acute myocardial infarction (AMI), as the elevation of CK-MB > 3 times normal value[13] and/or development of electrocardiographic changes following Novacode criteria[14] (Minnetosa code extension). In AMI patients, infarction was defined as the re-elevation of CK-MB[13] levels.

Statistical analysis was carried out through *Statistica* for *Windows*, Version 5.0 (*StatSoft Inc. Tulsa*, Oklahoma, USA). Categorical variables were percentually expressed and compared through Pearson's chi-square. Continuous variables were expressed as mean ± SD and analyzed through Student t test. $p<0.05$ was considered statistically significant. A multivariate analysis was then carried out to calculate DM odds ratio in primary end-point components: death, AMI, need for revascularization (surgical or percutaneous), combination of death/AMI (irreversible events), and total events in the group as a whole and for each clinical condition.

Results

Between January, 1997 and December, 2003 CENIC database showed 59,977 patients had been submitted to coronary stenting. From those, 11,874 (19.8%) were diabetics and 48,103 (80.2%), non-diabetics. Clinical and angiographic data can be found in Table 1. Diabetic patients reported a higher number of female patients, higher incidence of previous surgical revascularization, previous coronary angioplasty, severe left ventricle dysfunction, tri-arterial coronary disease, complex coronary lesions (type C, intracoronary thrombus, calcification, bifurcation), saphenous vein graft lesions, and more frequent use of GP IIb/IIIa inhibitors ($p<0.05$ for all comparisons).

Angiographic success rate was lower in the DM group (98.5%) x non-DM (98.8%) ($p=0.8244$), with higher post-procedure diameter stenosis: 8.89 ± 11.46 x 7.66 ± 10.56 ($p<0.0001$). Primary outcome occurred in the DM group (2.23%) x non-DM (1.44%) ($p<0.0001$). As for primary outcome components, incidence of death was higher (1.24% x 0.73%, $p<0.0001$), new PCI (0.28% x 0.15%, $p=0.0355$), and a trend towards a higher rate of AMI (0.61% x 0.48%, $p=0.0835$) in the diabetic population. No difference was shown by the groups regarding the need for surgical revascularization (0.08% x 0.07%, $p=0.7655$) (Fig. 1).

Table 1 – Clinical and Angiographic Data of General Population

	Total	DM	Non-DM	P
n (%)	59,977 (100%)	11,874 (19.8%)	48,103 (80.2%)	-
Treated lesions	74,422 (100%)	15,136 (20.3%)	59,286 (79.7%)	-
Ratio *stent*/patient	1.24	1.27	1.23	<0.0001
Age	61.86 ± 10.89	62.65 ± 10.57	61.08 ± 11.21	<0.0001
Females	19,495 (32.5%)	5,097 (42.9%)	14,398 (29.9%)	<0.0001
Previous MR	6,599 (11%)	1,640 (13.8%)	4,959 (10.3%)	<0.0001
Previous PCI	9,344 (15.5%)	2,150 (18.1%)	7,194 (14.9%)	<0.0001
IDDM*	1,954 (3.2%)	1,954 (16.4%)	-	-
1 vessel	30,452 (50.7%)	5,032 (42.3%)	25,420 (52.8%)	<0.0001
2 vessels	18,211 (30.3%)	3,898 (32.8%)	14,313 (29.7%)	<0.0001
3 vessels	9,487 (15.8%)	2,541 (21.3%)	6,946 (14.4%)	<0.0001
Not specified	1,827 (3.0%)	403 (3.3%)	1,424 (2.9%)	0.0138
LV Severe Dysfunction	2,556 (4.2%)	634 (5.3%)	1,922 (3.9%)	<0.0001
Lesions: A	3,125 (4.1%)	719 (4.7%)	2,406 (4.0%)	0.0002
B1	19,831 (26.6%)	3,992 (26.3%)	15,839 (26.7%)	0.3956
B2	35,816 (48.1%)	7,230 (47.7%)	28,586 (48.2%)	0.3225
C	13,547 (18.2%)	2,849 (18.8%)	10,698 (18.0%)	0.0269
Not specified	2,103 (2.8%)	346 (2.2%)	1,757 (2.9%)	0.0001
Visible thrombus	12,546 (16.8%)	2,386 (15.7%)	10,160 (17.1%)	0.0001
Calcification	15,387 (20.6%)	3,549 (23.4%)	11,838 (19.9%)	<0.0001
Extension > 10 mm	42,969 (57.5%)	8,864 (58.5%)	34,105 (57.5%)	0.0213
Bifurcation	20,861 (28.0%)	3,964 (26.1%)	16,897 (28.5%)	<0.0001
Adjunctive pharmacology:				
ASA	58,249 (97.1%)	11,577 (97.4%)	46,672 (97.0%)	0.0057
EV Heparin	21,712 (36.2%)	4,200 (35.3%)	17,512 (36.4%)	0.0358
LMWH**	5,915 (9.8%)	1,280 (10.7%)	4,635 (9.6%)	0.0002
SC Heparin	3,200 (5.3%)	542 (4.5%)	2,658 (5.5%)	<0.0001
GP IIb/IIIa Inhibitors	4,944 (8.2%)	1,267 (10.6%)	3,677 (7.6%)	<0.0001
Ticlopidine/clopidogrel	49,233 (82.0%)	8,541 (71.9%)	35,748 (74.3%)	<0.0001
Treated vessels:				
LAD	32,660 (43.8%)	6,424 (42.4%)	26,236 (44.2%)	0.0001
RCA	21,379 (28.7%)	4,262 (28.1%)	17,117 (28.8%)	0.0832
LM	15,373 (20.6%)	2,994 (19.7%)	12,379 (20.8%)	0.0029
SVG	651 (0.8%)	138 (0.9%)	513 (0.8%)	0.5840
Not specified	1,602 (2.1%)	431 (2.8%)	1,171 (1.9%)	<0.0001
	2,757 (3.7%)	887 (5.8%)	1,870 (3.1%)	<0.0001
Angiographic success	73,508 (98.7%)	14,915 (98.5%)	58,593 (98.8%)	0.0037
% Stenosis -Pre	90.48 ± 9.81	92.63 ± 9.75	88.34 ± 9.88	<0.0001
% Stenosis-Post	8.27 ± 11.01	8.89 ± 11.46	7.66 ± 10.56	<0.0001
Hyperinsuflation pressure	14.35 ± 3.10	14.35 ± 2.95	14.37 ± 3.26	0.0730

** - Insulin Dependent Diabetes Melittus, ** - Low molecular weight heparin*

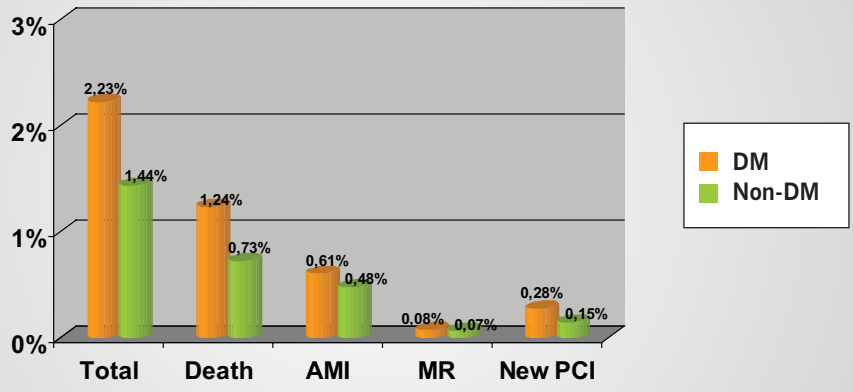

***Fig. 1** – Immediate Results: Adverse Events (Total Group). AMI – Acute Myocardial Infarction; MR –urgent Myocardial Revascularization surgery*

Subgroups Analysis

CCD -Among CCD patients (n = 38,366), 7,386 (19.2%) were diabetics and also reported unfavorable clinical and angiographic condition (Table 2), such as: age, females, previous myocardial revascularization (MR) and PCI, triarterial disease, severe dysfunction of LV, C lesions, calcification, bifurcation, and higher use of abciximab (p<0.05 for all comparisons). In regard to treated vessels, higher incidence of saphenous vein graft (2.3% x 1.6%, p<0.0001) and lower incidence of intervention in LAD (42.2% x 44.1%, p=0.0399) were reported.

Angiographic success rate was similar for DM (98.8%) x non-DM (98.8%) (p=0.8555) patients. Primary end-point occurred in 0.98% in DM x 0.91% in non-DM (p= 0.5971). No difference was reported related to incidence of death (0.26% x 0.29%, p=0.7532), AMI (0.41% x 0.41%, p=0.9241), or the need for surgical revascularization (0.05% x 0.07%; p=0.8017). However, the DM group reported higher need for a new PCI (0.26% x 0.14%, p=0.0284) (Fig. 2).

ACSNST - From patients with non ST elevation segment (n = 14,080), 3,142 (22.3%) were diabetics; similarly to the CCD group, those patients reported unfavorable clinical and angiographic data (Table III), such as: age, females, previous MR and PCI, triarterial disease, severe dysfunction of LV, intracoronary thrombus, bifurcation lesion, and higher use of abciximab (p<0.05). As for vessels treated, higher incidence of saphenous vein graft intervention (3.8% x 3.1%, p=0.0349), as well as lower

Table 2 – Clinical and Angiographic Data: Chronic Coronary Disease

	Total	DM	Non-DM	p
Patients	38,366 (100%)	7,386 (19.2%)	30,980 (80.8%)	-
Treated lesions	48,127 (100%)	9,477 (19.6%)	38,650 (80.4%)	-
Ratio *stent*/patient	1.25	1.28	1.24	0.0020
Age	61.77 ± 10.33	62.35 ± 9.96	61.2 ± 10.7	<0.0001
Females	12,523 (32.6%)	3,147 (42.6%)	9,376 (30.2%)	<0.0001
Previous MR	4,619 (12.0%)	1,081 (14.6%)	3,538 (11.4%)	<0.0001
Precious PCI	6,719 (17.5%)	1,466 (19.8%)	5,253 (16.9%)	<0.0001
IDDM	1,187 (3.0%)	1,187 (16.1%)	-	-
1 vessel	20,079 (52.3%)	3,297 (44.6%)	16,782 (54.1%)	<0.0001
2 vessels	11,563 (30.1%)	2,434 (32.9%)	9,129 (29.4%)	<0.0001
3 vessels	5,605 (14.6%)	1,404 (19.0%)	4,201 (13.5%)	<0.0001
Not specified	1,119 (2.9%)	251 (3.3%)	868 (2.8%)	0.0062
LV Severe Dysfunction	952 (2.4%)	233 (3.1%)	719 (2.3%)	<0.0001
Lesions: A	2,329 (4.8%)	454 (4.8%)	1,875 (4.8%)	0.8051
B1	14,672 (30.4%)	2,871 (30.3%)	11,801 (30.5%)	0.6512
B2	22,363 (46.4%)	4,392 (46.3%)	17,971 (46.5%)	0.7890
C	7,441 (15.4%)	1,559 (16.4%)	5,882 (15.2%)	0.0030
Not specified	1,322 (2.7%)	201 (2.1%)	1,121 (2.9%)	<0.0001
Visible thrombus	3,164 (6.5%)	653 (6.9%)	2,511 (6.5%)	0.1659
Calcification	10,089 (20.9%)	2,270 (23.9%)	7,819 (20.2%)	<0.0001
Extension > 10 mm	26,046 (54.1%)	5,241 (55.3%)	20,805 (53.8%)	0.0099
Bifurcation	13,368 (27.7%)	2,492 (26.3%)	10,876 (28.1%)	0.0003
Adjunctive pharmacology:				
ASA	37,242 (97.0%)	7,193 (97.4%)	30,049 (96.9%)	0.7260
EV Heparin	13,031 (33.9%)	2,486 (33.6%)	10,545 (34.0%)	0.5357
LMWH	3,713 (9.6%)	795 (10.7%)	2,918 (9.4%)	0.0004
SC Heparin	1,905 (4.9%)	307 (4.1%)	1,598 (5.1%)	0.0004
GP IIb/IIIa Inhibitor	1,857 (4.8%)	539 (7.3%)	1,318 (4.2%)	<0.0001
Ticlopidine/clopidogrel	28,658 (74.6%)	5,327 (72.1%)	23,331 (75.3%)	<0.0001
Treated vessel:				
LAD	21,051 (43.7%)	4,003 (42.2%)	17,048 (44.1%)	0.0010
RCA	13,395 (27.8%)	2,552 (26.9%)	10,843 (28.0%)	0.0284
CX	9,750 (20.2%)	1,982 (20.9%)	7,768 (20.1%)	0.0767
LM	421 (0.8%)	86 (0.9%)	335 (0.8%)	0.7029
SVG	874 (1.8%)	224 (2.3%)	650 (1.6%)	<0.0001
Not specified	2,636 (5.4%)	630 (6.6%)	2,006 (5.1%)	<0.0001
Angiographic success	47,582 (98.8%)	9,368 (98.8%)	38,214 (98.8%)	0.8555
% Pre-stenosis	83.69 ± 10.05	83.61 ± 10.01	83.78 ± 10.09	0.1925
% Post-stenosis	7.66 ± 11.51	7.99 ± 11.58	7.34 ± 11.45	0.1212
Hyperinsuflation pressure	14.41 ± 3.76	14.45 ± 4.05	14.38 ± 3.48	0.1328

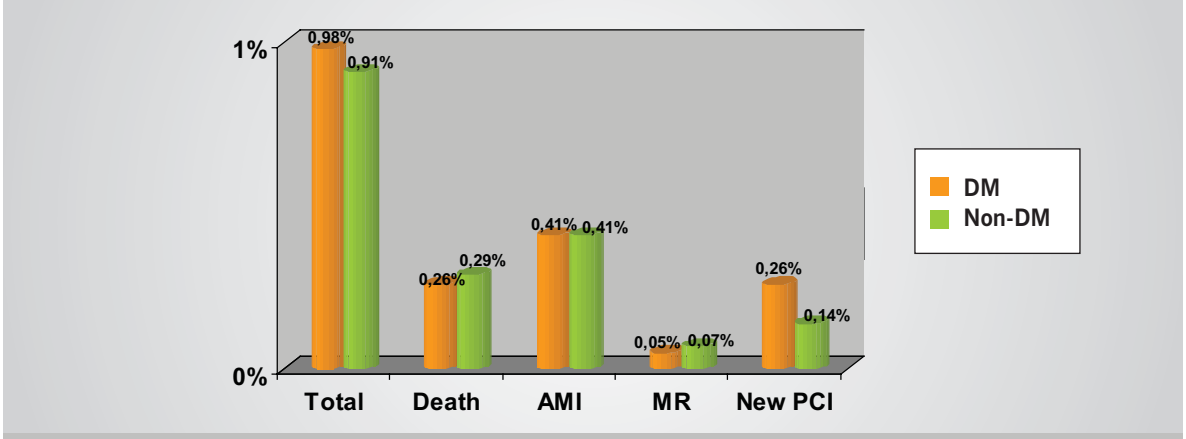

Fig. 2 – Immediate Results: Adverse Events – Chronic Coronary Disease. AMI- Acute Myocardial Infarction; MR- urgent Myocardial Revascularization surgery

incidence of anterior descending artery (AD) intervention (41.4% x 44.3%, p=0.0007) were reported.

Angiographic success rate was similar for DM (98.8%) x non-DM (98.8%) (p=0.7757) patients. Primary end-point was reported 2,76% in DM patients x 1.46% in non-DM (p<0.0001). Higher rate of death was reported in the DM group (1.50% x 0.64%, p<0.0001). However, no difference was observed related to AMI (0.83% x 0.59%, p=0.1931), or the need for surgical (0.13% x 0.07%; p=0.5691) or percutaneous (0.32% x 0.16%, p=0.1088) revascularization. (Fig. 3).

AMI - was presented in 7,531 patients (12.5%). From those, 1,346 (17.8%) were diabetics. Clinical and angiographic data can be found in Table 4. Diabetic patients reported more unfavorable clinical and angiographic data (age, female gender, previous MR and PCI, triarterial disease, cardiogenic shock, calcified lesions; p<0.05), as well as higher saphenous vein graft intervention (p<0.0001).

Angiographic success rate was lower for DM (97.6%) x non-DM (98.5%) (p=0.0244) patients. In this population, primary end-point was reported in 7.87% of DM patients x 4.1% in non-DM. (p= 0.0001). Incidence of death was higher (6.09% x 3.12%, p=0.001) as was reinfarction rate (1.26% x 0.68%, p=0.0444), with no difference in the need for surgical (0.15% x 0.06%; p=0.903) or percutaneous (0.37% x 0.24%, p=0.5903) revascularization. (Fig. 4).

Multivariate Analysis

Multivariate analysis can be found in Table 5. DM showed to be an independent risk predictor for death in the group as a whole. (OR 1.71 CI: 1.40 – 2.09; p<0.0001), AMI (OR 1.27 CI: 0.97 – 1.67; p<p=0.0740), new revascularization (OR 1.65 CI: 1,15 – 2.38; p=0.0045), as well as death/AMI (OR 1.59 CI: 1.36 – 1.86; p<0.0001).

In the CCD group, DM did not show to be a predicting factor for adverse events (p>0.05 for all assessments).

In the ACSNST group, DM also showed to be an independent risk predictor for death (OR 2.36 CI: 1.60 – 3.47; p<0.0001), new revascularization (OR 1.95 CI: 0.96 – 3.92; p=0.0410), and death/AMI (OR 1.90 CI: 1.41- 2.56; p<0.0001).

In the AMI group, DM was an independent predictor for death (OR 2.01 CI: 1.53 – 2.65; p<0.0001), AMI (OR 1.87 CI: 1.02 – 3.40; p=0.0276), and death/AMI (OR 2.01 CI: 1,57 – 2.58; p<0.0001).

Discussion

Based on our data, DM showed to cause adverse effects in coronary stenting immediate results when compared to the non-DM group. Such results are similar to those recently published in the literature[9,15-17]. As in all of these series, diabetic patients reported unfavorable clinical and angiographic data. It is important to point out that in spite of that, the use of coronary stents brought similar angiographic success to the groups. However, after the procedure, the angiographic analysis of diabetic patients showed higher grade of stenosis, which is associated to the increase of post-PCI restenosis, although not yet defined as a predictor for immediate adverse events.

Although diabetic patients have used GP IIb/IIIa inhibitors more often as compared to non-diabetics (10.6% x 7.6%, p<0.0001), such rate is lower than other series published in literature. Mathew[16] et al have reported the use of IIb/IIIa inhibitor in 25% of the 2,694 treated diabetics in the PRESTO study. Walton et al[18], in their turn, used it in 38% of the 707 treated diabetic patients at a community hospital in Washington DC. The benefit of IIb/IIIa inhibitors in diabetics has been demonstrated by randomized trials[7,8,19] as well as by non-randomized series [18,20,21]. The inhibitors might have had favorable action if used in a wider number of patients in this series.

Table 3 – Clinical and Angiographic Data: Acute Ischemic Syndromes with Non-elevated ST segment

	Total	DM	Non-DM	p
Patients	14,080 (100%)	3,142 (22.3%)	10,938 (77.7%)	-
Treated lesions	17,721 (100%)	4,086 (23%)	13,635 (77%)	-
Ratio *stent*/patient	1.25	1.3	1.24	0.0030
Age	62.08 ± 11.19	63.19 ± 10.66	60.97 ± 11.73	<0.0001
Females	4,733 (33.6%)	1,409 (44.8%)	3,324 (30.4%)	<0.0001
Previous MR	1,584 (11.2%)	456 (14.5%)	1,128 (10.3%)	<0.0001
Previous PCI	2,058 (14.6%)	544 (17.3%)	1,514 (13.8%)	<0.0001
DMID	554 (3.9%)	554 (17.6%)	-	-
1 vessel	6,788 (48.2%)	1,251 (39.8%)	5,537 (50.6%)	<0.0001
2 vessels	4,364 (30.9%)	1,023 (32.5%)	3,341 (30.5%)	0.0314
3 vessels	2,460 (17.4%)	758 (24.1%)	1,702 (15.5%)	<0.0001
Not specified	468 (3.3%)	110 (3.5%)	358 (3.2%)	0.5298
LV Severe Dysfunction	838 (5.9%)	214 (6.8%)	624 (5.7%)	0.0209
Lesions: A	702 (3.9%)	241 (5.9%)	461 (3.4%)	<0.0001
B1	4,106 (23.1%)	931 (22.8%)	3,175 (23.3%)	0.5059
B2	8,937 (50.4%)	2.004 (49.1%)	6,933 (50.8%)	0.0434
C	3,539 (19.9%)	818 (20.0%)	2,721 (19.9%)	0.9289
Not specified	437 (2.4%)	92 (2.2%)	345 (2.5%)	0.3137
Visible thrombus	3,603 (20.3%)	721 (17.6%)	2,882 (21.1%)	<0.0001
Calcification	3,883 (21.9%)	975 (23.8%)	2,908 (21.3%)	0.0006
Extension > 10mm	10,989 (62.0%)	2,525 (61.8%)	8,464 (62.1%)	0.7471
Bifurcation	4,976 (28.0%)	1,047 (25.6%)	3,929 (28.8%)	0.0001
Adjunctive pharmacology:				
ASA	13,717 (97.4%)	3,086 (98.2%)	10,631 (97.2%)	0.0014
EV Heparin	5,270 (37.4%)	1,130 (35.9%)	4,140 (37.8%)	0.0543
LMWH**	1,431 (10.1%)	317 (10.1%)	1,114 (10.2%)	0.8643
SC Heparin	991 (7.0%)	172 (5.4%)	819 (7.5%)	0.0001
GP IIb/IIIa Inhibitors	1,367 (9.7%)	374 (11.9%)	993 (9.1%)	<0.0001
Ticlopidine/clopidogrel	10,565 (75.0%)	2,361 (75.1%)	8,204 (75.0%)	0.8742
Treated vessel:				
LAD	7,745 (43.7%)	1,692 (41.4%)	6,053 (44.3%)	0.0007
RCA	4,918 (27.7%)	1,167 (28.5%)	3,751 (27.5%)	0.1882
CX	3,459 (19.5%)	816 (19.9%)	2,643 (19.3%)	0.4066
LM	166 (0.9%)	41 (1.0%)	125 (0.9%)	0.6140
SVG	593 (3.3%)	158 (3.8%)	435 (3.1%)	0.0349
Not specified	840 (4.7%)	212 (5.1%)	628 (4.6%)	0.1242
Angiographic success	17,497 (98.7%)	4,011 (98.1%)	13,486 (98.9%)	0.0002
% Ptenosis - Pre	93.24 ± 10.38	100 ± 10.08	86.49 ± 10.69	<0.0001
% Stenosis - Port	8.26 ± 12.5	8.85 ± 13.64	7.67 ± 11.37	<0.0001
Hyperinsuflation pressure	14.32 ± 2.68	14.34 ± 2.48	14.39 ± 3.27	0.4272

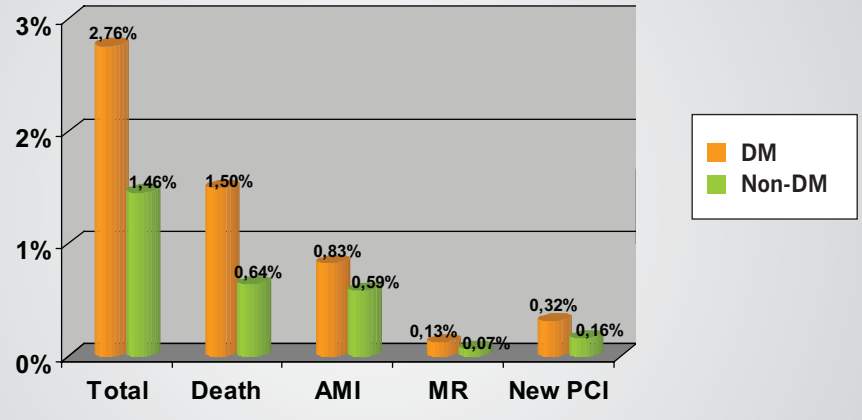

Fig. 3 *– Immediate Results: Adverse Events (SCANST). AMI- Acute Myocardial Infarction; MR- urgent Myocardial Revascularization surgery*

Table 4 – Clinical and Angiographic Data: Acute Myocardial Infarction

	Total	DM	Non-DM	p
Patients	7,531 (100%)	1,346 (17.8%)	6,185 (82.2%)	-
Treated lesions	8,574 (100%)	1,573 (18.3%)	7,001 (81.7%)	-
Ratio *stent*/patient	1.13	1.16	1.13	0.3186
Age	61.25 ± 11.71	62.43 ± 11.1	60.08 ± 12.33	<0.0001
Females	2,239 (29.7%)	541 (40.2%)	1,698 (27.4%)	<0.0001
Previous MR	396 (5.2%)	103 (7.7%)	293 (4.7%)	<0.0001
Previous PCI	547 (7.2%)	120 (8.9%)	427 (6.9%)	0.0100
IDDM	213 (2.8%)	213 (15.8%)	-	-
1 vessel	3,585 (47.6%)	484 (35.9%)	3,101 (50.1%)	<0.0001
2 vessels	2,284 (30.3%)	441 (32.7%)	1,843 (29.8%)	0.0319
3 vessels	1,422 (18.8%)	379 (28.1%)	1,043 (16.8%)	<0.0001
Not specified	240 (3.1%)	42 (3.1%)	198 (3.2%)	0.8782
Cardiogenic shock	766 (10.1%)	187 (13.8%)	579 (9.3%)	<0.0001
Lesions: A	112 (1.3%)	24 (1.5%)	88 (1.2%)	0.3993
B1	1,053 (12.3%)	190 (12.8%)	863 (12.3%)	0.7866
B2	4,516 (52.6%)	834 (53.2%)	3,682 (52.6%)	0.7591
C	2,567 (29.9%)	472 (30.0%)	2,095 (29.9%)	0.9488
Not specified	326 (3.8%)	53 (3.3%)	273 (3.8%)	0.3206
Visible thrombus	5,779 (67.4%)	1,012 (64.3%)	4,767 (68.1%)	0.0041
Calcification	1,415 (16.5%)	304 (19.3%)	1,111 (15.9%)	0.0008
Extension > 10mm	5,844 (68.1%)	1,098 (69.8%)	4,746 (67.8%)	0.1216
Bifurcation	2,517 (29.3%)	425 (27.0%)	2,092 (29.8%)	0.0243
Adjunctive pharmacology:				
ASA	7,290 (96.7%)	1,298 (96.4%)	5,992 (96.9%)	0.3999
EV Heparin	3,411 (45.2%)	584 (43.4%)	2,827 (45.7%)	0.1213
LMWH**	771 (10.2%)	168 (12.5%)	603 (9.7%)	0.0027
SC Heparin	304 (4.0%)	63 (4.7%)	241 (3.9%)	0.1854
GP IIb/IIIa Inhibitors	1,720 (22.8%)	354 (26.3%)	1,366 (22.1%)	0.0008
Ticlopidine/clopidogrel	5,066 (67.2%)	853 (63.4%)	4,213 (68.1%)	0.0008
Treated vessel:				
LAD	3,864 (45.0%)	729 (46.3%)	3,135 (44.7%)	0.2596
RCA	3,066 (35.7%)	543 (34.5%)	2,523 (36.0%)	0.2565
CX	1,164 (13.5%)	196 (12.4%)	968 (13.8%)	0.1528
LM	64 (0.7%)	11 (0.6%)	53 (0.7%)	0.8100
SVG	135 (1.5%)	49 (3.1%)	86 (1.2%)	<0.0001
Not specified	281 (3.2%)	45 (2.8%)	236 (3.3%)	0.3045
Angiographic success	8,429 (98.3%)	1,536 (97.6%)	6,893 (98.5%)	0.0244
% Stenosis - pre	94.4 ± 9.01	94.03 ±9.16	94.77 ± 8.87	0.0058
% Stenosis - post	8.91 ± 14.05	9.83 ± 15.43	7.99 ± 12.67	<0.0001
Hyperinsuflation pressure	14.32 ± 2.68	14.28 ± 2.32	14.37 ± 3.05	0.3076

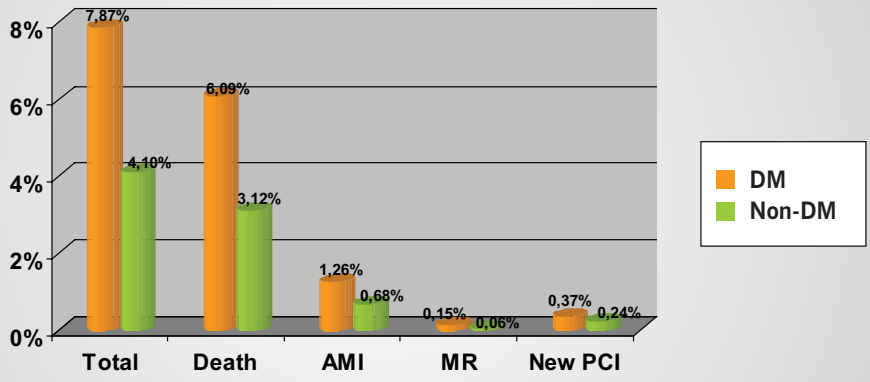

Fig. 4 – Immediate Results: Adverse Events (Acute Myocardial Infarction). AMI- Acute Myocardial Infarction; MR- urgent Myocardial Revascularization surgery

Table 5 – Multivariate Analysis

		OR	CI 95%	p
Total				
	Death	1.71	(1.40 – 2.09)	0.0001
	AMI	1.27	(0.97 – 1.67)	0.0740
	New revascularization (surgical or percut.)	1.65	(1.15 - 2.38)	0.0045
	Death / AMI	1.59	(1.36 – 1.86)	0.0001
	MACE	1.56	(1.35 – 1.81)	0.0001
AMI				
	Death	2.01	(1.53 – 2.65)	0.0001
	AMI	1.87	(1.02 – 3.40)	0.0276
	New revascularization (surgical or percut.)	1.70	(0.65 – 4.27)	0.2275
	Death / AMI	2.01	(1.57 – 2.58)	0.0001
	MACE	2.00	(1.57 – 2.54)	0.0001
ACSNST				
	Death	2.36	(1.60 – 3.47)	0.0001
	AMI	1.40	(0.86 – 2.25)	0.1504
	New revascularization (surgical or percut.)	1.95	(0.96 – 3.92)	0.0413
	Death / AMI	1.90	(1.41 – 2.56)	0.0001
	MACE	1.92	(1.46 – 2.52)	0.0001
CCD				
	Death	0.90	(0.53 – 1.50)	0.6614
	AMI	1.00	(0.66 – 1.51)	0.9947
	New revascularization (surgical or percut.)	1.51	(0.91 – 2.49)	0.0887
	Death / AMI	0.96	(0.69 – 1.32)	0.7751
	MACE	1.08	(0.83 – 1.42)	0.5470

Another important aspect to be pointed out is the higher incidence of venous surgical grafts in those patients. In the opinion of Ahmed et al[22], mortality rate is higher among diabetics who have been submitted to saphenous vein graft stenting, which does not favor hospital evolution for those patients. It is likely that the use of protection systems – to avoid distal embolization - may improve those results if used as routine procedure in this population.

Diabetes and CCD

To this point in time, it is still not clear whether myocardial revascularization - as early treatment strategy - is beneficial for diabetics with chronic coronary disease[23], except for multiarterial coronary disease patients (3 vessels and 2 vessels disease), with proximal AD portion commitment), left coronary main lesion, and significant ventricular dysfunction[24]. The use of stenting in percutaneous revascularization procedures seems to have neutralized diabetics' excessive risk level when submitted to conventional balloon angioplasty. Some difference can still be found, though, when compared to non-diabetics.

Diabetes has not shown to be a risk factor in post-PCI immediate results in CENIC database analysis. Our results agree with those by Abizaid et al[25], who have analyzed randomized patients in the stent subgroup of the ARTS study and have found no difference in the incidence level of adverse events in the hospital phase of diabetic patients (in that study, approximately 60% of the patients reported stable angina/ silent ischemia). While analyzing 386 patients who had been submitted to coronary stenting, Bayerl et al[26], in their turn, did not demonstrate any mortality rate increase among diabetic patients, although increased incidence of post-procedure AMI (7.4% x 1.9%, p=0.022) was reported, most likely due to distal microembolization as a result of higher atherosclerotic plaque burden – a characteristic in those patients[27].

The use of GP IIb/IIIa inhibitors does not seem to influence results of stable ischemic syndrome (stable angina/silent ischemia) in this group of patients, as demonstrated by Lima et al[28] Neither have Chaves et al[29], in the DANTE study, demonstrated any benefit from the use of abciximab in immediate results, or in the reduction of neointimal hyperplasia six months after stent implantation in diabetic patients. In the present study, only 23% of patients reported unstable angina. Finally, Kastrati et al[30] have not found any benefit in using abciximab when comparing to a 600 mg attack dose of clopidogrel in the subgroup of diabetic patients with chronic coronary disease who have been submitted to stent implantation. The analysis of those results suggests that the use of GP IIb/IIIa inhibitors in this group of patients is not to be based on DM condition only.

Diabetes and SCANST: This group of patients has benefited from early interventional procedure associated to the use of GP IIb/IIIa inhibitors if compared to clinical treatment[31]. DM causes changes in the coagulation system that favor thrombosis and decrease fibrinolysis, thus increasing the risk of death and non-fatal AMI.

Diabetes and ACSNST

Our results have shown that diabetic patients are also exposed to higher risk of adverse events when submitted to percutaneous intervention, similarly to other published series. While analyzing 279 patients with unstable angina who had been submitted to PCI, López-Minguez et al[32] found higher mortality rate and non-fatal AMI among diabetic patients in a 3-year clinical follow-up(11.6% x 4.6%, p=0.047). A post-hoc analysis of OASIS registry – carried out by Malmbert et al[33] – also found a 57% increase in the mortality rate of SCANST diabetic patients.

Although diabetics in our series have reported adverse clinical and angiographic profile, another factor that may have influenced unfavorable results was low use of GP IIb/IIIA inhibitors (11.9%), as compared to other non-randomized series, as that of López-Minguez, when abciximab was used for 47.8% of diabetic patients. The use of coronary stenting and of the GP IIb/IIIa inhibitor tirofiban in the TACTICS[31] study, and the in the recently published SYNERGY[34] was associated to significant risk reduction in diabetics with SCANST submitted to percutaneous intervention.

In our study, diabetes and AMI patients showed worse immediate results, in agreement with other published series in the literature. Silva et al[35] have analyzed 104 patients submitted to primary stenting. In that study, diabetics reported higher MACE incidence on day 30 (21% x 4%, p=0.009), particularly sub-acute thrombosis (18% x 1%, p=0.003). Harjai et al[36] have analyzed the results of 626 diabetic patients from the PAMI study database, having related no difference in the multivariate analysis in hospital death rate, although difference was found in mortality rate level at month 6. (OR 1.53 - IC95%: 1.03-2.26, p=0.03). While analyzing a total of 4,308 patients submitted to primary PTCA in the course of a 20-year period, Marso et al[16] also observed diabetes to be associated to higher hospital death rate (12.7% x 6.9%, p<0.001) – which was kept high at all time points in the analysis.

The use of stenting and GP IIb/IIIa inhibitors has also improved the results of primary PTCA in diabetic patients. In the ADMIRAL[37] study, the use of abciximab in patients who had been submitted to AMI stenting was associated to relative risk reduction (67%) in diabetic patients. In the CADILLAC[38] study, the reduction showed to be 44%. The future may see new forms of AMI percutaneous intervention (thrombectomy systems, distal protection, supersaturated liquid oxygen, and systemic hypothermia) to further improve the results for these patients.

Multivariate Analysis

Our results agree with those previously published regarding diabetes and percutaneous coronary intervention in current practice. While analyzing 100,253 procedures in the ACC-NCDR database, Shaw et al[39] found Diabetes Mellitus to be an independent predictor of death in the hospital phase (OR: 1.41 CI: 1.10-1.91 p<0.0001). However, no analyses were carried out based on clinical presentation. In our study, however, the multivariate analysis did not show higher risk for diabetic patients - carriers of chronic coronary disease – who have been submitted to percutaneous coronary intervention. Such information had not yet been reported in world literature.

Limitations

The present work has some limitations, since it is a retrospective analysis. Additionally, considering it is a national registry, differences in routines and procedures may exist between the different cardiology interventional services participating in CENIC registry. In spite of that, it does reflect the current practice for percutaneous coronary intervention in our country. Another limitation the study faces is lack of follow-up data on treated patients. CENIC database only stores immediate results from percutaneous procedures, which allows safety and efficacy assessment during hospital stay. However, no data are available on patients' follow-up, which in our view is crucial for better assessment of the results for the treatment of diabetic patients.

Conclusions

The study concludes that Diabetes Mellitus is still an independent risk factor for patients who have been submitted to percutaneous coronary intervention in current practice. In the lower risk group, however, such scenario is being reverted by the use of coronary stenting associated to pharmacological therapeutics.

The results of new treatment strategies are to be awaited: drug-eluting stents, protection devices, and new anti-thrombotic drugs associated to strict metabolic and risk factors control as part of Diabetes Mellitus multidisciplinary management.

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