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(for the Secretary of the Society)
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Contents

Comparative Results of Cypher and Taxus Stents

Bernhard Meier, MD[1]
Swiss Cardiovascular Center, Bern University Hospital, Switzerland

Randomized trials have clearly shown that stents reduce restenosis in virtually all patient and lesion subsets (1-5) (fig. 1). When drug eluting (active) stents were compared to bare metal (passive) stents, an additional advantage in terms of binary restenosis was documented in various randomized trials [6-1] (fig. 2). The restenosis rates of passive stents were around 20% when they were compared with balloon angioplasty but rose to around 40%, when comparing them with their new active form (not untypically for medical research). Compared with balloon angioplasty, passive stents had increased safety concerning endpoints like myocardial infarction or death during the hospital stay but lost that advantage because of subacute stent thrombosis after hospital discharge which is virtually unknown to balloon angioplasty. Active stents show no safety enhancement over passive stents at any time period [12]. Notwithstanding, the two commercialized drug eluting stents (Cypher and Taxus) significantly reduce restenosis. Hence, the introduction of active stents represents a welcome comfort μgain for patients but not a safety gain.

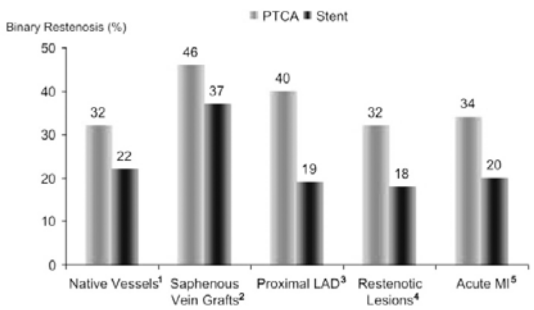

Figure 1. Binary restenosis rate in randomized trials comparing balloon angioplasty (PTCA) with stenting (Stent) in various subsets. LAD = left anterior descending coronary artery; MI= myocardial infarction.

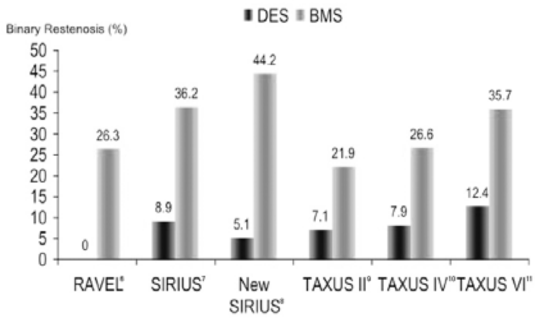

Figure 2. Binary restenosis rate comparing drug eluting stents (DES) with bare metal stents (BMS) in various trials using either sirolimus (RAVEL, SIRIUS)6-8 or paclitaxel (TAXUS) (9-11) elution.

[1] Bernhard Meier, MD
Professor and Chairman of Cardiology
Swiss Cardiovascular Center Bern
University Hospital
3010 Bern, Switzerland
Phone:41-31-632 30 77
Fax:41-31-382 10 69
e-mail:bernhard.meier@insel.ch
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Differences of the stent platforms

The Taxus stent is based on the Express stent and the Cypher stent on the BxVelocity stent, respectively. Both are made of 316 L stainless steel. The Express stent features an open cell design with a strut thickness of 130μm, the BxVelocity stent a closed cell design with a strut thickness of 140μm. The delivery balloons also play a role. The balloon/stent combination of the Taxus stent had the reputation to have a greater crossing potential but a certain risk of difficult balloon extraction after stent deposition. This reputation could not be objectivated in the recent randomized trials (REALITY and SIRTAX) [13,14] comparing the two devices head to head in 2,300 patients.

Differences of the drug carriers (polymer)

The polymer used on the Taxus stent is non-biodegradable, elastomeric, and of a matrix design, featuring a somewhat slower release than the polymer on the Cypher stent which is also non-biodegradable and elastomeric, but of a topcoat design. At 8 days the eluting fraction of the drug is half and at 30 days 4/5 released from the Cypher stent with about 1/5 of the drug remaining on the stent permanently [15,16], whereas the TAXUS stent is designed to only release a minor portion of the drug with the major portion remaining in the polymer for good.

Differences of the drugs employed

Paclitaxel is an active constituent of the taxeins that have been extracted from the bark of the pacific yew tree (Taxus brevifolia) since 1963 [17]. It has been approved by the FDA since 1992 for systemic use to treat malignancies, particularly of the female body. Paclitaxel promotes assembly (polymerization) of tubulin into stable microtubules and arrests the cell cycle in the M-phase.

Sirolimus is a macrolide antibiotic produced by fermentation of streptomyces hygroscopius first found in a soil sample on the Easter Islands (called Rapa Nui by the indigenous). It was initially named rapamycin. It acts via the mTOR (target of rapamycin) and blocks the cell cycle at the end of the G1 phase [18]. The major characteristics are summarized in table 1.

Clinical, nonrandomized comparisons

Figures 3 and 4 show the angiographic and clinical results of the major trials on which Food and Drug Administration approval of the Taxus stent (TAXUS IV) [10] and the Cypher stent (SIRIUS) [7] was based in the United States. Both stents drastically reduce restenosis and need for re-intervention. There was less late loss (neointimal hyperplasia) with the Cypher stent

Table 1. Major properties of the two leading drug eluting stents

	Paclitaxel Eluting Stent (Taxus)	Sirolimus Eluting Stent (Cypher)
Biolocical effect	– High affinity b-tubulin binding – Stabilization of tubulin polymerization – Cell cycle arrest at G2/M phase – Narrower therapeutic ratio: <4x (dose-density)	– High affinity for intracellular FKBP12 – Upregulation of cyclin-dependent kinase p27Kip1 – Cell cycle arrest at G1/S phase – Wide therapeutic ratio: >7x (dose-density)
Physicochemical properties	– Lipophilic – Solubility ≈ 6μg/ml – Molecular mass <1kDA	– Lipophilic – Solubility ≈ 6μg/ml – Molecular mass 914DA
Protein binding characteristics	– Microtubule concentration in arterial wall (10-5 M) – Remains primarily subintimal	– FKBP12 concentration in SMCs (10-5 M) – Distributes evenly through the artery
Dose density	– 100μg/cm²	– 140μg/cm²

resulting in a lower in-stent restenosis rate in the SIRIUS trial but this was compensated for by less intimal proliferation adjacent to the stent in the TAXUS IV trial. Target lesion revascularization rates were below 5% and target vessel failure below 10% with both stents. Interestingly, the passive stent control group of the SIRIUS trial had more restenosis and re-interventions than that of the TAXUS IV trial. This resulted in a more marked reduction of restenoes or events in the SIRIUS trial (figs. 3,4). The initial impression that there were more restenoses at the proximal and distal margins with the Cypher stent was no longer apparent, after some implantation modifications had been implemented for the Cypher stent and analyzed under the subheading New SIRIUS (fig. 5). Likewise, the initial contention that the Taxus stent fared better in diabetics (fig. 6) was not supported by a trial using the Cypher stent in diabetics exclusively (DIABETES trial) [19]. Finally, the initial contention that insulin dependent diabetics fared poorly with the Cypher stent was also invalidated by the DIABETES trial (fig. 7) and the DIRECT trial [20] (fig. 8). The stent thrombosis rates in studies and registries reported encompassing almost 20,000 patients were between 0.4% and 1.5%. Some underreporting has to be assumed. Nevertheless, the initial concern did fortunately not materialize that particularly subacute stent thrombosis would be significantly more common with active than with passive stents. Some concern was raised that the Taxus stent might be more prone for subacute stent thrombosis than the Cypher stent according to the comparison of the T-SEARCH (Taxus) with the RESEARCH (Cypher) registries of

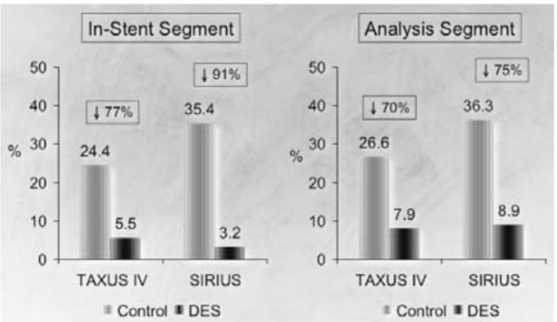

Figure 3. Binary restenosis rates concerning the in-stent segment and the entire analysis segment respectively in the TAXUS IV (10) and SIRIUS7 trials. DES = drug eluting stent.

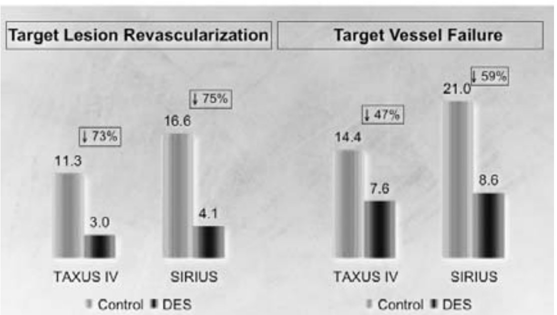

Figure 4. Target lesion revascularization and target vessel failure (target lesion revascularization or major cardiac adverse event) in the TAXUS IV (10) and the SIRIUS (7) trials. DES = drug eluting stent.

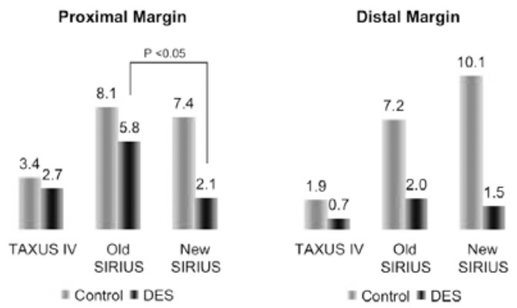

Figure 5. Restenosis (%). In the TAXUS IV (10), the SIRIUS (7) (named Old SIRIUS) and the New SIRIUS (8).

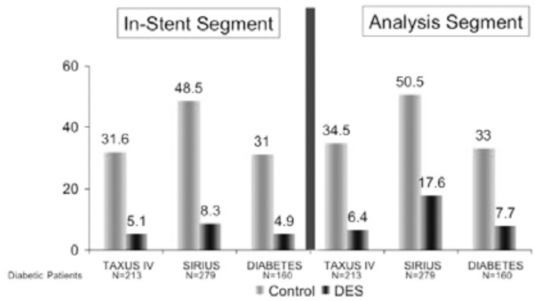

Figure 6. In-stent and analysis segment restenosis (%) in diabetic patients in the TAXUS IV (10), and DIABETES (19) trials. DES = drug eluting stent.

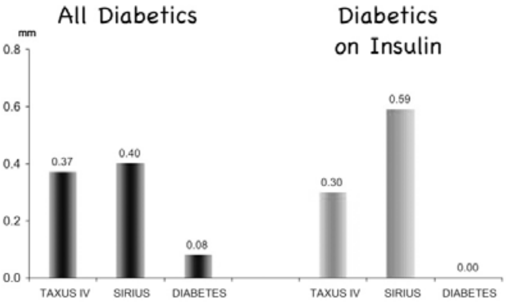

Figure 7. Late loss (concerning entire treated segment) in diabetics (left) and diabetics on insulin (right) in the trials of figure 6.

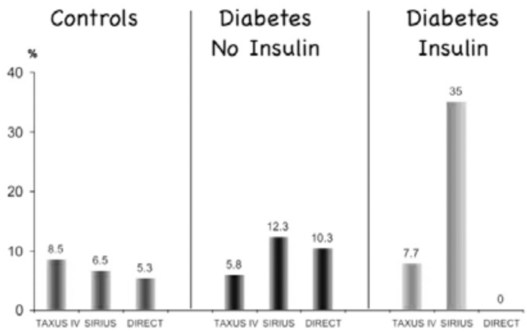

Figure 8. Restenosis (concerning the entire treated segment) in non-diabetics, diabetics without insulin, and diabetics on insulin, in the TAXUS IV (10), SIRIUS (7), and DIRECT (20) trials.

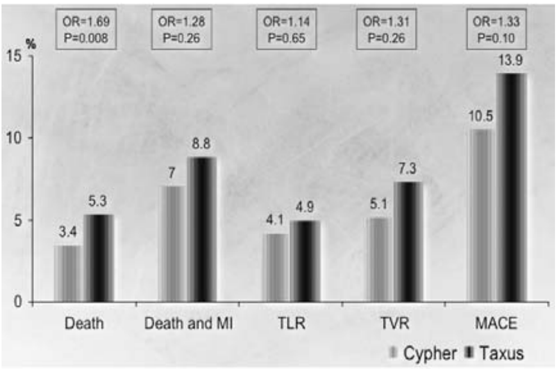

Figure 9. Comparison of 508 patients treated with Cypher stents and subsequent 576 patients treated with Taxus stents (21).

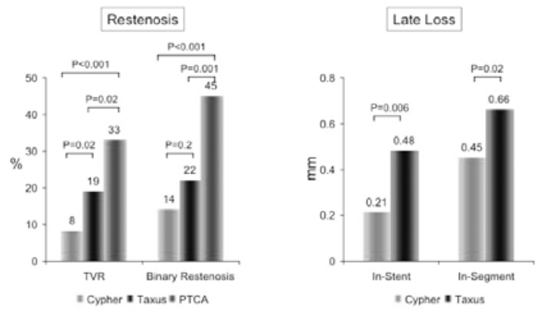

Figure 10. Target vessel revascularization (TVR), binary restenosis, and late loss in the stented and in the treated segment in the three groups of a randomized trial in patients with restenosis in a passive stent (23). PTCA = balloon angioplasty.

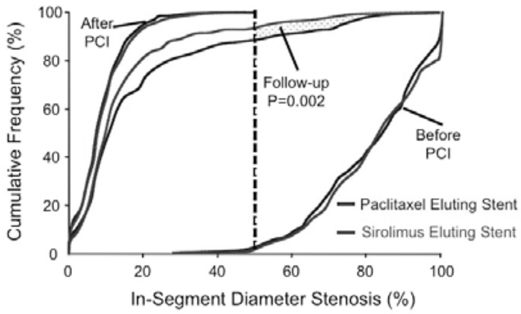

Figure 11. Cumulative distribution curves of in-segment diameter stenoses before stenting, after stenting (PCI), and at 9-month follow-up. The hatched area represents the difference in significant restenoses (>50%).

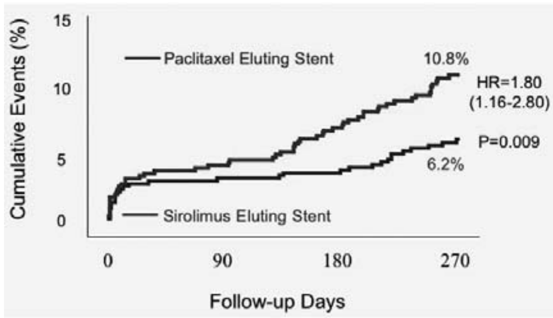

Figure 12. Primary endpoint curves (composite of cardiac death, myocardial infarction, or target lesion revascularization) in the SIRTAX trial up to 9 months.

Rotterdam, Holland. The difference was explained in part by a higher inclusion rate of acute myocardial infarctions in the T-SEARCH Registry (fig. 9) [21].

Randomized trials

A single center randomized trial (TAXI) comparing Taxus and Cypher stents showed no significant differences in about 100 patients in each group [22]. The trial was underpowered for the expected rare occurrence of its endpoints.

A similarly small randomized trial treated 100 patients with in-stent restenosis in a passive stent each with either balloon angioplasty, a Cypher stent, or a Taxus stent (ISAR DESIRE) [23]. Both active stents fared significantly better than balloon angioplasty in terms of restenosis and the Cypher stent had significantly less late loss than the Taxus stent (fig. 10).

The same center in Munich, Germany, presented a randomized trial on patients with diabetes (ISAR-DIABETES) (24), It randomized 250 patients into equal groups, treated either with Taxus or Cypher stents. There was no difference in hard endpoints with mortality rates of 4.8% (Taxus) and 3.2% (Cypher) and myocardial infarction rates of 2.4% and 4.0%, respectively. The angiographic restenosis rates were 16.5% and 6.9% (p=0.03) and the target lesion revascularization rates 12.0% and 6.4%, respectively. This study represented the first randomized evidence that one stent might indeed be superior to the other, at least in a particular indication. The evidence was in favor of the Cypher stent.

The REALITY trial [13] included a wide variety of patients (1,353) who were randomized to receive Taxus or Cypher stents. The major exclusion criteria were a stent diameter >3.0mm, acute myocardial infarction within 24 hours, ejection fraction below 25%, a totally occluded vessel, or an in-stent restenosis. There was no difference in the technical performance of the two devices with a 95% procedure success rate in both groups. Most angiogra-phic measures at follow-up were significantly in favor of the Cypher stent. The pertinent results are summarized in table 2. The primary endpoint (in-lesion binary restenosis) not being met, this study has to be considered a negative trial. However, the overall data speak in favor of the Cypher stent, particularly when taking into consideration that 1.8% of the patients receiving Taxus stents suffered acute or subacute stent thrombosis up to 30 days compared with only 0.4% receiving Cypher stents (p<0.05). This occurred in spite of a compliance

Table 2. Post procedure and 8-month results of the REALITY trial

Post stenting	Taxus (669 patients, 941 lesions)	Cypher (684 patients, 970 lesions)	P-Value
In-stent luminal diameter (mm)	2,16±0,37	2,08±0,35	<0,001
In-stent diameter stenosis (%)	15,00±7,49	15,96±6,91	=0,004
In-stent absolute gain (mm)	1,25	1,17	<0,001
At 8 months			
In-stent minimum luminal diam-	1,85±0,52	2,00±0,54	<0,001
In-lesion minimum luminal	1,71±0,49	1,79±0,51	<0,001
In-stent diameter stenosis (%)	26,70±15,84	23,11±16,59	<0,001
In-lesion diameter stenosis (%)	31,06±15,36	29,11±15,81	0,009
In-stent late-loss (mm)	0,31±0,44	0,09±0,43	<0,001
In-lesion late-loss (mm)	0,16±0,40	0,04±0,38	<0,001
In-stent net gain (mm)	0,94±0,55	1,08±0,54	<0,001
In-lesion net gain (mm)	0,79±0,52	0,88±0,50	<0,001
In-stent binary restenosis (%)	8,3	7,0	0,32
In-lesion binary restenosis (%)	11,1	9,6	0,31

with dual antiplatelet treatment of 99% in the Taxus group (97% in the Cypher group).

The SIRTAX trial [14] is in keeping with the angiographic data of both the REALITY and the ISAR-DIABETES trials. In roughly 1,000 all comers randomized to Taxus or Cypher stents, there was again no difference in technical success (99% with both devices) but a significant difference in angiographic outcome at 9 months. The salient variables are summarized in table 3. Cumulative distribution curves of in-segment diameter stenoses at follow-up show that the primary endpoint (cardiac death, myocardial infarction, or target lesion revascularization) and the angiographic restenosis rate (>50 % stenosis at follow-up) unveil a significant advantage of the Cypher stent (fig. 11). All variables yielded favorable absolute figures for the Cypher stent. However, there was no significant difference regarding death, cardiac death, or myocardial infarction while target lesion revascularization, target vessel revascularization, and target vessel failure (a composite of primary endpoint plus intervention to the vessel) were all significantly lower with the Cypher stent. In addition, the primary endpoint showed an accruing divergence throughout the second half of the follow-up (fig. 12). There was no difference in terms of stent thrombosis during the entire follow-up period. It was 1.6% with Taxus stents and 2.0% with Cypher stents (p=0.6), respectively. This is in contrast to the REALITY results.

Conclusions

Active stents represent a distinct advantage over passive stents. The advantage is restricted to endpoints without real prognostic significance, such as restenosis or target vessel reintervention. Neither registry nor randomized comparisons showed a significant difference between Taxus and Cypher stents in terms of mortality or myocardial infarction. The higher subacute thrombosis rate with Taxus stents in the REALITY trial is a finding supported so far only by registry data [21, 25, 26].

All randomized trials confirm the superiority of the Cypher stent in terms of less intimal hyperplasia and reduced angiographic restenosis. The fact, that the difference in the primary endpoint in the REALITY trial was not significant may be explained by the unexpected larger initial lumen in the Taxus cohort immediately after the procedure. This partially compensated for the larger late loss. Patient subgroups with a high propensity for restenosis (patients with in-stent restenosis or patients with diabetes) may bring out more conspicuously the small advantage of the Cypher stent. There is no evidence that active stents are fraught with a higher late thrombosis rate than passive stents, at least not up to 9 months of follow-up. This concern, however, cannot be completely discarded and must be further kept in mind. After all, the two active stents currently employed are covered with a polymer that may cause late problems and their mechanism implies less endothelial coverage. Keep in mind, it is a thick endothelial scar cap that prevents further infarction from a treated site [27].

Table 3. Results at 9 months of the SIRTAX trial

	Taxus (509 patients, 708 lesions)	Cypher (503 patients, 693 lesions)	P-Value
Late luminal loss (mm)	0,25±0,49	0,13±0,37	<0,001
In-segment late luminal loss (mm)	0,32±0,55	0,19±0,45	0,001
- no diabetes	0,23±0,47	0,13 ±0,37	0,003
- diabetes	0,32±0,60	0,11±0,38	0,002
In-stent binary restenosis (%)	7,6	3,2	0,013
In-segment binary restenosis (%)	11,9	6,7	0,020
- no diabetes	0,31±0,53	0,19±0,45	0,005

Diabetic patients: 59 with Taxus and 65 with Cypher stents

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Coronary Bifurcation Lesions: Outcomes for the Lateral Branches when Stenting Only the Main Arteries at the Site of Bifurcation

D. G. Iosseliani[1], D. G. Gromov, S. P. Semitko, A. G. Koledinsky, I. S. Topchyan
Moscow City Center of Interventional Cardioangiology, Russian Federation

Introduction

The issue of PTCA for stenotic lesions in the bifurcation of coronary arteries (frequency of such lesions occurrence is approximately 15-18%) remains quite urgent and is not completely resolved [1-16]. The incidence of restenosis of bifurcation branches remains high and, according to several reports, exceeds 60% [17-20], despite the advancements in angioplasty technique, introduction of new modifications of stents, including bifurcational and drug-eluting stents, and also the development of original methods of coronary endografting, e.g. crash-technique, Y- and T-stenting.

High incidence of restenosis of the lateral branches is caused not only by compromising their orifice during endovascular procedure, but also by lesser internal diameter of these vessels, due to which even a minor proliferation of intima cells in response to balloon dilatation and, furthermore, in response to stenting may lead back to initial state and even worsen it [2, 21]. Results of recent studies confirm this, showing the rate of restenosis in the lateral branches after implantation of two stents (in both vessels of bifurcation) to be significantly higher than after stenting of only one vessel (main artery) [17-19]. Our results (12 long-term follow-ups) demonstrated that stenting of major coronary arteries in conjunction with single-step PTCA of the lateral vessels through the stent strut leads to restenosis of these branches in 50% of cases, including 30% of cases with impairment of angiographic blood flow through these vessels. Therefore, despite significant sophistication of angioplasty technique (which leads to increasing cost of the corresponding procedures), the obtained result is by no means always stable. Thus, the search for more effective, and, whenever possible, less expensive methods and principles of achievement of the stated object goes on. In our opinion, one of such principles may appear to be focusing the main attention (at least during the first stage of treatment) at the major coronary arteries. That means that the endovascular procedures should be performed only on these main vessels, avoiding later simultaneous intervention on the lateral branches, leaving the opportunity to accomplish it in terms. To study such approach we conducted a retrospective analysis of the short-term and long-term results of 79 stenting procedures performed in this manner.

The study had the following objectives: to analyze the short-term and long-term clinical and angiographic data of CAD patients with coronary bifurcation lesions, who underwent stenting of only major coronary arteries while the lateral branches were either not subjected to endovascular interventions or underwent preliminary PTCA.

Clinical and angiographic characteristics of patients and methods of study

This analysis included data of 76 patients who underwent 79 stenting procedures in the abovementioned manner on bifurcation segments of coronary arteries in 2000-04. The indication for endovascular intervention was stenosis of the major artery that exceeded 50% of the lumen associated with clinical and instrumental data that demonstrated impairment of myocardial perfusion in the territory of this vessel. Mean age of subjects was 56.7±7.5 years. Eighty percent of subjects were male; 45% of patients had functional class I-IV angina pectoris; 30% of subjects had unstable angina, and 20% had the acute phase of myocardial infarction (Table 1).

Table 1. Clinical and historical data of subjects (n = 76)

Males	60 (78,9%)
Age	56,7±7,2
History of myocardial infarction	39 (51,3 %)
Left ventricular ejection fraction, %	61,7±8,9
Dyslipidemia	54 %
Diabetes mellitus	2 (2,6%)
Functional class I-IV angina	34 (44,7 %)
Unstable angina	23 (30,3%)
Non-Q myocardial Infarction	7 (9,2 %)
Q myocardial infarction	12 (15,7%)

Types 1, 2, 3, 4 and 4a bifurcation lesions were observed during selective coronary angiography in 19%, 22%, 12% and 18% of cases, respectively (Figure 1).

In 70% of cases the left anterior descending coronary artery was stented, in 13% it was the circumflex

Table 2. Angiographic data of subjects (n = 79)

Left anterior descending coronary artery	54 (70,1 %)
Circumflex artery	10 (12,9 %)
Right coronary artery	13 (16,9 %)
Proximal segment	50 (64,9 %)
Medium segment	22 (28,6 %)
Distal segment	5 (6,5 %)
Major artery diameter, mm	3,45±0,32
Degree of the major artery stenosis, %	86,4±9,45
Type B2 or C stenoses of the major artery	100 %

[1] Moscow City Center of Interventional Cardioangiology
Russia, 101000, Moscow, Sverchkov per., 5
Phone: 007 095 924 96 36
Fax: : 007 095 924 67 33
e-mail: davidgi@mail.ru
Manuscript received on March 20, 2005
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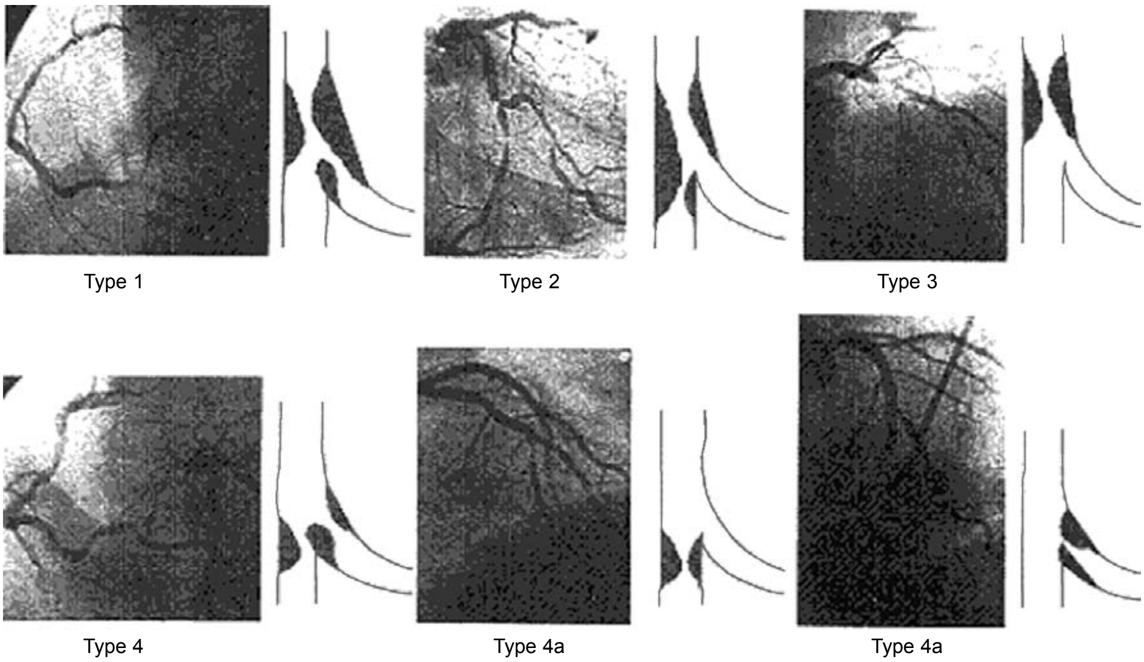

Figure 1. Bifurcation stenosis types

artery and in 17% it was the right coronary artery (Table 2).

The lateral vessels were represented by diagonal, large septal, and marginal branches. The diameter of the branches was approximately 2.2 ± 0.4 mm and varied between 1.5 and 2.7 mm. The degree of antegrade filling was TIMI I-III.

Endovascular procedures were performed using the conventional technique. Matrix and module stents without drug coating were used (predominantly manufactured by "Guidant" and "Cordis" companies (USA). In approximately 50% of cases the stents were implanted using direct technique. Preliminary PTCA of the lateral vessel for critical stenosis of its orifice was used in 5 (6.5%) subjects. After the procedures were finished, the standard drug therapy including aspirin and ticlid (or plavix) was used. The control examination, which included selective coronary angiography, was scheduled not less than 6 months after stenting procedure.

Results and discussion

An optimal angiographic result of stenting of the major coronary artery was successfully achieved in 100% of cases (criteria for optimal result were absence of residual stenosis and dissection of the major vessel, according to the data of selective coronary angiography at the end of the procedure). It is to be noticed that in 80% of subjects endovascular treatment led to elimination of all hemodynamically significant impairments of coronary circulation.

The condition of the branches arising from the stented segment of the main artery was evaluated separately. The following three groups were determined: in 55 cases (69.6%) the changes in angiographic pattern of the lateral vessels were not detected (group 1), in 18 cases (22.8%) the angiographic pattern of their stenosis was aggravated (group 2); and in 6 cases (7.6%) angiographic pattern of segmental occlusion was observed (group 3).

The deterioration of the vessels' condition immediately after stenting was observed significantly more frequently, if:

a) the angle of origin of the branch from the major artery exceeded 70°;
b) the branch arose from the major artery at the side of eccentric stenosis;
c) the diameter of the lateral vessel was < 2.0 мм;

Table 3. The rate of worsening of the lateral branches' condition depending on the baseline angiographic data

Diameter of the lateral branch < 2 mm	16 (52%)	$p < 0,05$
Diameter of the lateral branch > 2 mm	8 (17 %)	
Stenosis with involvement of the orifice of the lateral artery.	17 (68 %)	$p < 0,05$
Stenosis without involvement of the orifice of the lateral artery.	7 (13 %)	
The angle between two branches of the bifurcation > 70°	9 (50 %)	$p < 0,05$
The angle between two branches of the bifurcation < 70°	15 (25 %)	
Eccentric stenosis of the major artery at the side of the lateral branch	18 (64 %)	$p < 0,05$
Another combination of the major artery stenosis and lateral branch	6 (12 %)	

d) stenotic lesion of this branch' orifice was present prior to the procedure (Table 3).

Despite our observations of impairment of angiographic blood flow in the lateral branch immediately after stenting procedure on the major artery in almost 8% of patients, the incidence of clinical manifestations of these complications during in-hospital stage was several times lower: Only one patient (1.3%) developed Q myocardial infarction as a result of the lateral branch occlusion. The remaining 5 patients with the same angiographic complication had anginal attacks of varying intensity and duration, which were successfully stopped by drug therapy (narcotic or non-narcotic analgetics); at the same time there were no data suggesting acute myocardial infarction (i.e. no changes of ECG, EchoCG, troponin, myoglobin levels, other biochemical markers of myocardium impairment were detected). Further, during in-hospital stay, these patients did not experience recurrence of anginal pain. It should be noted that all those 6 patients with occlusion of the lateral branch immediately after stenting underwent an unsuccessful attempt of mechanical recanalization of the channel. During in-hospital stay there were no other complications (Q myocardial infarction, coronary shunting, or lethal outcome) as well as no angina attacks.

In the long-term follow-up (average 6.7 ± 1.5 months) after stenting procedure 100% of patients underwent complete control examination, including selective coronary angiography. Good angiographic outcomes of the procedure were seen in 67% of cases. In-stent stenosis and occlusion occurred in 32% and in 1.3% of cases, respectively (in-stent stenosis of the major artery was defined as lumen narrowing > 50% inside or at the stent's margins according to the coronary angiography data).

The changes in the angiographic picture of the lateral branches in each of the study groups in the long-term follow-up after major artery stenting are given in Table 4.

Table 4. Dynamics of condition of the lateral branches in the study groups in long-term follow-up after stenting of major coronary artery

Angiographic picture of the lateral branches	1 (n=55)	2 (n=18)	3 (n=6)
– no substantial changes	47 (85,4 %)	4 (22,2 %)	0
– worsening (increase of the stenosis degree)	7 (12,7 %)	0	0
– worsening (occlusion)	1 (1,8 %)	0	0
– improvement (reduction of the stenosis degree)	0	14 (78 %)	6 (100 %)

The table shows that worsening of angiographic picture of the lateral branches in the long-term follow-up was seen only in the 1st group (i.e. it occurred in the lateral branches whose condition did not substantially change immediately after stenting). In the other two groups the opposite tendency was seen: in the second group a decrease of the degree of stenosis was demonstrated in 78% of cases, and in the third group in 100% of cases complete or partial recovery of angiographic blood flow in the lateral branches occluded immediately after stenting was shown. Similar to the short-term evaluation, the worsening of the angiographic picture in long-term follow-up was observed more frequently in the branches whose diameter was lower than 2.0 mm. Additionally, in more than 70% of cases worsening of their condition was associated with the development of in-stent stenosis of the major coronary arteries.

At the control examination the clinical manifestations of ischemic heart disease were absent in 42 (55.3%) patients, in 29 (38.1%) there was functional class I-III exertional angina, and in 4 patients (5.3%) there was unstable angina. One patient (1.3%) had non-Q myocardial infarction as a result of occlusion of the lateral branch two months after stenting procedure. Any other complications were not seen.

In the vast majority of cases the reappearance of the clinical manifestations of the ischemic heart disease in the long-term follow up was associated with the development of restenosis of the main artery and/or hemodynamically significant impairment of another major artery. The presence of isolated stenosis of the lateral branch arising from the stented segment did not have substantial influence on the clinical manifestation of the disease. Thus, clinical signs of angina pectoris were observed only in 1 of 18 patients with such lesion (5.6%). This patient underwent balloon angioplasty of the lateral vessel through the stent strut with good angiographic and clinical outcome (Table 5).

Table 5. Condition of the coronary arteries in patients with and without clinical manifestations of ischemic heart disease 6.7 ± 1.5 months after stenting

Data of selective coronary angiography:	Clinical manifestation (n = 26)	No clinical manifestation (n = 50)
Restenosis or stenosis of the native artery > 50%	25 (96 %)	9 (18 %)
Isolated stenosis of the lateral branch > 50%	1 (4 %)	17 (34 %)
Stenosis of major artery or lateral branch 0-50%	0	24 (48 %)

Conclusions

1. In the short-term period approximately in 70% of CAD patients with coronary bifurcation lesions stenting of the main coronary artery only does not lead to worsening of the angiographic picture of the lateral branches, and also does not produce negative impact on the clinical condition of these patients. Worsening of the angiographic picture of these vessels, which occurs in approximately 30% of cases, happens more frequently when the lateral branch arises from the main artery at the angle exceeding 70° and at the side of eccentric stenosis, and also in cases when the diameter of the vessel is < 2 mm and when stenosis of the branch orifice is present before the procedure.

2. Approximately in 85% of cases which are not accompanied by impairment of the lateral branches immediately after stenting the angiographic picture of these vessels remains unchanged in long-term follow-up as well. Only in 15% of described cases the progression of stenotic lesion of both branches is observed, and it is frequently associated with the development of in-stent stenosis of the main artery.

3. In the vast majority of cases in which, at the moment of completion of the procedure, there is the angiographic picture of aggravation of stenosis and occlusion of the lateral branches, in the long term

course partial or complete restoration of the lumen of these vessels occurs.

4. Both in short-term and in long-term follow-up the isolated lesion of the lateral branch which was present before the procedure or appeared after stenting of the main artery does not influence the further course of ischemic heart disease (i.e. the probability of angina recurrence). However, in 1.3% of patients such occlusion may lead to the development of non-Q myocardial infarction.

Summary

Thus, our study demonstrated that in cases of coronary bifurcation lesions the stenting of the main coronary artery only without performing endovascular intervention on the lateral branches produces good clinical and angiographic results both in the short-term and long-term period in the vast majority of cases. However, in a small group of patients this procedure leads to significant worsening of angiographic picture of the lateral branches (up to complete occlusion of these vessels), which manifests as the aggravation of the clinical status of these patients. Considering that, currently the main task of a physician consists in determination of the risk factors for the above mentioned complications at the stage of diagnostic coronary angiography and to suggest other (safer) methods of myocardial revascularization for such patients.

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Multiple Multi-Level Stenting of Degenerated Vein Grafts 14 Years Following Aortocoronary Bypass

M.S.Olshansky[1]
Voronezh Regional Clinical Hospital №1, Department of Surgery №2,
Burdenko's Medical Academy of Voronezh, Russian Federation

Purpose of the study: To demonstrate the possibility of a single-stage endovascular treatment (stenting) of several degenerated vein grafts more than ten years following aortocoronary bypass.

Background: Endovascular repair of compromised vein grafts is believed to be useful only in the early period following aortocoronary bypass (CABG), as the rate of success is also determined by the age of grafts. Simultaneous repair of two or more grafts is uncommon. At the same time, redo surgery for adequate revascularization is not always possible because of patient's severe general condition. In such instances endovascular intervention can sometimes avail the patient.

Methods: A patient with LAD, CA, RCA occlusion underwent multi-level angioplasty and stenting of two vein grafts (to LAD and OMB) with three BiodivYsio stents 14 years following CABG. After predilatation of stenoses (95% in the proximal and 80% in the middle segment) in the graft to LAD, two stents (3.0 x 22 mm in the distal segment and 3.0 x 18 mm in the proximal segment) were deployed followed by direct stenting of the graft to OMB from the ostium using 3.5 x 28 mm stent.

Results: Follow-up during 3 months postoperatively demonstrated, that the patient returned to work, passing up to 3 kilometers daily and using isoket spray once daily occasionally. There were no episodes of chest pain equal to that before surgery.

Conclusion: In some instances stenting of degenerated vein grafts can be performed more than 10 years following CABG. The effect is possibly determined by the extent of revascularization.

Introduction

Endovascular therapy for vein graft stenosis is quite a difficult intervention and its success, among other factors, is believed to depend on the age of vein grafts. Diffuse lesions involving vein grafts are found 5 years or, according to some authors, 3 years following CABG [1, 2]. Graft interventions are commonly limited to a single site or a small number of lesions [3]. Multiple interventions are infrequent [4]. Many problems associated with vein graft stenting are poorly elucidated in literature and the results presented are conflicting [5]. In Russia, stenting of degenerated vein grafts has been performed in rare instances. This situation has led us to an opinion, that the below case report concerning a patient, who underwent angioplasty and stenting of two vein grafts at different levels 14 years following CABG, might be of interest for many specialists.

Case report

Patient M. (63 years old) with a 15-year history of CHD was operated on by professor V.P. Kertsman (Bakoulev Scientific Center for Cardiovascular Surgery) in 1990. The intervention implied aortocoronary bypass grafting to LAD, DB, OMB, RCA. Angina pectoris was completely reduced immediately after surgery. The patient had further been exposed to high physical stress and hadn't taken any drugs except aspirin. Exactly 14 years after CABG the patient presented with symptoms equal to those observed preoperatively: chest pain caused by minor physical strain, pain-free walking distance below 50 m, night episodes of chest pain, forced sitting position while sleeping, poor effect of nitrates (sydnopharm, nitrosorbide, nitrogranulong, etc.), the need to take up to 30 tables of nitroglycerine per day.

ECG monitoring revealed myocardial ischemia at rest and during exercise, 2-mm ST dislocation even at night. Echocardiography showed normal size of heart chambers, LVEF of 50%.

Coronary angiography and vein graft angiography revealed severe changes in coronary arteries: LAD occlusion immediately distal to the origin of the first diagonal artery (DA), which, in turn, was narrowed and had severe atherosclerotic changes; CxA proximal occlusion (Fig. 1); obtuse marginal coronary artery (OMB) and posterolateral artery (PLA) could not be visialized; proximal occlusion of RCA. Severe atherosclerotic changes were found at the origin and in the proximal segment of the posterior descending

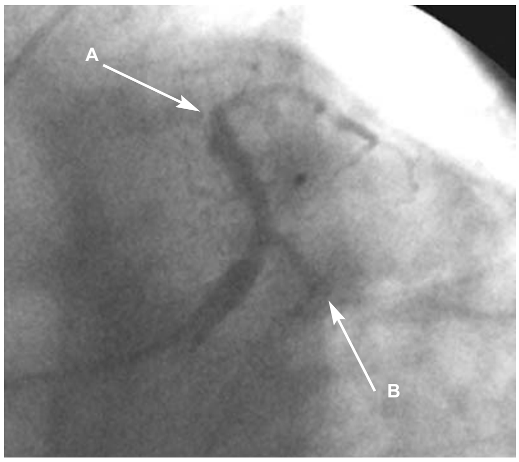

Figure 1. Patient M, aged 63. Coronary angiography showing occlusion of LAD (A) and CxA (B)

[1] Olshansky M.S.,
394082, Voronezh, Moskovsky prosp., 151, bld.1
Voronezh Regional Clinical Hospital N1, Dept. of Endovascular Methods of Diagnostics and Treatment
Phone: 8 0732 13 37 72; 9 910 349 63 85
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artery (PDA). Vein graft angiography included the following steps: graft origin and proximal anastomosis were assessed at least in two perpendicular views. The middle segment of the graft was further evaluated at different levels. Then the distal anastomosis and the distal portion of the graft were examined. Visualization was performed under fluoroscopic guidance using Angiostar Plus (Siemens) Interventional Radiology Unit by trial manual injection of contrast medium (Omnipak-350) diluted with normal saline (1:1) with simultaneous slow rotation of the gantry. The optimal view was recorded using undiluted contrast medium injected so as to achieve tight filling at a rate no exceeding 2 ml/s. The graft angiograms obtained were assessed immediately after the recording and, if necessary, accompanied by a more detailed examination with different magnification levels and various positions of image amplifier (IA). Positioning of JR 3.5 diagnostic catheter in the origins of the grafts to LAD and OMB was performed by advancing the catheter with slightly retracted diagnostic guidewire into the left aortic sinus. The guidewire was then carefully removed, 2 ml of blood aspirated and a syringe with contrast medium connected to the catheter. Positioning of a soft diagnostic catheter into the graft origin was performed by

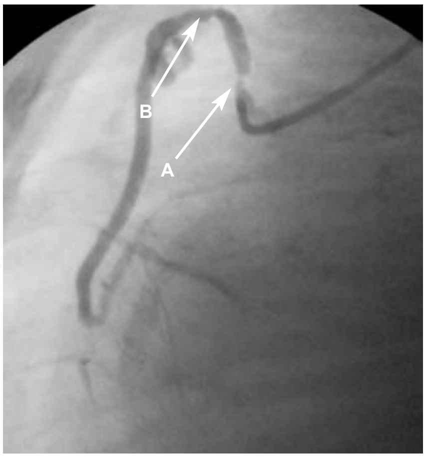

Figure 2. Patient M, aged 63. Vein graft angiography with arrows showing stenosis of the proximal LAD graft segment (A) and lesions in the middle LAD graft segment (B)

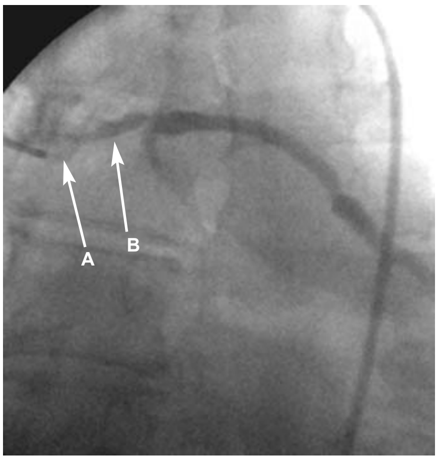

Figure 3. Patient M, aged 63. Vein graft angiography with arrows showing stenosis in the origin (A) and the proximal segment of the graft to OMB (B)

smooth backward motion of the catheter with simultaneous slow rotation in eater side (clockwise and counter-clockwise). Catheter position was confirmed by angiography in left lateral aspect and RAO 9°. Serial angiography of the vein grafts revealed 95% stenosis in the proximal portion of graft to LAD and 80% stenosis in the middle portion of graft 23 mm away from the origin (Fig. 2). About 50% stenosis was found in the middle segment. A 65% stenosis was found in the origin of the graft to OMB and a 60% stenosis - 25 mm away from the origin (Fig. 3). Contour of the lesion was distinct in the graft to OMB and obscure in the graft to LAD. The graft to LAD had a 95% stenosis with a lesion over 40 mm in length located in its distal segment. Endovascular treatment was considered possible by a group of specialists - endovascular surgeon, cardiac surgeon and cardiologist - taking into the account the patient's state, the course of disease, results of coronary angiography and vein graft angiography. In view of the life-threatening condition angioplasty and stenting of proximal and distal portions of grafts to LAD and OMB were considered.

Ticlid (0.25 g x twice per day) and a single dose of aspirin (125 mg) were administered five days prior to surgery. Three days prior to surgery the patient received 0.3 ml fraxiparine daily. One day before surgery IV isoket was started through catheter inserted in the subclavian vein.

The procedure was performed as follows: a 8F sheath was introduced into the right common femoral artery under standard topical anesthesia and 2,500 U heparin injected. JR 3.5 guidewire catheter was advanced into the ascending aorta. The technique of rigid catheter placement was slightly different. We felt it more convenient to bend the catheter from aortic sinus and advance it in upward direction, pressing the bend to aortic wall. This provided more smooth motions of the catheter tip. We didn't encounter any difficulties while securing the catheter tip in LAD graft origin or positioning a standard coronary guidewire into the distal third of the graft. However, these did occur during the attempt to advance the stent through the site of stenosis in the graft origin. Predilatation with Pleon 2.0-20 mm balloon (Biotronik) enlarged the origin, but the distal part of lesion didn't allow for stent advancement. Therefore, repeated predilatation of a more distal site was performed. In spite of the fact, that some authors pointed out the predominant use of low pressure for predilatation (3-4 atm.), in order to decrease the risk of fat embolisation of the distal coronary bed, we succeeded to dilate the stenosis only at 10 and 14 atmospheres (Fig. 4). This was accompanied by ECG signs characteristic of acute ischemia, which had been observed for quite a long time and didn't reside completely on nitroglycerine and calcium channel inhibitors. At the same time, this ischemic episode was well tolerated by the patient. As a result, stent implantation was performed quickly. BiodivYsio stent 3.0 - 22 mm was deployed in the dis-

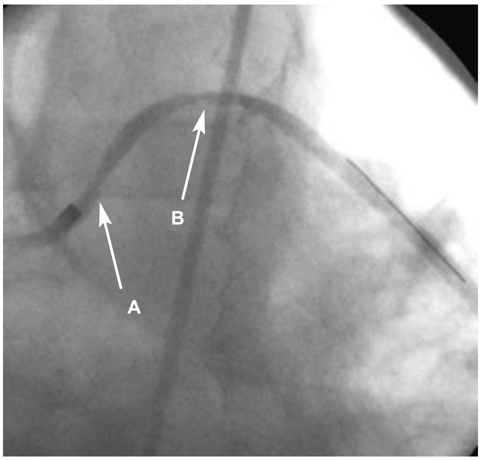

Figure 4. Arrows showing over 50% residual stenoses in the graft to LAD (A and B) after angioplasty

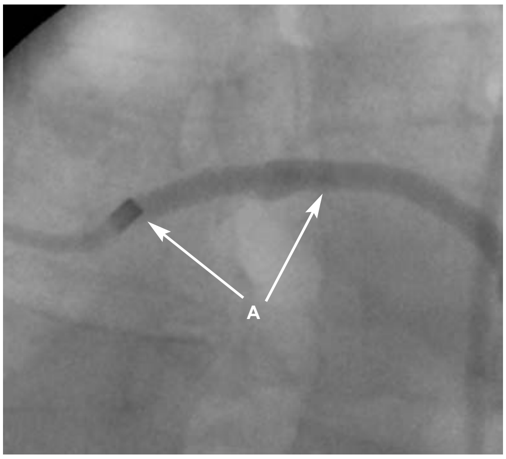

Figure 6. Graft to OM after direct stenting in the origin using Biodiv-

tal part of graft to LAD, BiodivYsio 3.0 - 18 mm - in the graft origin. We tended to observe the following rules during the implantation of two stents: the stents must completely cover the site of stenosis and extend 1 mm away on either end. Firstly, a stent is implanted into the proximal portion, and then - into the distal portion. The overlap is 1 mm. The stent must extend 1 mm from the artery origin. We tried to achieve the most complete adherence of the stent to the graft wall. The tip of catheter was moved slightly back to the aorta while stenting the graft origin. ECG returned to normal immediately after stenting. Completion graft angiography performed after a 5-min interval confirmed successful stenting (Fig. 5).

The second step consisted in direct stenting of vein graft to OMB from its origin using BiodivYsio 3.5 - 28 mm stent. Completion multiposition angiography

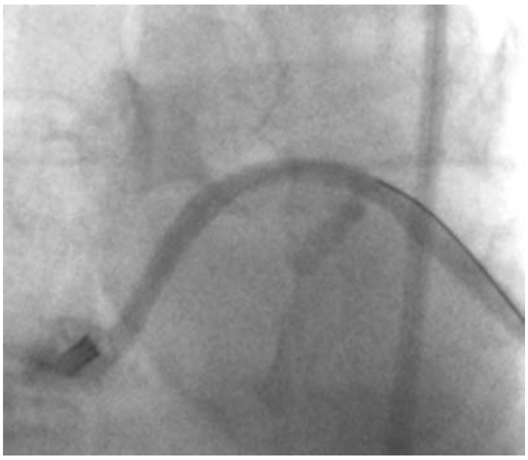

Figure 5. LAD graft after implantation of BiodivYsio 3.0-22 stent into the middle segment (A, arrows) and BiodivYsio 3.0-18 stent into the origin (B, arrows)

of the graft also confirmed angiographic success. The entire time of the procedure was 1 h 56 min, fluoroscopy time - 14 min. Over 300 ml of non-ionic contrast medium (Omnipak-300) was used. The patient was re-admitted to the intensive care unit, where the basic hemodynamic parameters were monitored and symptomatic therapy was instituted in addition to treatment administered preoperatively. Fourteen hours after the procedure the sheath was removed from the femoral artery, hemostasis secured and the patient returned to the cardiological ward. The next day he could already walk by himself in the ward. Continuous walking distance of 50 m didn't cause any pain. There was no need to take nitrates throughout the day. There were no episodes of chest pain during the entire hospital stay. Nocturnal angina pectoris didn't recur and the patient could sleep in supine position instead of sitting on the bed. By the time of discharge continuous walking distance was increased to 500 m. Three months after the intervention the patient returned to work as the deputy chief engineer of a large factory, passing every day up to 3 km without stop and taking isoket spray once daily occasionally, when intensive movement causes a feeling of heaviness in the chest. There were no episodes of chest pain equal to that before surgery, nor did the patient suffer any chest pain at night.

Conclusion: Immediate results of the intervention suggest the possibility to perform complicated endovascular repair of degenerated vein grafts at different levels, provided that the patient's condition is adequately assessed and the results of high-quality graft angiography are considered.

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Comparison of the Early (within 24 hours) Versus Delayed (up to 21 days) Stenting in Patients with Acute Myocardial Infarction

D. G. Iosseliani[1] , S. V. Rogan, S. P. Semitko, A. V. Arablinsky, M. V. Yanitzkaya, O. P. Solovyov
Moscow City Center of Interventional Cardioangiology, Russian Federation

Introduction

Currently, it is considered that the restoration of blood flow in the infarct-related artery (IRA) as early as possible, saves a certain part of ischemic myocardium, preserves contractility and reduces the necrosis area in acute myocardial infarction (AMI) [1, 2, 3]. At the same time it is known that a more delayed (2nd-21st days) performance of endovascular procedures (EVP) for AMI may also improve the prognosis of the disease. The probable mechanism of positive influence of the procedure may be explained by acceleration of scar tissue formation, prevention of dilatation and remodeling of the left ventricular myocardium (LV) and by restoration of hibernated myocardium [8]. How effective, durable and justified are the procedures of delayed restoration of blood flow in the infarct-related artery (IRA) in AMI patients?

The purpose of this study consisted in a comparative analysis of the short-term and mid-term results in patients after stenting of the infarct-related artery at different stages of the AMI.

Clinical materials and methods

Two hundred and eighty AMI patients underwent implantation of 347 stents in terms up to 21 day from onset of the disease in our Scientific and Practical Center of Interventional Cardioangiology during the period since July 1997 to June 2004.

In 135 (48.4%) patients (1st group) the procedure was performed under urgent conditions and stent was placed in the infarct-related artery in the first 24 hours since the onset of the angina attack (average in 8.7±5.5 hours), and in 145 (51.6%) cases the delayed procedure (2-21 days, average 14.2 days) was used. The indications for delayed procedure were early postinfarction angina pectoris and positive results of the stress tests at 8 - 10th days of the disease. These patients formed the 2nd group. The baseline clinical features of the two groups did not differ substantially (Table 1). The only significant differences noted were in the number of patients with Q-wave AMI (84.4% vs. 58.6%) and in the baseline ejection fraction of the left ventricle (LVEF) (55.4±11.4% vs. 51.3±11.2%), $p<0.05$.

Age of the patients was approximately 54±12.3 years. The majority of patients were male - 231 (82.5%). The most frequent risk factors were arterial hypertension (67.4% and 68.9%) and dyslipidemia (65.9% and 78.6%), respectively ($p>0.05$). Left ventri-cular ejection fraction in the groups was 55.4±11.4% and 51.3±11.2% respectively. Hence, it was significantly higher ($p<0.05$) in the first group, which may be accounted for the compensatory hyperfunction (hyperkinesis) of intact areas of the left ventricle. Analysis of the segmental ejection fraction demonstrated higher contractility of the intact areas (hyperkinesis) in the patients of the first group compared to that in patients of the second group. With this, it was noted that irrelevant to the time period between the onset of the disease and the performance of an angioplasty procedure, ejection fraction in patients with initial occlusion of the infarct-related artery was significantly lower than that in patients with stenosis of the infarct-related artery (51.3±11.3 vs. 59.3±11.8) (Figure 1).

It is also to be noted that longer time period between the onset of AMI signs and the performance of the procedure in patients with initial occlusion of the infarct-related artery was associated with further LVEF decreasing (from 51.3±11.9% to 42.9±11.8%), $p<0.05$. In patients with initial stenosis of the infarct-related artery no significant differences were detected for this parameter.

The artery supplying the infarct zone and, therefore, being most frequently stented, was the left ante-

Table 1. Baseline clinical features

Feature	Group 1 (n=135)	Group 2 (n=145)	P
Average age	54,8±24,0	53,2±21	P>0,05
Males	108 (80 %)	123 (84,8 %)	P>0,05
Arterial hypertension	91 (67,4 %)	100 (68,9 %)	P>0,05
Smoking	87 (64,4 %)	98 (68 %)	P>0,05
Diabetes mellitus	9 (6,6 %)	12 (8,3 %)	P>0,05
Hypercholesterolemia	89 (65,2 %)	114 (78,6 %)	P>0,05
Previous AMI	25 (18,5 %)	26 (17,9 %)	P>0,05
Q-wave AMI	114 (84,4 %)	85 (58,6 %)	P<0,01
Left ventricular ejection fraction (LVEF), %	55,4±11,4	51,3±11,2	P<0,05
Systemic thrombolytic therapy	19 (14,1 %)	11 (7,6 %)	P>0,05
Time since the onset of the attack:			
< 3 hours	10 (7,4 %)	—	—
3 - 6 hours	77 (57 %)	—	—
6 - 12 hours	23 (17 %)	—	—
12 - 24 hours	25 (18,6 %)	—	—
1 - 6 days	—	25 (17,2 %)	—
7 - 14 days	—	53 (36,5 %)	—

[1] Moscow City Center of Interventional Cardioangiology
Russia, 101000, Moscow, Sverchkov per., 5
Phone: 007 095 924 96 36
Fax: : 007 095 924 67 33
e-mail: davidgi@mail.ru
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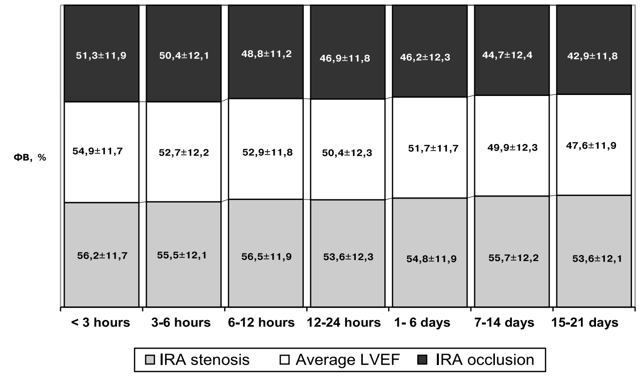

Figure 1. Time from onset to endovascular procedures; state of the infarct-related artery and values of LVEF

Table 2. Baseline angiographic data of the patients

Characteristics	Group 1 (n=135)	Group 2 (n=145)	P
Number of diseased arteries:			
- one	71 (52,6 %)	47 (32,4 %)	P<0,05
- two	43 (31,8 %)	32 (22,1 %)	P>0,05
- three or more	21 (15,5 %)	66 (45,5 %)	P<0,05
Localization of the lesion:			
Left main coronary artery	2 (1,5 %)	—	P>0,05
LAD	60 (44,4 %)	85 (58,6 %)	P<0,05
CxB	17 (12,6 %)	15 (10,3 %)	P>0,05
RCA	51 (37,7 %)	37 (25,5 %)	P<0,05
OMB	2 (1,5 %)	6 (4,1 %)	P>0,05
DB	3 (2,2 %)	2 (1,4 %)	P>0,05
Type of the lesion (AHA/ACC):			
Class A/B1	12 (8,8 %)	31 (21,4 %)	P<0,05
Class B2	27 (20 %)	41 (28,3 %)	P>0,05
Class C	14 (10,3 %)	13 (8,9 %)	P>0,05
IRA occlusion	82 (60,7 %)	60 (41,4 %)	P<0,01
Stenosis length, mm (after IRA recanalization)	15±6,0	14±5,0	—
Final balloon diameter, mm	3,2±0,8	3,3±0,5	—
Maximal pressure, atm	12±2,2	13,0±2,3	—

rior descending (LAD) - 44.4% and 58.6% of cases, then went the right coronary artery (RCA) - 37.7% and 25.5%, and the left circumflex artery (LCx) in 12.6% and 10.3% cases respectively. In the first group the patients with one-vessel disease prevailed - 52.6%, whereas in the second group the most frequently encountered was three-vessel disease - 45.5% of cases (p<0.05). The analysis of the types of coronary lesions using AHA/ACC classification demonstrated more severe impairment of the coronary arteries in the group of patients with bailout stenting of the IRA: 8.8% vs. 21.4% - class A/B1, 20% vs. 28.3% - class B2, and 10.3% vs. 8.9% - class C, respectively. Substantial differences in the number of occluded IRA were also noted - 60.7% vs. 41.4%, p<0.05.

In the vast majority of cases selective coronary angiography (CAG) and left ventricular angiography (LVA) were performed using M. Judkins technique.

Intravenous bolus heparin 10,000 IU was administered before the procedure. During the procedure patients received an intravenous infusion of nitroglycerin, rheopolyglukin, heparin under the control of the activated coagulation time (ACT). The ACT value was maintained at the level of 330-350 seconds. Just before stenting the patients were administered Ticlopidine at 500 mg per 24h and 325 mg of aspirin. After the procedure patients were observed in the intensive care unit. The introducers were removed 4-6 hours after the procedure.

Analysis of general and segmental contractility of the left ventricle was performed using Lipton method on the hard-and-software system DIMOL-IC [11,12]. Five segments were defined for the purposes of this analysis: 1 - anterior basal segment, 2 - anterior lateral segment, 3 - apical segment, 4 - posterior diaphragmal segment and 5 - posterior basal segment. Percentage of shortening of the axis connecting the center of each segment with the geometric center of the left ventricle and percentage of reduction of the area of the sector adjacent to the corresponding segment were evaluated.

During control coronary angiography, the state of the coronary arteries and the state of the target segment (the pattern of narrowing, the degree of narrowing as a percentage of the reference diameter and in millimeters) were evaluated. PTCA of the IRA and stenting were performed according to conventional technique.

Indications for stenting after PTCA of the IRA were as follows:

1) Suboptimal result after PTCA of the IRA (residual stenosis up to 50% with or without type A-B dissection) - 51.1% vs. 38.6% of cases (p< 0.05);

2) Acute occlusion or critical dissection of the arterial intima after PTCA of the IRA — in 10.4% vs. 7.6% of cases in the second group (p>0.05). In addition, the primary stenting was performed after successful PTCA of the IRA with the residual stenosis up to 30% in order to optimize the result in 22.8% and 27.3% of cases, respectively (p>0.05). Direct stenting of the IRA was done in 15.5% and 26.2% of cases respectively (p<0.05).

In order to optimize the stent sizing, computerized calculation of the degree and length of the lesion, and diameter of the adjacent intact portion of the vessel was performed on Hicor computer using the software application for calculation of the stenosis dimensions provided by Siemens Corporation.

As a total, 280 patients received 347 stents. In the first group, 147 stents were placed into the IRA, and in the second group 157 stents were implanted. Most frequently used stents were CrossFlex (Cordis, Johnson Johnson) — 14.8% and 17.2%, Angiostent (AngioDynamics NJ) — 27.4% and 13.1%, BxVelocity (Cordis, Johnson Johnson) — 15.5% and 17.2%, BioDivysio (Biocompatibles) — 11.8% and 13.7%, and MultiLink (Guidant, Santa Clara, CA) — 15.5% and 10.3%, respectively. Two stents were implanted into the IRA in ten patients of the first group and in ten patients of the second group. Three stents were implanted in one patient in each group. In the other 124 and 134 cases respectively, only one stent was used. In the majority of cases stents 15 mm in length or longer (average 18±9 mm) and 3-3.5 mm in diameter (average 3.3±1.05 mm) were used. Stents were

Table 3. Peculiarities of stenting procedure

Feature	Group 1 (n=135)	Group 2 (n=145)
Stent types in IRA:		
- Cross-Flex (Cordis, Johnson & Johnson)	20 (14,8 %)	25 (17,2 %)
- Angiostent (AngioDynamics NJ)	37 (27,4 %)	19 (13,1 %)
- BxVelocity (Cordis, Johnson & Johnson)	21 (15,5 %)	25 (17,2 %)
- BioDivysio (Biocompatibles)	16 (11,8 %)	20 (13,7 %)
- MultiLink(Guidant, Santa Clara,CA)	21 (15,5 %)	15 (10,3 %)
- Others	20 (14,8 %)	41 (28,3 %)
Stent diameteres in the IRA:		
2,0-2,9 mm	16 (11,8 %)	17 (11,7 %)
3,0-3,5 mm	100 (74,1 %)	124 (85,5 %)
4 mm and more	19 (14,1 %)	4 (2,8 %)
Stent lengths in the IRA:		
8-12 mm	14 (10,4 %)	11 (7,6 %)
13-16 mm	62 (45,9 %)	72 (49,7 %)
17 mm and more	59 (43,7 %)	62 (42,7 %)

Table 4. Short-term results of ira stenting

Parameters	Group 1 (n=135)	Group 2 (n=145)	P
- No angina pectoris	117 (86,6 %)	133 (91,7 %)	NS (non significant)
- Recurrent ami (non-fatal)	2 (1,5 %)	1 (0,7 %)	NS
- Mortality			
Total mortality	3 (2,2 %)	1 (0,7 %)	NS
Cardiac mortality	3 (2,2 %)	1 (0,7 %)	NS
Acute/subacute stent thrombosis	9 (6,6 %)*	5 (3,4 %)*	NS
Emergency repeated PTCA	5 (3,7 %)	3 (2,1 %)	NS
Emergency CABG	—	—	—
Uneventful course of the disease**	126 (93,3 %)	140 (96,5 %)	NS

* All patients with fatal outcome and recurrent AMI were included.
** No fatal cases, recurrent MI, angina requiring additional TCA or CABG.

implanted at average pressure of 12±2.3 atm and 13±2.3 atm, respectively. If optimal angiographic result was achieved, then stenting procedure was completed, otherwise repeated balloon dilations were used until optimal result was achieved. Repeated balloon dilations in the majority of cases were done using the same balloon. The result of stent implantation was assessed visually, and the diameter of the vessel before and after the procedure was calculated as well. In cases of multi-vessel lesions, IRA stenting was combined with simultaneous endovascular procedures on other arteries in 20 (14.8%) patients of the first group and in 40 (27.6%) patients in the second group, including stent use in 10 (7.4%) and 33 (22.7%) cases, respectively. Complete revascularization was performed in 83 (61.5%) patients of the first group and in 87 (60%) patients of the second group.

Results of the study

In-hospital course. Immediate angiographic success of the procedure (residual stenosis < 20%, no type C-F dissections and restoration of antegrade blood flow (TIMI 2-3)) amounted to 99.2% in the first group and to 98.6% in the second group (p>0.05). Early after the procedure one patient from the first group and two patients from the second group had complications of stenting procedure — critical dissection at the distal end of the stent, which was accompanied by pain and ECG changes and required an additional stent. Antegrade blood flow (TIMI 2) after the procedure was seen in 9 (6.6%) patients of the first group and in 5 (3.5%) patients of the second group (p>0.05). After the procedure, average residual stenosis was 12.1±16.2% and 10.3±14.0%, respectively (p>0.05). In both groups residual stenosis did not exceed 20%; the edges of the vessel at the site of the implanted stent were regular and smooth without stenotic changes. The course of the disease during in-hospital stage after the endovascular procedures on the IRA is shown in Table 4.

As for the severe complications, in the first group there were 5 (3.7%) cases of acute stent thrombosis in the first 4-12 hours after the procedure and 4 (2.9%) cases of subacute thromposis 2-4 days after the procedure. In 3 (3.1%) cases of stent thrombosis, despite the intensive care and undertaken endovascular measures, the patients died. Two patients (1.5%) with stent thrombosis experienced recurrent MI. In second group patients acute and subacute stent thrombosis occurred in 3 (2.1%) and 2 (1.4%) cases, respectively. One (0.7%) of these cases had fatal outcome, and another (0.7%) patient had recurrent AMI. Four (2.9%) patients of the first group and 3 (2.1%) patients of the second group underwent mechanical recanalization and PTCA with restoration of the vessel lumen. Further course of the disease in these patients was uneventful.

Analysis of stent thrombosis cases demonstrated general similarity between the two groups and revealed significant relation with the following risk factors: 1) decreased blood flow (TIMI-2) after the procedure; 2) performing of emergency (bailout) stenting.

Thus, uneventful course of the disease in the first and the second groups was seen in 93.3% and 96.5% of cases, respectively, p>0.05. No significant difference in this parameter between the two groups was detected. Study groups had no significant differences (p>0.05) in cardiac mortality, recurrent MI, stent thrombosis and in the number of angina pectoris-free patients.

Mid-term follow-up (Table 5). Information was received at 8.9±2.7 months of the follow-up for 121 patients of the first group and at 8.1±2.3 months of the follow-up for 132 patients of the second group. The control coronary angiography and left ventriculography were performed in 80 patients of the first group and in 95 patients of the second group. The study groups were comparable in terms of clinical and historical data.

In the mid-term follow-up 73.5% of patients in the first group and 68.9% of patients in the second group were free of angina, p>0.05. There was no significant difference in incidence of recurrent (non-fatal) AMI (1.6% vs. 0.8%) and cardiac mortality (0.8% vs. 0.8%). Angina attacks, recurrent MI and death were observed mainly in patients with unsatisfactory mid-term results of endovascular procedures on the IRA (restenosis or reocclusion).

Incidence of in-stent stenosis (according to Mehran classification, 1999) was 24 (30%) and 31 (32.6%) in the first and the second group, respectively. According

Table 5. Mid-term clinical and angiographic results

Parameters	Group 1 (n=121)	Group 2 (n=132)	P
No angina	89 (73,5 %)	91 (68,9 %)	NS
Recurrent MI (non-fatal) in the IRA	2 (1,6 %)	1 (0,8 %)	NS
Mortality			
- total mortality	4 (3,3 %)	1(0,8%)	NS
- cardiac mortality	1 (0,8 %)	1(0,8%)	NS
	(n=80)	(n=95)	
Good result of the procedure	56 (70 %)	64 (67,4 %)	NS
Reocclusion	3 (3,7 %)	5 (5,3 %)	NS
Restenosis	21 (26,2 %)	26 (27,4 %)	NS
Repeated PTCA	18 (22,5 %)	23 (24,2 %)	N/A
CABG	6 (7,5 %)	11 (11,6 %)	NS

to this classification in 5 (21%) and 7 (22.6%) cases there was local stenosis (up to 10 mm); in 9 (37.5%) and 12 (38.7%) cases it was diffuse stenosis (more than 10 mm) not extending beyond the stent's ends; in 7 (29.2%) and 7 (22.5%) cases it was diffuse proliferative stenosis more than 10 mm and extending beyond the stent's ends; in 3(12,5%) and 5 (16.1%) of cases there was total occlusion (TIMI 0). Repeated PTCA in the cases of in-stent stenosis was successfully performed in 18 out of 24 patients (75%) in the first group, and in 23 out of 31 patients (74.2%) in the second group. Analysis of the factors that influence occurrence of in-stent stenosis demonstrated, that among clinical and historical factors only previous MI (post-infarction cardiosclerosis) and LVEF less than 40% had significant influence on the development of such complication. Considering angiographic factors, we noticed a significant relevance of B2/C morphological type of stenosis, presence of calcifications and ostial lesion, proximal localization of the lesion, presence of well-developed collaterals to the IRA, length of the lesion 17 mm and more, baseline degree of stenosis 90% and more. With this, initial occlusion of the IRA was a significant predictor of in-stent stenosis only in patients with delayed stenting. Considering procedure-related factors, significant influence on development of in-stent stenosis was demonstrated for stents measuring 2.75 mm and less in diameter, 17 mm and more in length; for stent implantation at low pressure (7.5 atm), coil stent, bailout stenting, use of stent caliber smaller than vessel lumen size, and also for cases when the obtained diameter of the stented segment exceeded the true diameter of the vessel by more than 10% ($p<0.05$).

Thus, the analysis of the mid-term clinical and angiographic results did not reveal any substantial differences between the study groups in the clinical course of the disease and incidence of the severe complications (mortality, recurrent AMI, need for CABG or repeated TCA), ($p>0.05$). Early (within the first 24 hours) as well as delayed (up to 21 day) stenting in AMI patients appeared to be effective and useful method, which promotes favorable course of the disease and improves the prognosis for the patients with AMI. We noticed a similarity of the IRA state in the mid-term follow-up in both groups with the same incidence of restenosis and reocclusion and other similar risk factors of unfavorable outcomes in this vessel. Significant influence of the time of stenting of the initially occluded artery on the development of in-stent stenosis was also noted (in the second group, occluded IRA appeared to be a risk factor for development of in-stent stenosis). Most frequently found type of in-stent stenosis in these groups was diffuse type (37.5% and 38.7% of cases).

In the mid-term follow-up ejection fraction of the left ventricle in the study groups increased significantly. In the first group it increased from 55.4±11.4% to 60.2±12.7%, $p<0.05$; and in the second group it increased from 51.3±11.2% to 62.5±11.5%, $p<0.005$. The increase of the LVEF in both groups occurred mainly on account of patients with preserved antegrade blood flow (TIMI 3) in the IRA, even when there was in-stent stenosis of the IRA. No significant increase of the left ventricular ejection fraction was observed in patients with complete occlusion of the stented segment. In the group with partial revascularization only a trend towards increase of the ejection fraction and decrease of end diastolic and end systolic volumes was seen. The differences observed were non-significant. Maximum significant increment of ejection fraction ΔEF (6.34±1.5%) and significant decrease of end diastolic volume ΔEDV (-7.4±2.3 mL) and end systolic volume ΔESV (9.6±2.5 mL) were observed in patients with preserved antegrade blood flow in the IRA and complete revascularization. In the second study group they were predominantly patients with initial stenotic lesion of the IRA and antegrade blood flow TIMI3; in case of delayed stenting of initially occluded IRA the increment of ejection fraction and decrement of the volumes of the left ventricle were nonsignificant (Table 7).

Table 6. Dynamic changes of ejection fraction of the left ventricle

	Ejection fraction of the left ventricle, %		P
	before endovascular procedure	mid-term follow-up	
Group 1 (bailout stenting):			
- Good result with complete revascularization	56,4±11,1	61,6±10,6	<0,003
- Good result with partial revascularization	47,2±12.1	51,9±10,7	>0,05
- Restenosis	55,5±9,2	59,4±9,4	<0,05
- Reocclusion	50.3±1,1	47.2±11.6	0,2
Total LVEF (sum):	55,4±11,4	60,2±12,7	<0,005
Group 2 (delayed stenting):			
- Good result with complete revascularization	57,9±11,2	62,9±11,7	<0,01
- Good result with partial revascularization	55,2±10,7	59,8±11,4	>0,05
- Restenosis	55,1±10,2	59,9±9,2	<0,05
- Reocclusion	44,3±10,1	47,9±10,5	0,22
Total LVEF (sum):	51,3±11,2	62,5±11,5	<0,005

Thus, the delayed angioplasty of the IRA with stenting leads to a significant improvement of the left ventricle myocardial contractility. This phenomenon is observed only in case of persistence of the effect of procedure in mid-term follow-up and absence of concomitant lesions in other coronary arteries, primarily in patients with initial stenotic lesion of the IRA. In the first group, the most pronounced effect of stenting of the IRA on the functional capacity of the left ventricle was noted in patients with acute anterior wall MI, initial

Table 7. Values of ΔEF, ΔEDV and ΔESV in relation to the initial state of the IRA

	EF-delta	EDV-delta	ESV-delta
IRA stenosis	+ 8,22±1,4	-7,74±2,13	-12,25±3,21
IRA occlusion	+ 3,12±1,1	-2,28±3,35	-4,36±3,79
p (Mann-Whitney criterion)	<0,002	<0,004	<0,003

left ventricular ejection fraction < 40% and in case of the most early revascularization of the myocardium. Analysis of segmental contractility in these patients showed, that increase of left ventricular ejection fraction is promoted by the improvement of contractility left ventricular segments supplied by the IRA. The study demonstrated that the increase of the time interval between the onset of anginal pain and the performance of the procedure leads to decrease in the percentage of patients with significant improvement of the left ventricle function. For instance, in cases when stenting was performed in the first three hours after the onset of anginal status, more than 80% of patients had significant increase of the ejection fraction, no matter had the ARI been occluded completely, or did it have only a stenotic lesion. If the stenting was performed three to six hours after the onset of the anginal attack, this value decreased to 66.1%; whereas if this procedure was performed more than six hours from the onset of the attack improvement of the left ventricle function was seen only in 32%. When the procedure was done two weeks after the onset of the AMI, the improvement was obtained in only 16% of patients.

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Indications and Conditions for Endovascular Repair of Popliteal Artery Aneurysm

V.A. Ivanov[1], O.V. Pinchuk, S.V. Volkov, Yu.A. Bobkov, I.V. Trunin, S.A. Terekhin, A.V. Ivanov
A.A. Vishnevsky Central Military Clinical Hospital №3, Krasnogorsk, Russian Federation

X-ray endovascular treatment of aortic and peripheral arterial aneurysms is an alternative surgical option and contributes to the shortening of hospital stay, significantly decreasing the time of postoperative recovery [1, 2]. Percutaneous endovascular repair of peripheral aneurysms yields good immediate and long-term results, thus being a potential substitute for surgery. However, aneurysms of popliteal region still require more accurate indications and conditions to choose an adequate therapy [3, 4].

We have summarized the first experience with endovascular stent-grafting of popliteal artery aneurysm at A.A. Vishnevsky Central Military Clinical Hospital. Between 1990 and 2004 in the Department of Vascular Surgery a total of 19 patients were treated for the above condition. Indications to surgery and the extent of manipulation were determined according to clinical data, contrast angiography and duplex ultrasound study. The decision on the use of endovascular method was taken by both vascular surgeons and interventional radiologists together. In July 2004 we were the first to perform successful stenting of popliteal artery aneurysm among all healthcare institutions of the Russian Federation Ministry of Defense. The case report is presented below.

Patient E., born 1972 (aged 32), case history N13449, was admitted to the Department of Vascular Surgery of A.A. Vishnevsky Central Military Clinical Hospital N3 on July 14, 2004. She presented with a history of popliteal mass since 2001 and had no prior examination or treatment. The patient applied for medical care in July 2004 and was admitted to the Department of Surgery of Oncological Clinical Hospital with the diagnosis of left shin soft tissue tumor (suspected sarcoma). An attempt of open biopsy (12.07.04) caused profuse bleeding, which was stopped by aneurysm capsule suture. The patient has history of type C hepatitis and drug addiction. Contrast angiography was performed on the day of transfer to the Department of Vascular Surgery (Fig. 1-4). The study confirmed popliteal artery aneurysm and subsequently stent-graft implantation was successfully performed (Fig. 5). The patient made an uneventful postoperative recovery. The patient was discharged for out-patient management at day 3 postoperatively.

An essential technical condition for an endovascular intervention is contrast visualization of the segment of artery "originating" from the aneurism and adequate contrast visualization of distal arterial bed during diagnostic angiography. One patient aged 83, who presented with severe comorbidities, had ruptured popliteal artery aneurysm. Surgery was chosen in view of life-saving indications. Endovascular intervention was considered a method of choice due to its minimal invasiveness. The case report is presented below.

Patient G., born 1921, (83 years of age), case history №14628; emergency admission to the Department of Vascular Surgery of A.A. Vishnevsky Central Military Clinical Hospital №3 on August 02, 2004 with referring diagnosis: ruptured aneurysm of the left popliteal artery. The patient had over 10-year history of bilateral aneurysms of the popliteal and femoral arteries. Elective surgery was not performed previously for old age and severe comorbidities. Within this period, his claudication became more

Figure 1. Patient E., born 1972, case history №13449. Preoperative angiography showing aneurysm of the middle portion of the left popliteal artery

Figure 2. Patient E., born 1972, case history №13449. Preoperative angiography showing the connection between the popliteal artery and the aneurysm cavity

Figure 3. Patient E., born 1972, case history №13449. A single stage of endovascular repair. Stent-graft balloon catheter (the arrow) positioned at the site of junction between the popliteal artery and the aneurysm cavity

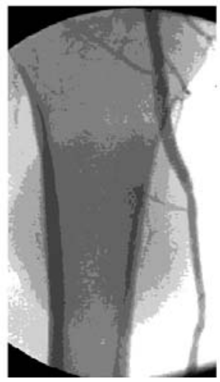

Figure 4. Patient E., born 1972, case history №13449. Completion angiography after stent-graft implantation. Aneurysmal cavity is isolated from the main arterial circulation

[1] V.A. Ivanov
Russia, 143420, Krasnogorsk,
Vishnevsky Central Military Hospital N3
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Figure 5. Stent-graft

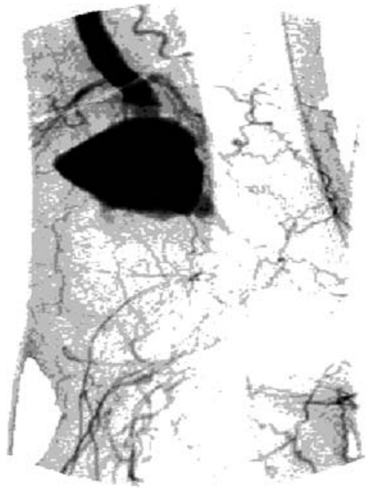

Figure 6. Patient E., born 1921, case history №14628. Preoperative angiography showing ruptured aneurysm of the proximal portion of the left popliteal artery, aneurysms with ill-defined contours, no contrast medium is identified in the middle and distal portions of the popliteal artery and arteries of the shin

pronounced and progressive trophic lesions of the skin of both shins appeared. Acute pain in the left popliteal region and lower third of the thigh occurred on July 28, 2004, which was accompanied with substantial enlargement of palpable mass. On admission: severe general state; the patient appeared weak and torpid. Heart sounds were irregular and muffled. HR 110 b.p.m, weak; BP 120/70 mm Hg. Three pulsatile palpable masses identified in the right popliteal region measured 6.0, 5.5, and 6.5 cm in diameter. Tense pulsatile mass in the lower third of the left thigh and left popliteal region measured 15.0 x 20.0 cm in size with large subcutaneous hematoma were revealed as well. There was normal groin pulse and no foot pulse. Both feet were cold, pale and cyanotic. The patient was diagnosed with disseminated atherosclerosis of the aorta and its branches, aneurysms of both femoropopliteal arterial segments, ruptured aneurysm of the left popliteal artery, stage III obliterating atherosclerosis of the lower limbs; bilateral occlusion of shin arteries. Urgent contrast angiography showed large pulsatile hematoma, which extended deep into the soft tissues of the left thigh and left popliteal region (Fig. 6.).

No contrast medium was identified in the middle and distal portions of the popliteal artery and arteries of the shin. Endovascular intervention was therefore considered impossible. The patient underwent open surgery with minimum manipulation (ligation of the afferent portion of the popliteal artery with isolation of the aneurysm from the main arterial circulation). The patient developed acute ischemia of the left lower limb postoperatively, which regressed to the preoperative degree after vasoactive treatment.

Despite the apparent benefits of the endovascular method, thorough patient selection is still required [5]. The presence of a stent in the popliteal artery substantially limits the patient's physical performance, which, in turn, can result in deformation and thrombosis of the stent [6]. Therefore, indications for endovascular treatment of popliteal artery aneurysm must include the patient's ability to observe closely these forced restrictions. Unfortunately, in one instance we didn't take account of this rule having performed stenting of popliteal artery aneurysm in a patient with marked circulatory encephalopathy. The case report is presented below.

Patient M., born 1930 (74 years of age), case history №13773. Emergency admission on July 19, 2004 for ischemic pain at rest, decreased sensitivity and limited motions of the left toes. The above symptoms, as well as distal left foot coldness appeared suddenly one day prior to admission. The patient was referred to the cardioreumatological department with the diagnosis of gouty arthritis. He was referred to vascular surgeon because of unclear clinical pattern. Examination revealed round-shaped pulsatile mass in the left popliteal region measuring 4.0x3.5 cm in size. There was normal dorsalis pedis and posterior tibialis pulse. The toes and distal portion of the left foot were cold, pale and cyanotic. There were sharp decrease of deep sensitivity and restricted motion of the toes. The diagnosis of left popliteal artery aneurysm causing distal embolism into the arterial arch of the foot was established. Conservative vasoactive therapy did not result in regress of ischemia. The diagnosis was confirmed by contrast angiography on 22.07.04 (Fig. 7). Due to the

Figure 7. Patient E., born 1930, case history №13773. Preoperative angiography showing aneurysm of the middle portion of the left popliteal artery

Figure 8. Patient E., born 1930, case history №13773. Completion angiography after the endovascular intervention with stent-graft implantation. No signs of popliteal artery aneurysm are identified

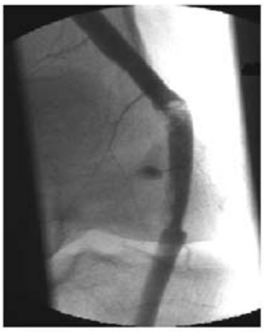

Figure 9. Patient M., born 1930, case history №13773.
Contrast angiography showing filling defect (denoted by arrow) in the proximal portion of the stent implanted

Figure 10. Patient M., born 1930, case history №13773.
X-ray showing defect (twisting) in the proximal portion of the stent

patient's age, severe concomitant diseases (including grade II-III circulatory encephalopathy) we thought it appropriate to indicate endovascular treatment. The patient underwent stenting of popliteal artery aneurysm with JOSTENT stent-graft (Fig. 8).

The patient was notified about the need for the left knee motion limitation; however, he disregarded this advice. Foot ischemia increased on July 26, 2004. Control angiography showed deformation and twisting of the stent with impaired blood flow in the popliteal artery (Fig. 9, 10).

Left-side autovenous femoropopliteal bypass was urgently performed. Despite adequate reconstruction limb ischemia progressed. Amputation of the left lower limb on the level of thigh was performed on July 30, 2004 for bypass thrombosis.

Conclusions

Endovascular grafting with stent-grafts is an effective and minimally invasive treatment for popliteal artery aneurysm. The results obtained in this study confirm the need for strictly individual approach in determining the indications for endovascular therapy for popliteal artery aneurysms. It is necessary to perform comprehensive assessment of the patient's general state, severity of comorbidities, location and size of the aneurysm, characteristics of the "afferent" popliteal artery portion and distal arterial bed of the shin.

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Importance of Heart Rate Variability in the Estimation of the State of CAD Patients after PTCA and/or Coronary Artery Stenting

E.Ya. Parnes[1], R.I. Stryuk*, D.G. Iosseliani***
**Moscow State Medical Stomatological University*

*** Moscow City Center of Interventional Cardioangiology*
Moscow, Russian Federation

The in-stent stenosis is one of the problems related to coronary stenting [1-3] and according to different authors, it occurs in 10-50% of cases [1-3]. Some authors believe, that the aggravation of the disease, for example, in unstable angina pectoris, the prognosis for in-stent restenosis development is much worse than in patients with stable course of CAD [4-6]. Probably, it depends on the morphological substrate forming the base of the disease, in particular, on the state of stenosing atherosclerotic plaques in the coronary arteries. Some works suggest, that just the presence of a soft plaque determines the unfavorable prognosis in terms of in-stent stenosis development [6]. However in-stent stenosis develops also in patients with stable angina. Undoubtedly, the risk of this complication development depends also on stenosis localization, vessel's diameter, stent length and characteristics. Thus, the problem of search for the methods, allowing to determine the group of CAD patients at high risk of this complication prior to stenting along with the determination of the risk factors for in-stent stenosis in each case, becomes very urgent.

Evaluation of the heart rate variability (HRV) is one of the methods which allow for the evaluation of CAD prognosis [7]. It is known, that the indices of HRV in patients with unstable angina are lower [8, 9] than in patients with stable angina. In our previous study it was shown that the level of pro-inflammatory cytokine messenger RNA synthesis in peripheral blood lymphocytes in patients with stable angina correlates inversely with HRV values [10]. This proves the opinion, that the pathophysiological mechanisms in some patients with stable angina are more similar to unstable angina. Also, it is worth noticing, that soft plaques are encountered in about 40% of patients with stable angina [11], and in 26% of them asymptomatic plaques/ ruptures have been noticed [12]; this can, in part, explain the risk of in-stent stenosis development in patients with stable angina.

In connection with abovementioned we decided to study the predictive value of HRV for the development of in-stent stenosis after successful PTCA and/or coronary artery stenting. We found just few works concerning the study of HRV in patients undergoing PTCA [13-17], and no articles on the study of HRV after coronary stenting. Besides, we wanted to study the mechanisms of HRV decrease in patients with acute coronary syndrome in a model of intraprocedural rupture of the coronary artery's intima.

Materials and methods

One hundred and four male patients (mean age 51.4±9.2) were examined; 20 of them had unstable angina, and 84 had stable angina (table 1). Patients with heart failure, heart rhythm disorders, diabetes mellitus, chronic diseases aggravation or decompensation, neoplasia, endocrine disorders, acute inflammatory diseases were excluded from the study. The control group included 20 normal patients. PTCA was performed in 9 patients, coronary artery stenting — in 53 patients. In 42 patients with coronary disease only PTCA was performed. All diagnostic and medical endovascular procedures were performed in the morning, between 10 a.m. and 1 p.m. In order to exclude the influence of surgical technique particularities on HRV all stenting procedures were performed by one surgeon (D.G. Iosseliani). All patients received the same drug therapy: β-blockers, aspirin, nitrates (if needed) and angiotensin-converting

Table 1. Clinical characteristics of patients with CAD

Data		Abs.
Arterial hypertension	Yes	76
	No	28
Smoking	Smokers	37
	Currently do not smoke, but have a history of smoking	43
	No history of smoking	24
Obesity	Android	21
	Gynoid	20
	No	63
Alcohol consumption	Abuse	23
	Mild	62
	No	19
Angina	Unstable	20
	Stable	79
	No	5
Old myocardial infarction	Anterior	31
	Inferior	39
	No	34
Ejection fraction	Under 40%	3
	40-60 %	42
	Over 60%	58
Number of stenoses	3 and more	35
	2	32
	1	37
Coronary flow in maximally diseased artery (TIMI)	0	39
	I	10
	II — III	55

[1] E.Ya. Parnes
e-mail: parnes@pochta.ru
Phone: (095) 125-04-47
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enzyme inhibitors. During PTCA and/or stenting heparin and tiklid were added.

Patients with CAD underwent ECG monitoring (by means of Cardiotens-01, Meditex, Hungary) with calculation of temporal (SDNN, SDNN index, r-MSSD, SDANN, pNN50%, triangular index) and spectral indices of HRV (by means of Medibase 1.54 application) a day before PTCA and/or stenting/angioplasty and on the day of procedure performance (in a total within 48 hours). The spectral indices of HRV were calculated by the fast Fourier transformation method. The spectral analysis was applied for the study of the high frequency (HF) (0.15-0.40Hz) power component of HRV, which gives the evidence of the impact of parasympathetic nervous system, and the low frequency (LF) power component (0.04-0.15Hz) of HRV, which shows the predominant influence of sympathetic nervous system. Besides, we determined the total-frequency power of heart rate variability and LF/HF ratio — the index, which reflects the effect of sympathovagal balance on heart rhythm [9]. HRV was analyzed at 24-hours basis, as well as separately for the day and the night, on the 2nd day we analyzed also the period after the procedure (up to 10 p.m.) and nocturnal period (from 10 p.m. to 8 a.m.).

Twenty four patients underwent repeated selective coronary angiography 6 months after successful PTCA and/or stenting. In the late follow-up a particular attention was paid to such problems as the development of myocardial infarction or acute coronary syndrome, the development of in-stent stenosis, marked progression of stenosing atherosclerosis. Hereinafter those complications will be referred to as end-points.

The statistical analysis of findings was performed by means of "Microsoft Excel 2000" and "SPSS 10.0 for Windows" applications. Nonparametric statistical analysis was performed according to Mann-Whitney, Kruskal Wallis and Wilcoxon criteria. The results are shown as mean and standard deviation (M±SD).

Results and discussion

1. Baseline HRV data depending on clinical course of CAD.

Analysis of the baseline HRV data in examined CAD patients confirmed literature data that in patients with unstable angina the HRV values are significantly lower than in patients with stable angina (10, 11). However after detailed analysis of the stable angina group we have selected 17 patients whose HRV parameters were practically similar to those in patients with unstable angina. Thus, patients with CAD were divided into 3 groups: group 1 — stable angina (n=67), group 2 — unstable angina (n=20), group 3 — patients with clinical signs of stable angina, but with the HRV parameters consistent to those in stable angina (n=17). According to Kruskal Wallis criterion the groups did not differ as for age, presence of arterial hypertension, prior myocardial infarction, the degree of left ventricular hypertrophy, ejection fraction, number and severity of coronary stenoses.

The comparison of HRV indices between those groups revealed the greatest difference in temporal index (SDNNindex), and in spectral LF index (especially during night-time) (table 2). We didn't find any reliable LF/HF ratio value reflecting sympathovagal balance.

As shown on fig. 1, spectral indices of HRV increased reliably in patients with stable angina and un normal persons during sleep, while in other groups not only they didn't increase, but in patients with unstable angina the LF impact on the heart rate even decreased (although insignificantly) (fig. 1). So, the first stage of our study showed that HRV in patients with CAD is determined primarily by clinical course of disease. The study also allowed for a conclusion, that the group of patients with stable angina is heterogeneous, because HRV data in some patients of this group are similar to those in unstable angina.

Taking into account that the groups of CAD patients differed mainly by spectral indices, we thought it reasonable to study the influence of endovascular procedure on the HRV as reflected in LF and HF dynamics.

2. Dynamic of HRV indices after PTCA and/or stenting

In order to determine the possible influence of

Table 2. HRV indices in patients with stable course of CAD, with unstable angina, with stable angina but having HRV consistent to that in unstable angina, and in healthy persons

Data	Patients with stable CAD (n=67)	Patients with unstable angina (n=20)	Patients with stable CAD similar to unstable (n=17)	healthy (n=20)	Kruskal Wallis Test p =
Age	50,6±9,2	51,1±8,5	55,8±9,0*	40,7±8,8**	0,0001
SDNN мs (24hour)	143,8±31,4	109,5±24,9*	108,1±19,3**	178,4±36,9*	1,4E-07
SDNNindex мs (24 hour)	66,0±14,9	42,8±13,8**	41,7±5,4**	75,1±15,5*	2,6E-10
Triangular index (24 hour)	37,1±9,2	26,8±8,0**	28,2±4,7**	46,7±8,4**	5,6E-09
LF мs² (24 hour)	941,3±687,4	339,4±168,6**	320,9±107,7**	1402±669*	3,5E-11
HF мs² (24 hour)	368,9±310,9	137,1±68,0**	137,0±57,4**	487,2±210*	6,5E-08
LF / HF (24 hour)	3,3±1,7	2,7±1,3	2,5±0,7*	3,4±1,6	0,061
Total power мs² (24 hour)	3924±2102	1738±873**	1962±537**	4827±1956*	1,4E-10
LF мs² (day)	824,3±631,9	352,9±189,7**	277,7±119,8**	1209±579*	4,9E-10
HF мs² (day)	301,7±310,7	124,3±81,2*	101,6±45,1**	351±173*	8,2E-07
LF мs² (night)	1112,2±836,0	286,4±129,1**	371,6±198,3**	1834±1002*	7,6E-11
HF мs² (night)	472,4±409,2	145,1±46,2**	179,8±94,8**	733±412*	3,5E-08

* P<0.05
** P<0.001 (Mann-Whitney U test) - compared to group of patients with stable angina

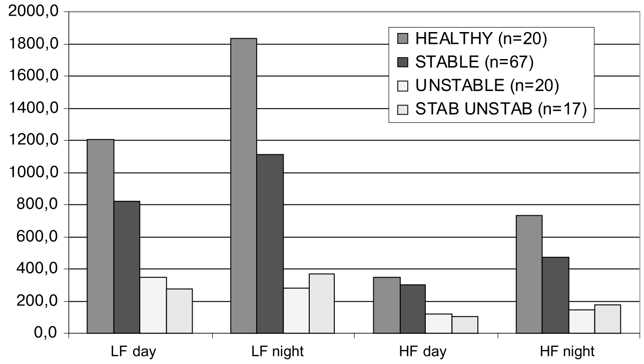

Figure 1. HRV spectral values in healthy persons and in patients with CAD
(* - Wilcoxon criteria < 0.05)

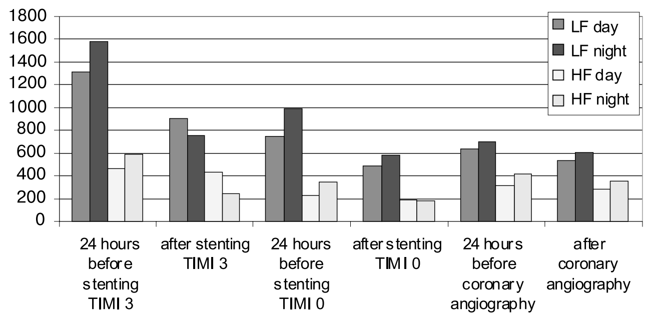

Figure 2. Spectral values of HRV during 24 hours befor and after stenting/coronary angiography in patients with stable angina
(* - Wilcoxon criteria< 0.05)

coronary intima rupture during PTCA and/or stenting on HRV values, we investigated spectral indices before and after procedure in the stable angina group. The group 1 included 23 patients with blood flow TIMI 2-3 after stenting/PTCA, group 2 — 15 patients after stenting for coronary occlusion. For the purposes of comparative analysis we have created two more groups of patients who underwent only diagnostic selective coronary angiography, One of those groups, that is, group 3 comprised 14 patients with stenotic lesions and TIMI 2-3 blood flow, while group 4 comprised 15 patients with totally occluded coronary vessels. The dynamics of HRV spectral values before and after coronary angiography was similar in both groups; thus, we rallied these patients in one group. The study showed that coronary stenting in patients with stable angina and TIMI 2-3 leads to abrupt significant (according to Wilcoxon criterion) decrease of LF index in day-time after the procedure, as compared to that on previous day (p=0.04), to decrease of LF in night-time following the procedure as compared to previous night (p=0.0012), to decrease of HF in night-time following the procedure as compared to previous night (p=0.0022). It is important to note, that nocturnal values of spectral data were lower compared to those in day-time. So the HRV in patients with stable angina after PTCA/stenting became similar to HRV in patients with unstable angina. In stable angina patients with coronary occlusion the restoration of blood flow also led to spectral indices' decrease. However this decrease was significant (according to Wilcoxon criterion) only for day-time LF value measured after the procedure, as compared to that on previous day (p=0.046). Other spectral indices decreased slightly during day-time and night-time (p=0.11), that is, less significantly than in patients with TIMI 2-3. This is probably related to the fact, that the restoration of antegrade blood flow after endovascular procedure and, hence, a significant improvement of myocardial perfusion, has partly leveled the negative impact caused by intima rupture.

In patients with CAD who underwent only coronary angiography the spectral indices decrease was very insignificant and unreliable (Wilcoxon criterion, p=0.34). It is important to note, that HRV values in this group of patients were higher during night-time compared to those in day-time, i.e. the same as before procedure. Thus, the infusion of the contrast medium, irradiation and strict bed regime after coronary angiography did not exert significant influence of HRV indices, and one cannot explain the post-procedural HRV decrease by those factors. Therefore, only a procedure accompanied by the intra-coronary plaque rupture leads to the situation, when spectral HRV values in patients with stable angina, being close to the normal range before the procedure, became similar to those in patients with unstable angina.

The stenting procedure in patients with unstable angina patients with TIMI 2-3 blood flow, as well as in patients with clinical picture of stable angina but with HRV indices consistent with unstable angina, did not change significantly the spectral values of HRV, moreover, they even tended to increase (fig. 3). Probably, this was caused by the improvement of myocardial perfusion due to the restoration of full blood flow in the vessel.

3. Prognostic significance of the HRV values for long-term results of endovascular procedures

The end-points were revealed in 14 out of 24 reexamined patients (3 patients after PTCA, 11 patients after stenting). In the remaining 10 patients (1 patient after PTCA and 9 after stenting) no serious complications were revealed in the late follow-up. In the group

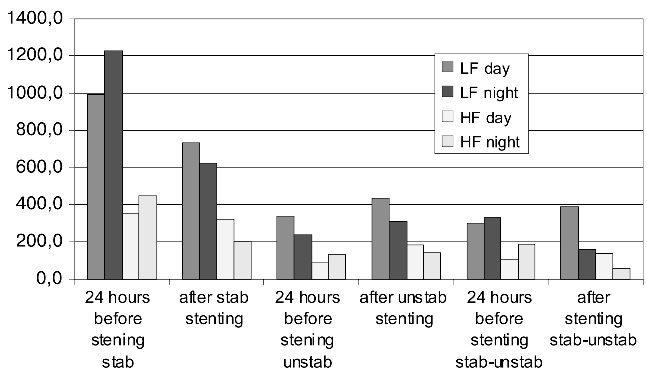

Figure 3. Spectral values of HRV 24 hours before and after stenting (TIMI 3) in patients with stable, unstable and stable-unstable angina
(* - Wilcoxon criteria < 0.05)

of patients with developed end-points the following stents were used: Angio Stent in 1 patient, Multilink tetra in 3, R-stent evolution in 2, BiodivYsio OC in 2 and BxSonic in 5 patients, respectively. In patients without end-points development Multilink tetra was used in 1 patient, Chopin in 1, AVE S7 in 1, Cypher in 3 and BxSonic in 5 patients, respectively. It is important to note, that the main characteristics of the stents used in both groups were not significantly different. However Cypher stents have an antibiotic (rapamycin) coating, preventing the proliferation of neointima.

Four of the re-examined patients had unstable angina while undergoing coronary stenting procedure. In all of them the end-points points were found: in-stent stenosis in 3 patients (with myocardial infarction development in 1 patient); marked progressing of the coronary artery stenosis in 1 patient.

The initial analysis showed that development of end-points was not typical for unstable angina only, as they were also found in 9 patients with stable angina. However a more careful analysis showed that some persons among 9 patients with stable angina had HRV consistent with unstable angina, which led to the identification of a separate group. As a result of a repeated analysis performed with account of above-mentioned the groups became reliably different (Kruskal Wallis criterion p=0,007) as for the risk of end-ponts development (fig.4)

After revealing a significant correlation between HRV values and development of end-points (fig. 5), we came to the conclusion that the probability of restenosis and atherosclerosis progressing mostly depends on baseline values of LF power component of heart rate. In patients with low values of HRV, especially with day-time LF values less than 600 ms2 in both unstable and stable angina, the end-points developed in 12 out of 14 cases.

In previous publications concerning investigation of HRV after PTCA [13-17] the repeated evaluation of HRV parameters was provided, as a rule, immediately after the procedure [13, 17], at 3-5 days [15, 16], at one month [13, 14, 17] and at 6 months [14, 15] after PTCA. The authors came to the following conclusions:

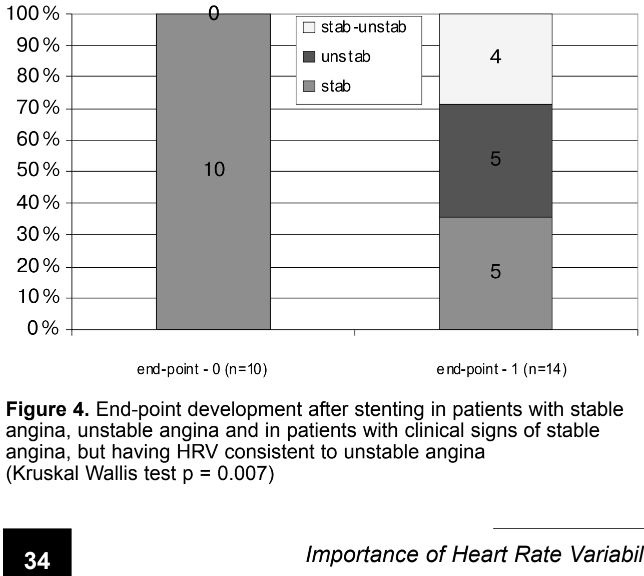

Figure 4. End-point development after stenting in patients with stable angina, unstable angina and in patients with clinical signs of stable angina, but having HRV consistent to unstable angina
(Kruskal Wallis test p = 0.007)

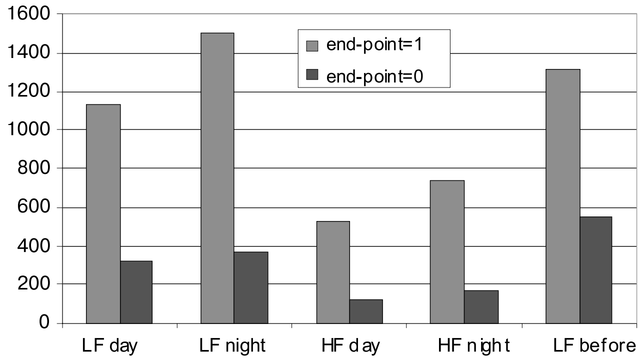

Figure 5. Initial HRV spectral values in patients with CAD, in whom the end-points were monitored
(* - Mann-Whitney criteria p < 0.05)

immediately after PTCA there is a decrease of HRV values [15, 17]. With this the ejection fraction and number of diseased coronary arteries do not affect the post-PTCA changes of HRV [15]. However, 2 weeks after successful PTCA the indices of HRV started to increase, mainly due to partial recovery of high-frequency power component of HRV [14-17]. Such dynamics of HRV values allows to make a conclusion, that ischemia is one, but not the unique cause of HRV decrease [14].

We couldn't find any publications related to the analysis of the causes of HRV decreasing during PTCA. However there is one work suggesting that balloon inflation during PTCA causes vagus stimulation via baroreceptor activation [18], but in such case the HRV values should be increased. Also involvement of the cardio-cardiac reflex occurring as a result of asynchronous contraction of the adjacent segments of the myocardium [19] is supposed to be a cause of the HRV values increase. However be this mechanism the main or the leading one, the changes in HRV values after angioplasty should be similar in patients with both stable and unstable angina. Step-by-step recovery of the HRV after PTCA may suggest, that the end of some processes in coronary arteries exerting negative influence on HRV and initiated by angioplasty, requires some time. As a result even after a successful PTCA the positive influence of myocardium reperfusion on heart rate regulation is somewhat leveled for a certain time. Only after this negative influence comes to the end, the improved myocardial blood supply can contribute to the increase of HRV.

Our results may be interpreted in the following way: despite a significant improvement of myocardial blood supply after successful PTCA or coronary stenting procedure, the inflammatory reaction [20], appeared in response to the plaque rupture and intima damage, stent implantation in this vessel is enough for decreasing HRV values.

In distinction from the patients with stable angina, an additional intima damage during PTCA or stenting in those with unstable angina with already existing inflammatory process at the site of plaque rupture or formation of a new soft plaque [21], does not not lead to additional decrease of HRV values. Moreover, in these patients there was a tendency for HRV indices improvement, probably caused by myocardial perfusion improvement after endovascular procedure.

Thus, our study showed that HRV values' decrease in patients with clinical and electrophysiological signs of unstable angina is mainly caused by inflammatory process in the vessels' intima. Among patients with stable angina there were patients with the HRV values and outcomes of PTCA and stenting similar to those in patients with unstable angina. This is most likely due to the presence of the soft plaques in the coronary arteries and concomitant inflammation.

Maybe, it would be reasonable to perform an intravascular ultrasound investigation in patients with low HRV values; that would greatly contribute to the solution of the existing questions.

Our results allow for the conclusion about the reasonability of studying HRV indices in patients before endovascular procedures in order to determine the prognosis of those procedures. IIf the LF power component of heart rhythm during day-time is low (less than 600 ms^2) the patients should be treated as ones with unstable angina. Perhaps the restenosis problem in these patients may be solved by the use of rapamycin-coated stents (e.g. Cypher type), and with administration of higher doses of statins.

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Cardiovascular Multidetector Computed Tomography: A Review

James K. Min MD, Rick Koch MD, Daniel Appelbaum MD, Samuel Wann MD[1]*
University of Chicago Hospitals, Department of Medicine, Division of Cardiology;
**University of Chicago Hospitals, Department of Medicine, Division of Radiology;*
Cardiovascular Medicine, Wisconsin Heart Hospital, USA

Atherosclerotic cardiovascular disease is the leading case of morbidity and mortality in the modernized world. In the last several years, many novel noninvasive imaging techniques have been developed to enhance diagnosis of coronary and peripheral vascular disease. These techniques include electron beam computed tomography, cardiovascular magnetic resonance imaging, and multi-detector row computed tomography (MDCT). MDCT has transformed CT from a single-slice trans-axial imaging modality to a true three-dimensional imaging technique, with image acquisition speeds 50 times that of conventional single-slice CT scanning. MDCT scanning also imparts the ability to acquire true three-dimensional sub-millimeter volumetric imaging. These benefits propel the field of MDCT into new areas of imaging, such as cardiac and coronary anatomy, that were not previously possible. In this report, we discuss advantages and limitations of MDCT in cardiovascular imaging and disclose the protocols we found most advantageous with our current generation MDCT scanner.

Introduction

Atherosclerotic cardiovascular disease is the leading cause of morbidity and mortality in the modernized world. Several novel noninvasive imaging techniques have been recently developed to enhance diagnosis of coronary and peripheral vascular disease. These techniques include electron-beam computed tomography (EBCT) [1-6], magnetic resonance angiography (MRA) [7-11], and most recently, multi-detector row computed tomography (MDCT) [12-18].

By transforming CT from the single-slice trans-axial imaging modality to a true three-dimensional imaging technique, MDCT has significantly broadened the potential for diagnosing cardiovascular disease. The current generation of 16-, 40-, 64- and even 128-slice scanners generate image acquisition speeds that exceed 50 times that of conventional single-slice CT scanning. This advantage will only be amplified as newer generation scanners are developed that possess additional detector rows as well as innovative software programs that enhance data transport and image acquisition. The speed of MDCT tenders the advantage of shorter breath-hold time, reduced overall examination time, and decrease in the amount of intravenous contrast required, all without compromise in scan range or section collimation. Consequently, MDCT has been shown to be useful in imaging coronary arteries, carotid circulation, and renal arteries, thoracic and abdominal aorta as well as lower extremity run-off studies [19-26].

Besides image acquisition speed, MDCT provides a revolutionary transformation in the type of data obtained. In comparison to the trans-axial images of conventional single-slice CT, MDCT imparts the ability to acquire true three-dimensional volumetric imaging, which is advantageous for a multitude of reasons. The sub-millimeter imaging capability of MDCT advances CT closer to the "holy grail" of isotropic imaging. The current generation MDCT scanners can create nearly isotropic images which can be viewed not only in standard trans-axial planes but rather in any arbitrary plane the viewer wishes. Both of these benefits propel the field of MDCT into new arenas of imaging, such as precise definition of cardiac and coronary anatomy, that were heretofore not possible. This report is aimed to describe our recent experience with MDCT for coronary and vascular imaging. Specifically, we will discuss advantages and limitations of MDCT and will disclose the protocols we found most advantageous with our current generation MDCT scanner (Philips Brilliance 16-slice CT scanner, Andover, MA).

MDCT Cardiac Imaging and Coronary Angiography

Since development by Dr. Mason Sones, selective coronary angiography has been considered the gold standard for identifying epicardial coronary lumen dimensions and estimation of coronary artery stenosis severity [27]. It is, however, an invasive procedure with potential harmful complications. These complications may be minor (such as hematoma or mild bleeding) but potentially may be more severe (such as myocardial infarction, coronary artery dissection, cerebrovascular accident, and even death) [28]. As it is estimated that approximately 40-50% of diagnostic angiograms do not result in intervention, it would be ideal to cultivate techniques for coronary artery stenosis detection that are non-invasive [29]. Recently, much of the effort of noninvasive coronary artery imaging has been focused on EBCT (Figure 1). With electrocardiographic gating, tomographic images can be obtained by EBCT at speeds as fast as 5 msec in the cine mode and 100 msec in the high resolution mode with resolutions as thin as 1.5 mm slices [1-6, 30-36, 38]. This has facilitated calcium scoring,

[1] Samuel Wann, MD, MACC
Wisconsin Heart Hospital
10000 Bluemound Road
Milwaukee, WI 53226 USA
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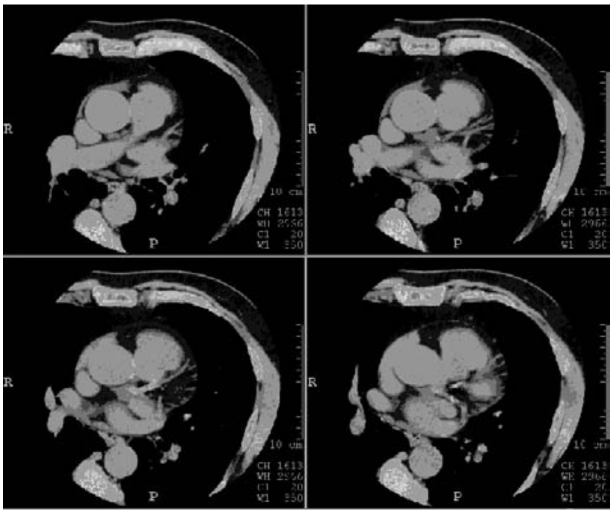

Figure 1. Example of coronary calcium scoring by MDCT. Axial mode with 120 KV, 140 mAs with 0.420 rotation. Detector collimation 8 x 3 mm. Slice thickness and increment 3x24 mm. No intravenous contrast

assessing bypass graft patency, and evaluating overall ventricular function and anatomy [41-56]. In particular, coronary calcium scoring has been useful in identifying atherosclerotic plaque and serves as a fair predictor of future adverse cardiac events [57,58].

Despite its utility, however, EBCT technology lacks the resolution to detect the degree of epicardial coronary artery stenosis, when compared to invasive diagnostic coronary angiography. The small luminal diameter of the coronary arteries and movement of the heart during the cardiac cycle render it difficult for both EBCT and conventional CT scanning to exactly display coronary arteries. While EBCT has sufficient temporal resolution to image the heart despite cardiac motion, it lacks the spatial resolution needed to detect lesions within the coronary artery lumen.

With the introduction of additional detector arrays and the resultant temporal and spatial resolution improvements, MDCT has both the temporal and spatial resolution to resolve anatomic detail within the epicardial coronary arteries. Acquisition of 16 slices simultaneously allows imaging of the heart in less than 30 seconds with 0.6 mm spatial resolution, and temporal resolution of 200 ms [59].

As technology has progressed rapidly from single slice to multislice scanners with 16 or more slices, there is a paucity of formal studies analyzing the utility of MDCT for effective coronary angiography. Even with the older 4-slice MDCT scanners, however, data regarding noninvasive coronary angiography has been optimistic. Recently published investigations demonstrate sensitivities between 83-85% and specificities between 76-90% for diagnosing significant coronary artery lesions [17, 60]. More importantly, perhaps, is that even with 4-slice MDCT imaging, the negative predictive value is exceptionally high when compared to the "gold standard" of invasive coronary angiography [46, 61, 62, 67]. With 16-slice MDCT imaging, the negative predictive value is 97%.

A recent meta-analysis of 25 published investigations on either EBCT or 16-slice MDCT showed 92% sensitivity for detecting significant stenosis, with a sensitivity and specificity of 83% and 85% for all vessels. [10] (Figure 2). Contemporary studies with higher slice MDCT are ongoing and are expected to vastly improve the accuracy of noninvasive coronary artery stenosis grading as well as the percent of assessable vessels.

It appears plausible that the advantage of new-generation MDCT imaging may lie not only in its absolute ability to quantify stenosis of coronary artery lesions but moreover, to characterize the type of lesion present. While much work has been performed in coronary MRA to distinguish vulnerable plaques (or those that present imminent risk to an individual for an acute coronary event) from stable ones, MDCT imaging perhaps possesses enhanced promise by its ability to identify "hard" (or calcified) versus "soft" (non-calcified or potentially "vulnerable") lesions (Figure 3). This capability of MDCT may render it superior to conventional invasive coronary angiography for detecting lesions that pose risk to an individual for untoward coronary events. Characterization of the type of epicardial coronary arterial lesion provides information that cannot be obtained by conventional angiography,

Figure 2. Example of coronary MDCT angiography. Helical mode with 1240 KV, 400 mAs with 0.420 rotation. Detector collimation 16x0.75 mm. Slice thickness and increment 0.8x0.4 mm. 100 cc intravenous iodinated contrast with 50 cc normal saline push.
A) 3D maximal intensity projection reconstruction demonstrating cardiac structure and coronary artery anatomy and course
B, C) Short axis volume-rendered image of aortic root demonstrating the takeoff of the left main and right coronary arteries
D) Volume-rendered image displaying trifurcation of the left main artery into the left anterior descending (LAD), ramus intermediate, and left circumflex arteries
E) Tracking of the LAD artery displayed as a linear structure with the proximal portion of the artery serving as a reference to the obstruction in the mid-section

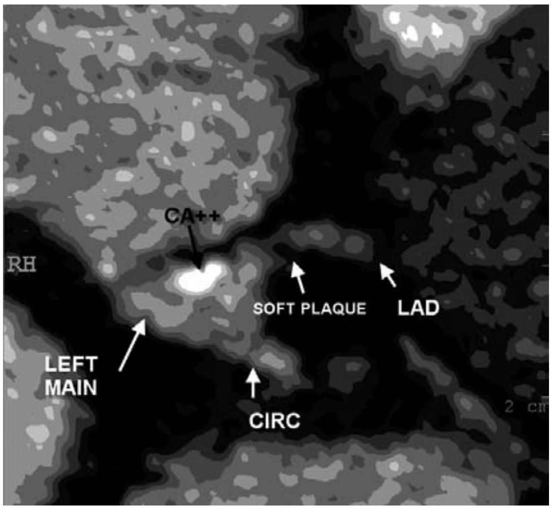

Figure 3. Example of "hard" and "soft" plaque. Comparison of the distal portion of the left main artery displaying bright signal calcium (__Hounsfield units) to the proximal LAD artery demonstrating soft plaque (__Hounsfield units)

and has preliminarily been demonstrated to identify patients as risk as well as to determine appropriate therapy [14, 63]. While further investigations need to be pursued, MDCT may provide valuable information for those who require prophylactic intervention before an event has occurred rather than therapeutic intervention after an acute coronary syndrome has already developed.

MDCT cardiac imaging has already been demonstrated to be invaluable in follow-up of bypass grafts and stent placements, anomalous coronary arteries, and coronary aneurysms [64-67] (Figure 4). In addition to the vascular data obtained, a single MDCT study is also useful for evaluating overall myocardial

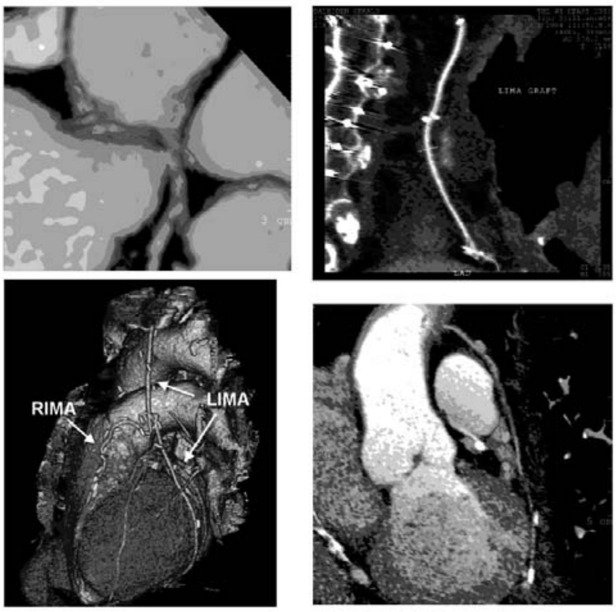

Figure 4. A) Volume-rendered image of aortic root in short axis revealing an anomalous origin of the right coronary artery in the left coronary cusp.
B) Sagittal section revealing a patent left internal mammary (LIMA) graft.
C) 3D maximal intensity projection reconstruction demonstrating a patent LIMA and right internal mammary artery graft.
D) Oblique section demonstrating a patent saphenous vein to left circumflex artery bypass graft

Figure 5. A) MDCT depiction of the left atrium. The right superior and inferior pulmonary veins are widely patent. No left superior pulmonary vein is seen. There is a significant stenosis in the left interior pulmonary vein.
B) Depiction of the left atrial appendage

function, identifying intra- and extra-cardiac masses, and detecting intracardiac thrombus [68-72] (Figure 5). Further studies with MDCT will be pursued to determine whether CT will serve as a useful modality for assessing myocardial perfusion in patients with stunned, hibernating, or nonviable myocardium.

Largely due to its recent introduction, it has yet to be determined exactly which patient population for which MDCT will be most useful. Certain proponents believe that MDCT finds its largest utility in imaging individuals with atypical chest pain or asymptomatic individuals at high risk, while others believe that MDCT should be used additionally for symptomatic individuals as well as individuals with established coronary heart disease who require follow up. Further investigations will clarify this issue.

Aorta and thoracic and abdominal vasculature

With MDCT, the ability to rapidly acquire the volume necessary for the entire thoracic and abdominal aorta is achieved with virtually isotropic resolution. Given the multitude of detector arrays, the aorta and its branches can be imaged quickly, with exquisite resolution, and in a single-breath hold [73-82]. MDCT angiography offers the ability to perform a swift, yet exceptionally comprehensive exam of individuals who

Figure 6. Examples of abdominal aortogram. Helical mode with 120 KV, 180 mAs with 0.50 rotation. Detector collimation 16x1.5 mm. Slice thickness and increment 5x5 mm. 4cc iodinated contrast intravenously injected per second
A) 3D MDCT angiogram of the abdominal aorta and bifurcation of the common iliac arteries revealing mild calcifications with significant obstruction.
B) 3D MDCT angiogram of the thoracic and abdominal aorta.
C) Volume-rendered image of distal abdominal aorta revealing a large abdominal aortic aneurysm with superimposed thrombosis

Figure 7. Example of aortic and lower extremity runoff MDCT angiography. Helical mode with 140 KV, 165 mAs with 0.50 rotation. Detector collimation 16x1.5 mm. Slice thickness and increment 5x5 mm. 4cc intravenous iodinated contrast injected per second.
A) 3D MDCT angiogram of distal abdominal aorta revealing abundant calcifications throughout without significant stenosis.
B, C) 3D MDCT angiogram of pelvic vasculature revealing significant left common femoral arterial stenosis.
D) Maximal intensity protection of distal lower extremity arterial runoff revealing normal three-vessel runoff on the right and significant signal void in the left distal lower extremity

present with signs, symptoms or hereditary risk factors suggestive of aortic pathology (Figure 6). MDCT is useful for the detection and longitudinal evaluation of aortic aneurysms as well as in post-operative follow up [79-83]. In patients with suspected aortic dissection, MDCT is able not only to accurately diagnosis ascending aortic or arch dissections (which had been previously difficult with conventional single-slice CT) but also descending thoracic or abdominal dissections (which is difficult with other imaging modalities such as transesophageal echocardiography) [84, 85]. Also, given its speed and scan range, MDCT may now considered the preferred imaging modality for the evaluation of traumatic aortic pathology [86].

Lower extremity run-offs

One of the most stirring areas of investigation in MDCT imaging is in the evaluation of lower extremity arterial disease. Historically, invasive peripheral angiograms with digital subtraction angiography (DSA) have been considered the "gold standard" imaging modality for evaluating individuals suspected of having significant peripheral arterial disease. Given the limited information imparted by the trans-axial slices of single-slice scanners, CT was not considered useful for evaluating lower extremity vasculature. However, after the advent of MDCT imaging, comprehensive evaluation of lower extremity arteries can be easily achieved by CT (Figure 7). It is now able to detect luminal stenoses as well as to quantify the extent of arterial calcification in a highly efficient manner with sub-millimeter resolution that results in near-isotropic resolution. Preliminary studies that employed MDCT imaging have demonstrated a high sensitivity and specificity of 91% and 92%, respectively, for detecting hemodynamically significant peripheral arterial plaques [87]. With newer generation MDCT scanners, physicians will soon be able to evaluate the extent of lower extremity arterial disease to determine the next step of therapy in a noninvasive manner. Studies comparing magnetic resonance angiography with MDCT angiography will reveal which noninvasive imaging modality is most efficient and cost effective.

Renal

The field of renal vascular and parenchymal imaging has been similarly bolstered by the introduction of MDCT imaging. Single-slice CT scanners had previously encountered difficulty in accurately imaging renal arteries because of both technical and anatomic issues. The single-slice CT scanners lacked the ability to procure the necessary volume of information as the slices obtained were too thick. Moreover, as the renal arteries are often oriented obliquely (or even parallel) to a single tomographic plane, it was difficult for single-slice CT scanners to detect renal artery stenoses accurately. The introduction of the new generation MDCT scanners has largely solved this problem, tendering rapid scan acquisition times without

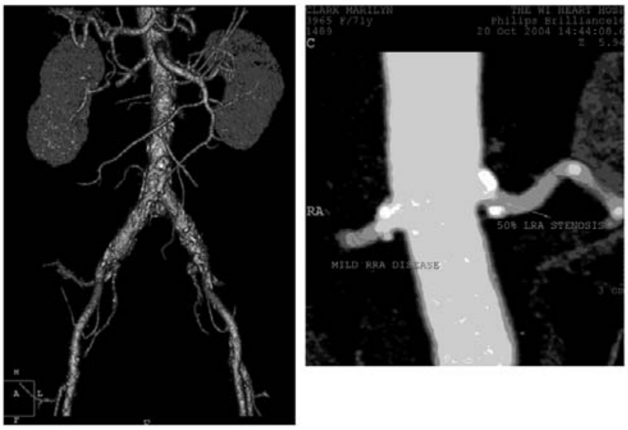

Figure 8. Example of renal MDCT angiography. Helical mode with 140 KV, 165 mAs with 0.50 rotation. Detector collimation 16x1.5 mm. Slice thickness and increment 3x3 mm. 4cc intravenous iodinated contrast injected per second.
A) 3D maximal intensity protection revealing left and right renal arteries
B) Volume rendered imaging of left and right renal artery revealing calcium at both ostia and a mild stenosis of the left renal artery

volume procurement compromise, sub-millimeter spatial resolution with diminution of artifacts (Figure 8). Accordingly, MDCT, in a more efficient manner, provides excellent z-axis resolution with near isotropic imaging. MDCT is useful for preoperative evaluation of potential living-related kidney donors [88-90]. MDCT is also valuable for the detection of hemodynamically significant renal artery stenosis. In one recent study, the utility of MDCT was borne out by its ability to detect hemodynamically significant stenosis in the renal arteries with 96% sensitivity and 99% specificity [91]. This noninvasive ability to detect significant stenoses allows appropriate planning for percutaneous and/or surgical intervention. Once the intervention has occurred, MDCT can be helpful in the follow up of individuals who have undergone renal artery stenting. MDCT offers enhanced diagnostic benefit over invasive renal angiography by often providing important information not only on renal vasculature but also on renal parenchyma regarding size and masses.

Limitations

As with many new technologies, while the introduction of new generation MDCT scanners heralds limitless potential, it begets certain obstacles as well. Along with the promise of obtaining near isotropic volumetric imaging comes the dilemma of how to resourcefully archive and reconstruct this data [92]. The amount of data that is acquired through MDCT imaging has historically not been encountered. This issue will only be intensified with the ever increasing numbers of detector arrays available on MDCT scanners. The solution to this complex issue will likely encompass a combination of novel algorithms for data transfer, data archiving, and image interpretation. The solution, as is the MDCT technology which dictates its necessity, will likely be evolutionary.

Concern also exists that the increase in volume of information acquired by MDCT imaging is at the expense of increased radiation exposure to the patient. The degree of radiation exposure is similar to that of conventional invasive angiography and greater than conventional single-slice CT scans [93-96]. While novel approaches are being continually developed to diminish overall radiation exposure, for the time being, the tradeoff between improved z-axis resolution and increased radiation dose should be evaluated.

Currently, the need for iodinated contrast for effective vascular MDCT imaging may exclude certain individuals from its potential utility. This concern is similar to that of conventional invasive angiography. While some prophylatctic treatment strategies for prevention of contrast-induced nephropathy have been promising (e.g., N-acetylcysteine or sodium bicarbonate), the physician will need consider the benefit-to-risk ratio when imaging such at risk individuals [97,98].

Conclusion

Despite these present day challenges facing MDCT imaging, the opportunities offered by this modality for the noninvasive diagnosis and surveillance of cardiac and vascular anatomy and pathologies are enormous. MDCT provides the advantage of shorter scan duration without compromise of overall scan range or section collimation. This invariably translates into fewer motion artifacts and near isotropic imaging, resulting in the visualization of arbitrary imaging planes with multi-planar reconstruction in three dimensions. The ongoing efforts to: optimize acquisition and storage of data, reduce patient radiation exposure, develop effective contrast agents which are non-nephrotoxic, and create software tools offering more accurate and novel diagnostic abilities are actively being pursued. Moreover, clinical investigations using new-generation MDCT scanners in cardiac and vascular imaging will likely bear out the promise that has been suggested in studies with older-generation MDCT scanners. MDCT is an exciting development with emerging applications in the arena of cardiovascular diagnostic imaging.

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Information and Communication Technologies in Interventional Cardiology and Radiology

D.G. Iosseliani, E.P. Velikhov, V.G. Gnedenko, E.M. Fainberg[1]
Moscow City Center of Interventional Cardioangiology,
Russian Scientific Center "Kurchatov Institute", Moscow, Russian Federation

Introduction

The development and introduction into the medical practice of modern information and communication technologies aimed at the automation and improvement of quality of diagnostics and treatment of cardiovascular diseases is an actual problem attracting special attention worldwide including Russia.

One of the basic directions of medical technologies automation consists in the creation of electronic case histories. Convenience and overall effectiveness of work with electronic case histories were already experienced by the physicians from many countries.

The last 20 years were marked by a prevalence of surgical and endovascular methods of cardiovascular diseases treatment. By now PTCA and stenting of coronary arteries, as well as coronary artery bypass grafting (CABG), became the leading methods of treatment of ischemic heart cardiac disease. Over 2 million angiographic procedures and interventions are performed in the world every year, which became widely used and now are the alternative to open heart surgery.

Mass application of angiographic procedures determines the expediency and, in many cases, the necessity of automation of diagnostic and treatment processes for the interventional cardioangiology. The distinctive feature of those processes consists in the necessity to have a possibility to process, to analyze and to store large volumes of video data in order to make the correct diagnosis, to choose the optimum strategy and tactics of treatment. It is also very important for the physicians to have a timely access to the results of all previous diagnostic and treatment procedures, including angiographic ones, to be able to perform a prompt, adequate and dynamic assessment of their efficiency and to determine the current state of patients.

The increase of the number of people affected by cardiovascular diseases or interested to pass regular examinations allowing for the evaluation of their cardiovascular state, urges the creation of a potent cardiological service. The arrangement of such service includes both the hospitals where the diversified medical care, including operational interventions, can be rendered and a wide network of polyclinics and other institutions, situated rather wide apart. Creation of an uniform information network, in which all institutions of the cardiological service could work, will allow for a significant improvement of medical care for the patients, will reduce the duration of diagnostic and treatment processes, will lower the expenses for the whole medical technological process. In order to create such information network it is necessary to solve a number of tasks:

- Development of electronic case histories both for hospitals and for the institutions of outpatient service.
- Transition of medical institutions to the technology of processing and storage of electronic case histories in a database.
- System engineering of the automated classification and coding of the information, which provides the opportunity to work with a uniform standard normative base to medical staff of different institutions .
- Besides the case histories, the results of all examinations of the patient, including diagnostic images and videotapes (angiographic images) should be stored in a digital database.
- The medical institutions must be connected through a high-speed (for example, fiber-optical) communication lines.
- Creation of a uniform database for hospitals and institutions of outpatient care to provide a prompt exchange of data about a patient and about all the studies performed irrespective of the clinic where they have been made.

Systems for automation of processes of picture acquisition, analysis and archiving (PACS - Picture Archiving and Communication Systems)

As for the present, the effective solution of the tasks of automation of processes of picture acquisition, analysis and archiving consists in the development of such systems as PACS (Picture Archiving and Communication Systems). The basic purpose of these systems is the acquisition, digitization, transfer, visualization, mathematical processing and storage of medical images.

The experience with the use of PACS systems confirms their obvious advantages in comparison with the traditional film and/or paper technology of work with images. Listed below are only some of these advantages:

- Acquisition of images in digital form allows to spare materials and the time spent on film development.

[1] Evgueny M. Fainberg,
Russia,123182 г. Moscow, Kurchatov square, 1
Phone: 007 095 196 98 69
Fax: 007 095 196 81 11
e-mail: fainberg.evg@ivtem.kiae.ru
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- Archives of digital data allow to quickly find the necessary images, are not space-consuming, provide the safety and the duplication of the information.
- The computer graphics and mathematical processing of digital images used in PACS systems increase manifold the information capacity of the diagnostic data, provide an essentially new level of quality of the medical care rendered.
- Images in PACS systems are always accessible to the physicians, allow to come back repeatedly to previous studies and to re-analyze them, thus frequently reducing the necessity to perform the repeated studies, which in turn reduces the exposure dose and other harmful side effects on patients and the medical staff.
- Use of data transmission networks allows for quickly transfer of the images and the accompanying information simultaneously to several users in different places in the world. It gives a unique opportunity for experience exchange and carrying out of consultations.
- Ample opportunities for carrying out of research works on the basis of statistical analysis of the information accumulated in a database during clinical work.

Some clinics effectively utilizing PACS systems (according to press information) are listed below:

- Hospital Lourdes (Paducah, Kentucky, USA) — a hospital designed for 210 beds and serving a district with 400,000 population.
- Hospital Wilson (Sidney, Ohio, USA) — a hospital designed for 112 beds and performing about 43,000 of diagnostic and medical procedures annually.
- Hospital Presbyterian (Dallas, Texas, USA) — incorporates 4 computer radiological plants, 2 plants for carrying out of ultrasonic examinations, 2 angiographic units and 2 nuclear tomographs.
- Medical center Palmetto (Columbia, South Carolina, USA) — includes a network connecting six medical institutions, two of which (Palmetto Baptist Medical Center (PBMC) and Palmetto Richland Memorial Hospital (PRMH) have started to implement PACS systems.
- Medical center Beth Israel Deaconess (Boston, Massachusetts, USA) — the nuclear medicine department of the Israeli medical center designed for 500 beds and serving as the main clinical base of Harvard medical school.
- Hospital Chestnut Hill (Philadelphia, Pennsylvania, USA) — designed for 200 beds, treating about 90,000 patients annually.

The analysis of practical implementation of PACS systems suggests their obvious efficiency for the solution of tasks of acquisition, digitizing, visualization and analysis of images. However, the necessity of complex automation of all medical diagnostic processes, including — registration of patients; creation and maintenance of electronic case histories; presence of the uniform normative base and the automated system of classification and coding of the medical information; acquisition and processing of the diagnostic data and its interconnecting; formation of output documents; carrying out of statistical researches; input, transfer, storage, processing and display of the video information (angiographic images, x-ray images, etc.) —, substantially changes the principles of systems engineering for automation of diagnostic and treatment processes in interventional cardioangiology.

System of complex automation of diagnostic and treatment processes in interventional cardioangiology ("DIMOL-IC")

The Russian Scientific Center "Kurchatov Institute" (RSC "KI") and Moscow City Center of Interventional Cardioangiology (CIC) have developed and in 2000 implemented the first domestic system of complex automation of diagnostic and treatment processes for the clinic of interventional cardioangiology — "DIMOL-IC" complex. In 2003 DIMOL-CDO complex intended for automation of work in the outpatient services was introduced into the medical practice.

Arrangement and principles of the DIMOL-IC functioning

Described below are the arrangement and the principles of the above system functioning (Fig.1). The system consists of workstations (PC) installed in different rooms all around the clinic and connected with the help of network hardware into a uniform hard- and software system. The server provides operation of DIMOL database and processing of information inquiries for network users. "Angiography" PC uses the archive of dynamic images for storage and operative distribution of the video data received during interventional procedures. Functional workstations are intended for automation of different physicians' activities. It is possible to work on these PCs with a complete case history, angiographic films and images. It is also possible to analyze and process the dynamic images, to prepare medical reports based on the results of angiographic and other examinations and procedures. The clinic may have several catheterization laboratories (cath. labs), where angiographic procedures and interventions can be performed all at once. In such case the number of "Angiography" PCs

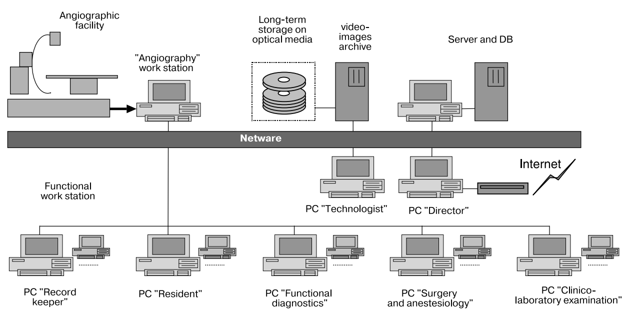

Figure 1. "DIMOL-IC" functional block diagram

should correspond to the number of cath. labs. "AKSh" PC was developed for cath. labs and operating rooms, in which vascular procedures and/or CABG operations are performed.

"Director" PC is installed on a workplace of the head of a clinic. "Director" PC possesses the capacities of any other functional PC and has the access to administrative subsystems of DIMOL. The most important feature of this PC is that it provides the clinic director to observe the angiographic procedures "online" and to cooperate with the surgical team in a videoconference mode without leaving his office.

"Technologist" PC represents a workplace of DIMOL administrator. The system has printers for preparation of hard copies of case histories, including the most informative diagnostic images. "DIMOL-IC" system can use the Internet for information exchange and consultations of cardiologists from all over the world.

All workstations of the system are built on the basis of IBM-compatible personal computers incorporated into a local network with 100 MBPS bandwidth.

The total number of workstations in the hospital and outpatient services makes about 100. The central control system is built on the basis of two fat servers. Two Raid-controllers on each server are connected to an appropriate rack of the Raid-arrays intended for archiving of all medical and general information. The archives built on the basis of Raid-arrays have the capacity of about 1000 Gb. CD-RWs and additional hard drives are used for long-term archiving. For recording of angiographic information the "Angiography" workstations are completed with videoblasters. The complex includes three "Angiography" PCs in total, which can work with the devices with both analog and digital outputs. The general system software is Windows 2000 Advanced Server for servers and Windows 2000 Professional for workstations. The applied software is written using Sybase products and C ++ programming language.

"Angiography" workstation

"Angiography" PC works in two basic modes: "on-line" and "off-line". In "on-line" mode it is possible to observe on the PC monitor the "live" image coming to the PC from the cath.lab. This mode is used during PC configuration, angiographic images are compressed and recorded on a hard disk and the films are reviewed during monitoring and recording. For viewing and analyzing the previously recorded angiographic tapes on the PC, it is possible to enter the data into the system from the videorecorder.

The following is performed in the "off-line" mode:

– Video viewing using the videoblaster, both during data input and output — viewing of digitized video recorded on the PC hard disk.
– Cyclic reviewing with adjustable speed down to a manual step-by-step mode.
– Viewing a consecutive set of frames in the multi-image mode.
– Simultaneous reviewing on the monitor of 2 and more frames from different angiographic films.
– Hardware and software decompression of films.
– Mathematical processing of angiographic films.

The following basic algorithms are realized in "Angiography" PC:

– Quantitative measurements on individual frames, their contrast adjusting and edge enhancement.
– Subtraction (various variants) of an angiographic film.
– Calculations necessary to determine the amount of narrowing of coronary vessels.
– Ventriculographic examinations necessary for left ventricular function assessment, calculation of total and segmental ejection fraction.

There are general and special processing methods and algorithms. The following are the general purpose algorithms:

– Calculation of the area inside the closed contour on the image.
– Calculation of coordinates of the centre of gravity of the given area on the image.
– Plotting of a histogram of contrasts in the specified area.
– Image contrast enhancement and smoothing of a brightness image.
– Edge enhancement.
– Smoothing of contours and calculation of curvature.

Special purpose algorithms realized in "Angiography" PC:

– Subtraction.
– Outlining of coronary vessels, enhancement and calculation of stenotic vessel areas.
– Definition of the left ventricle volume in various phases of the cardiac cycle and ejection fraction, both total and segmental.
– Calculation of the area enclosed inside the closed contour on the image.
– Calculation of coordinates of the centre of gravity of the given area on the image.
– Plotting of a histogram of photographic densities in the specified area.
– Image contrast enhancement, etc.

The videodata coming to "Angiography" PC input are digitized, compressed and recorded on a hard disk. After the recording session is complete the PC automatically switches to the mode of data conversion. The data is transformed to the usual 8-bit format. Thus the information is compressed approximately by 3 times in comparison with the initial volume of angiographic films and recorded in a local PC archive. Now it is possible to work with the received data, make all necessary calculations, to write in the operations log, the surgical protocol and the report. At any moment the data can be sent from the local archive to the global one. During the transfer, which is performed practically without a loss of quality, the information is additionally compressed again approximately by 7 — 8 times. As soon as the data is recorded in the global

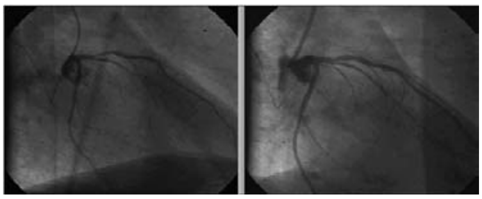

Figure 2. Right interventricular branch before (left) and after (right) the angioplasty

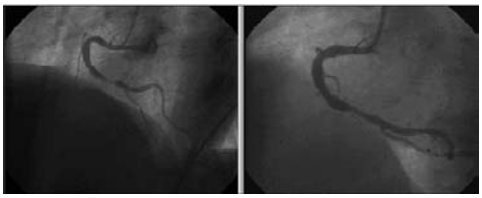

Figure 3. Right subclavian artery before (left) and after (right) PTCA

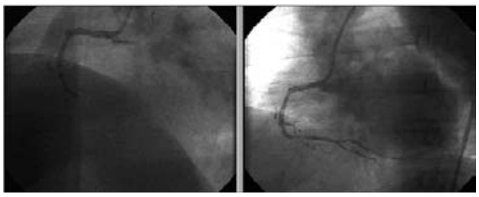

Figure 4. Right subclavian artery before (left) and after (right) mechanical recanalization

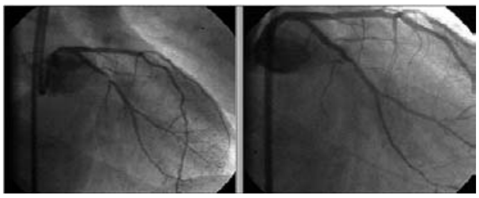

Figure 5. Left subclavian artery before (left) and after (right) PTCA

Figure 6. Proximal right interventricular branch before (left) and after (right) PTCA

archive, it becomes accessible to any workstation of the system. For this purpose it is necessary for the user to recall from the global archive the necessary angiographic films. Additional decompression of the information is not required. Transfer of one film from the global archive to the local one on a physician's workstation takes about 1-2 seconds. The physicians can, without interfering in the work of a surgical team, conduct on their workstations the analysis of angiographic data, fill in all necessary medical documents. The medical report prepared on the base of the results of angiographic examinations is automatically included into the electronic case history and the corresponding section of the medical record. Fig. 2-11 shows the examples of angiographic frames received using "DIMOL-IC" during angiographic procedures for real clinical patients and the results of their subsequent mathematical processing.

Figure 7. The form for preparation of medical reports by the ventriculography results

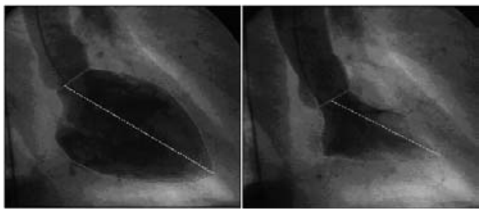

Figure 8. Outlining of the diastole (left) and the systole (right)

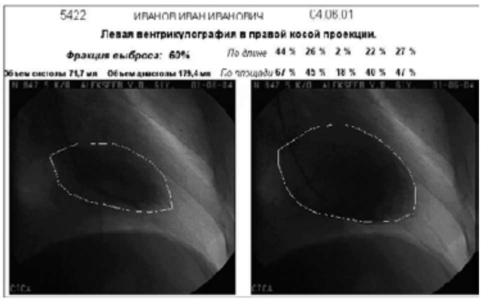

Figure 9. Systolic (left) and diastolic contours (right) and results of ventricular calculations

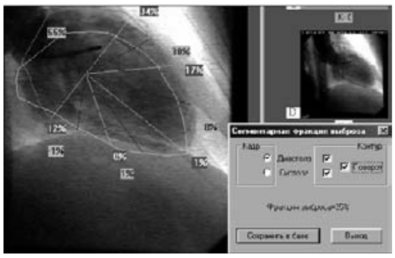

Figure 10. Quantitative ventriculography: calculation of ejection fraction and segmental characteristics

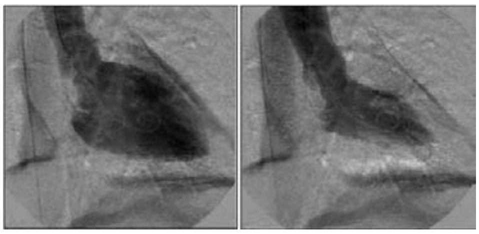

Figure 11. Images of the diastole (left) and systole (right), received

Archiving system

The archiving system of "DIMOL-IC" is built on the hierarchical principle. Each workstation possesses a local data archive necessary for current physician's work. The current archive comprises all registration and medical data (including angiographic films) for the last several years. The current archive allows to receive, practically in no time, at any moment all necessary information on any patient treated in the hospital within the last several years. The long-time archive provides reliability of the whole archiving system by duplication of the data of the current archive on optical media. The data deleted from the current archive are also stored in the long-term archive.

The archiving system plays a major role in the information support of the clinical work. At the admission of a patient with acute complications of cardiovascular disease, just few minutes are left to the physician to adopt the only correct decision on a method and tactics of treatment. If the patient was previously treated in a hospital equipped with the electronic archiving system, then his data are in the global archive. Their search and acquisition will take only few minutes or even seconds. With this the physician receives at once the systematized and generalized information, sees the data of all previous functional examinations, can evaluate the real cardiovascular state during previous hospital stay. It is of utmost importance, that the physician can review the angiographic films for detailed evaluation of heart performance and the state of vessels. Only after the results stored in the archive are analyzed, the physician can choose the optimum mode of further examinations. If necessary, it is possible to return to the analysis of previously made angiographic films.

The advantage of the electronic archiving system is that it allows to perform the researches on the basis of a rich factual material. While in the past it took many months to find and select the necessary data, now one can do it in less than an hour. And the availability of the dynamic angiographic data in the archive contributes to the uniqueness of these scientific researches.

The technology of digital archiving realized in "DIMOL-IC", together with the workstations located in various offices and rooms of the clinic, allows for the conduction of repeated and detailed on-line analysis and processing of the received angiographic data. Due to the parallel work of the surgical team and the physicians analyzing the results of examinations, as well as to a sharp decrease of the time spent for the search and analysis of required information, the patient capacity of the clinic and the effectiveness of costly angiographic equipment is considerably increased. Other PACS systems, in distinction from "DIMOL-IC", are designed only for input of static images, thus, the most important information on dynamics of the patient's cardiovascular system functioning is irrevocably lost.

System of classification and coding of the medical information

The main difference of "DIMOL-IC" from the majority of other PACS systems consists in the developed system of classification and coding of the medical information, including the set of qualifiers of diagnoses, medical reports by the results of basic diagnostic procedures, pharmacotherapy, clinico-laboratory analyses, etc.:

1. Studies (catheterization).
2. Procedures (catheterization).
3. Interventions (catheterization).
4. Complications (catheterization).
5. Diagnoses (directional, basic, surgical).
6. Pharmacological agents (surgery and anesthesiology).
7. Procedures and surgical interventions (surgery and anesthesiology).
8. Duplex scanning of vessels.
9. Clinico-laboratory researches.
10. Drugs.
11. Referral to clinico-laboratory researches.
12. Complications.
13. ECG monitoring.
14. 12-lead ECG.
15. Veloergometry.
16. Ergonovine test .
17. EchoCG.

The normative base of the qualifiers is prepared using unified international classification, official documents issued in Russia and the experience of skilled Russian cardiologists.

Due to the introduction of a system of classification and coding, the physician prepares medical reports by choosing a variant from the tree of conjugate alternatives. Such technology of work provides the unity of normative base used by the physicians and correctness of information input. The system for information search included in "DIMOL-IC" allows to find in few seconds any ranked data on the examinations performed for the last five and more years. Thus, the physicians have the possibility to perform unique scientific researches on the basis of the material actually stored in a digital archive. According to available information, such rich opportunities are not offered by any another PACS system.

Results of "DIMOL-IC" use

During the period of use of "DIMOL-IC" system, about 20,000 patients suffering from cardiovascular diseases were hospitalized in the Moscow City Center of Interventional Cardioangiology. The number of wrong diagnoses was minimized to only single instances. The mortality form myocardial infarction makes about 4-5 % with Moscow the average value of 16-18%. The number of catheterization procedures has increased up to 4000/year, and during the last year 1500 PTCA and stenting procedures were performed. The "DIMOL-IC"'s archive allows for on-line access to the information on all patients treated in the Center during the last 5 years. This information includes complete case histories, diagnostic images and angiographic films. It means that the physicians can receive any patients' data for any given period of time within few seconds.

Principles of telemedicine systems

development for cardiology

In the majority of the countries of the world including Russia, the system of heath service was built on a hierarchical principle. Such system can be presented as a tree, with the patient initially standing at its roots, and, as the diagnosis is made and depending on the complexity of a case, he moves upwards, getting on this or that branch, corresponding to specialized medical institutions of a corresponding profile. AS a result the medical data on the patient appears distributed between several medical institutions.

At the same time, in order to make a correct diagnosis and define the optimal tactics and strategy of treatment, the physicians must have a possibility to access to all available data on the patient — the results of analyses, diagnostic researches and medical procedures, medical reports, etc. It is also important to the physician to have a possibility to consult the experts from other medical institutions. For this reason the hospitals all around the world are badly in need of the systems providing an possibility of various medical information exchange.

At present the solution of this challenging problem is connected with development of telemedicine considered to be the most promising trend. This conclusion proves to be true by the analysis of literature. However, the telemedical systems can function effectively only in clinics, where the whole amount of diagnostic and treatment information is digitized and stored in electronic data archives and, thus, is accessible and suitable for transmission over telecommunication channels. Development of digital information technologies will inevitably result in creation of a territorially distributed network of hospitals able to exchange the data on diagnostics and treatment. Creation of such networks is now possible both by territorial (district, city, area) principle.

Development of a telemedical system for cardiology appears to be interesting. While exchanging with the data, the physicians will be able to develop together optimal strategy and tactics of treatment, to determine the need for various operations, to plan their place and time. It will allow to reduce essentially the duration of diagnostics and treatment, to increase clinics capacity, will result in the overall improvement of professional skills and the level of service of the population.

Taking into account the world experience with PACS systems application and also the positive experience with the use of "DIMOL-IC" system consisting in essential increase of efficiency and quality of treatment and patient capacity, it is possible to recommend implementation of the developed system the for creation of telemedical systems in medical institutions (fig. 12).

The current level of development of communication facilities can provide the a necessary data transfer rate (about 10 Mbps) between the hospitals. Such rate will for the allow exchange of the data of any format, including dynamic video information, which is necessary for diagnostics and treatment of cardiovascular diseases. The existing and well-mastered fiber-optical lines can be used as a communication tool between the clinics. The combination of fiber-optical and coaxial cables, as well as the "twisted pair", are usually used inside one clinic. However often it can

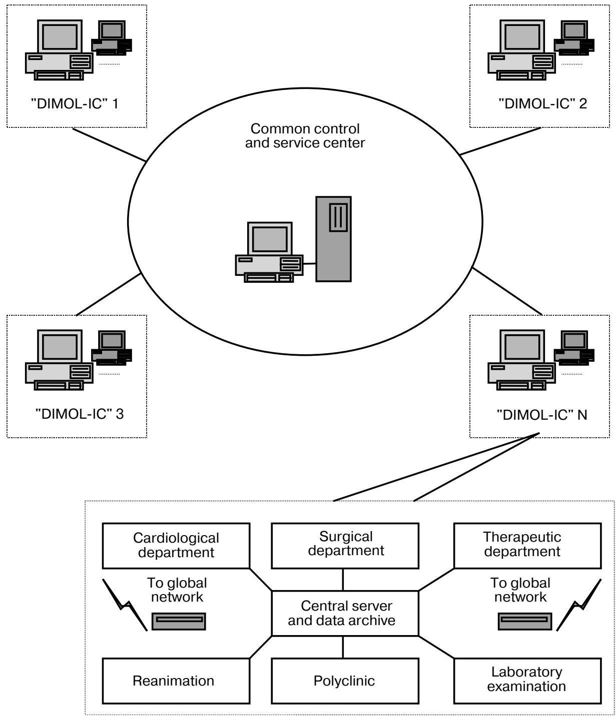

Figure 12. Unified network of systems for automation of diagnostic and treatment processes in interventional cardioangiology

be difficult to lay the wires in a hospital. The modern technology offers new kinds of communication — wireless radio-modem channels. Wireless bridges are especially effective, if the clinical buildings are situated at a great distances from each other.

Development of a network of cardiological clinics will provide availability of all the stored data about a patient and will allow to perform on-line diagnostics, consultations and choice of an optimum strategy and the tactics of treatment, irrespective of how far is the reference medical institution situated.

Another important field of telemedicine application consists in the development of a system of medical staff training on the basis of the leading hospitals of a city, a branch or the whole country. The first experiments are already being carried out in this direction. Equipping of the leading hospitals with the modern automated information and measurement systems, such as "DIMOL-IC", will allow to expand essentially the possibilities of these training systems, will help to increase their efficiency.

The first unified territorially allocated information system in Russia is being developed under the auspices of the Government of Moscow, the Moscow committee of science and technologies on the basis of Moscow Coty Center of Interventional Cardioangiology.

This Center comprises a hospital and a consultative and diagnostic department situated in the Central administrative district; an out-patient service situated in the Western administrative district; and the rehabilitation department situated in Bykovo (Moscow region).

Association of all Center's departments into one information space, enabling the physicians to work with the unified normative base of medical knowledge, the use of the results of examinations performed in any department within the last 5-10 years, including angiographic films, radiologic and tomographic images, laboratory and clinical research data, etc., — all this will allow for a significant increase of the treatment quality, of patient capacity without creation of new beds, will raise the efficiency and will reduce the cost of treatment.

Fig. 13 presents the block schematic diagram of Moscow City Center of Interventional Cardio-angiology unified information system being developed now on the basis of DIMOL-IC automated hardware-software system. The fiber-optic line (fig. 13) bridges the Center's services situated at a big distances from each other. DIMOL-IC system is being installed in the hospital, the consultative and diagnostic department and in the out-patient service. All researches are recorded into the digital database, which can be accessed from any workplace. So, the physicians from the consultative and diagnostic department can familiarize with the details of angiographic interventions, vascular or CABG operations, performed in the Center. Results of radiological, tomographic and other researches, which were performed during patient's stay in the hospital, also are accessible. On the other hand, when a patient previously followed in the consultative and diagnostic department or the out-patient service is admitted to the hospital, all his/her registration and medical data automatically enter the electronic case history of the hospital. The physicians get rid of the great volume of work for those data duplication, for repeated expensive diagnostic procedures. The time spent on routine operations is reduced; the physicians can concentrate on choosing the optimum tactics and strategy of treatment. As a consequence, the general unbiased indices of the clinical work increase significantly. Maintenance of electronic case histories and electronic patient medical records is performed using the automated system of medical information classification and coding. The information retrieval system, being a part of DIMOL-IC system, allows to receive in few seconds the statistical information on any medical inquiry, to estimate the efficiency of a particular method, a drug or a procedure, used for patient's treatment in the clinic.

An integrated information and communication system can be built for medical institutions of Moscow on the basis of "DIMOL" technology. It would be reasonable to utilize the experience of RSC "Kurchatov Institute" and Moscow City Center of Interventional Cardioangiology for the improvement of such system. The principle of such system development is present-

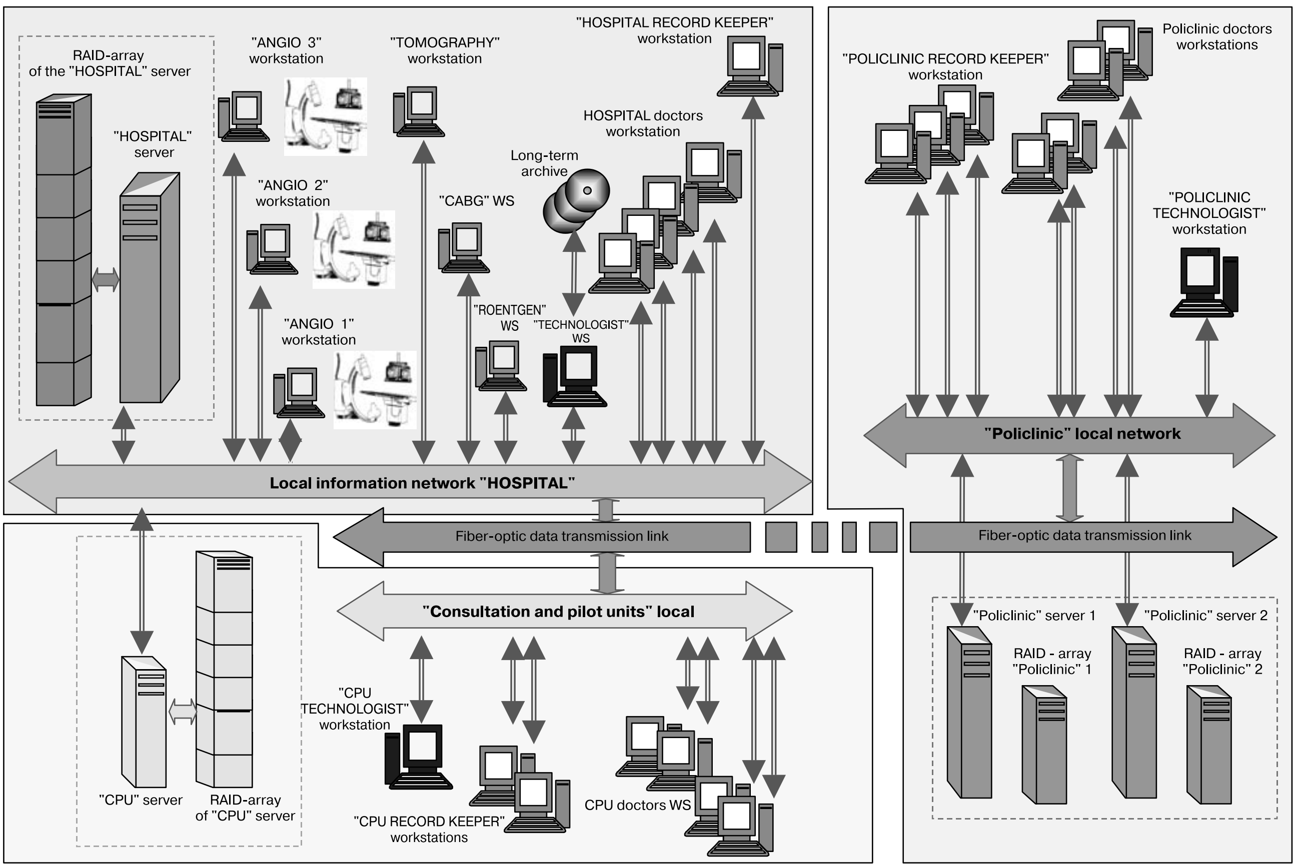

Figure 13. Territorial distribution of information system in the Moscow City Center of Interventional Cardioangiology

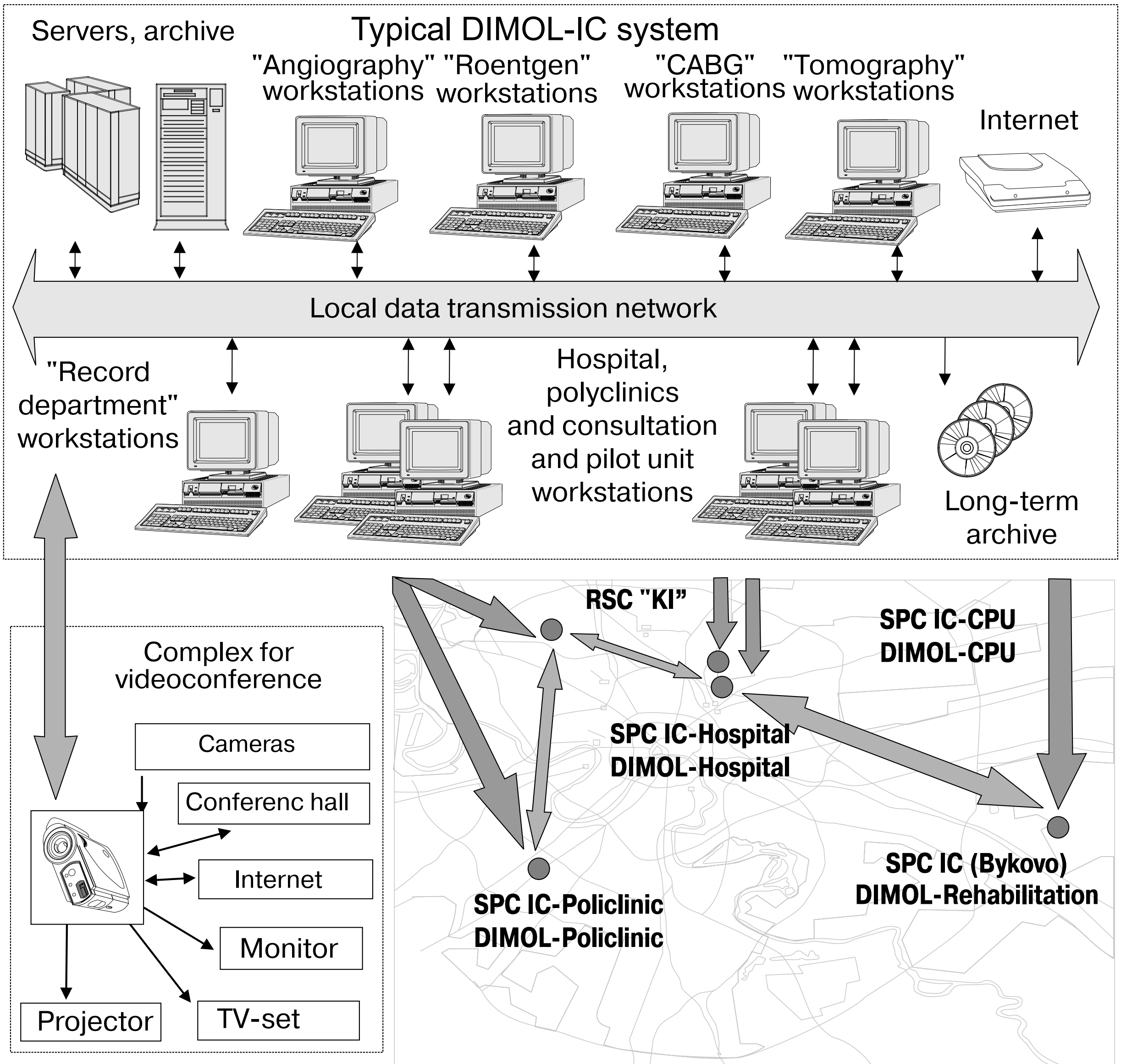

Figure 14. Integrated information and communication system for medical institutions of Moscow

ed on Fig.14 on example of the Center of Interventional Cardioangiology.

The unified complex system includes both the hardware and software developers and various clinics of the city. Such approach will allow for on-line improvement of the software, for the repair and service of tools for medical technologies automation. The implementation of an integrated information and communication system within the frame of the Moscow Department of Healthcare will allow for significant improvement of the health service rendered to the population, for substantial strengthening of the control of medical institutions and for the optimization of their structure. This opens the prospect for an essentially new approach to the application of information technologies for the needs of telemedicine, for association of large medical institutions' efforts on the rendering of emergency medical care, consulting services on the basis of the analysis of a complete set of the examinations and procedures performed. Fig.14 shows the distribution of the Center of Interventional Cardioangiology and RSC "Kurchatov Institute" departments on the city map. The scheme of a standard DIMOL system and of a functional structure of the system used for videoconferences is also presented below.

It can bee seen from Fig. 14, that the videoconference modes can include the data exchange from the database of medical institutions, broadcasting from operating rooms, collective discussions of thrilling medical problems, solution of any questions connected to diagnostics and treatment of patients in on-line or off-line modes.

Conclusion

The experience gained during the development and the use of "DIMOL-IC" system can be applied in many medical institutions of the Russian Federation, as well as in various European and American clinics. On the basis of the developed technologies we suggest to equip the medical institutions with the "DIMOL-IC" system and to link them into an unified territorially allocated distributed computer network providing data exchange of electronic case histories, diagnostic data, including images and video information. It will allow to create a unified electronic bank of text, graphic and video information, to use modern information technologies of analysis and processing of the angiographic data, to considerably increase the clinics capacity, and also to increase efficiency and quality of diagnostics and treatment.

The Second Russian Congress of Interventional Cardioangiology (Information Statement)

S.P. Semitko, A.V. Arablinsky[1]

– Secretaries of the Scientific Society of Interventional Cardioangiology

The Second Russian Congress of Interventional Cardioangiology held in Moscow on March 28-30 has finished its work. The agenda of the Congress included Sectional Sessions discussing all main scientific trends in modern interventional cardiology and angiology. Each meeting was preceded by a Plenary Session with survey reports of leading specialists and acknowledged authorities in the field. In their reports, the participants of the Congress summed up the results of their scientific and research activities demonstrating a considerable increase of scientific and practical potential during three years after the previous congress. Notwithstanding that the priorities of the Congress were the matters of invasive cardiology, a number of Sectional Sessions and Satellite Symposia were dedicated to current problems of oncology, neuroradiology, obstetrics and gynaecology, hepatology and nephrology.

Over 800 specialists have participated in the 2nd Congress of the Russian Society of Interventional Cardioangiology. The scientific program of the forum included 134 reports from over 50 cities of the Russian Federation and other countries. Table 1 presents the

Alma-Aty, Kazakhstan	A. N. Syzganov Scientific Centre of Surgery
Almetyevsk	
Archangelsk	Municipal Institution "First Municipal Clinical Hospital"
Barnaul	
Belgorod	
Blagoveschensk	
Vladimir	Vladimir Regional Clinical Hospital
Volgograd	Volgograd Regional Cardiologic Center
Voronezh	Voronezh Regional Clinical Hospital
Yekaterinburg	Novaya Bol'nitsa [New Hospital] Medical Institution
Izhevsk	Cardiologic Clinical Dispensary
Irkutsk	
Kazan	Children's Clinical Hospital
Kaliningrad	Kaliningrad Regional Clinical Hospital
Kemerovo	
Krasnodar	Centre of Thoracal Surgery
Krasnoyarsk	Cardiosurgical Centre
Lipetsk	
Magnitogorsk	
Makhachkala	
Moscow	Moscow City Center of Interventional Cardioangiology Center of Endosurgery and Lithotripsy Russian Research and Practical Cardiologic Complex Burdenko Central Military Clinical Hospital Scientific Research Institute of Transplantology and Artificial Organs N. N. Blokhin Russian Oncologic Scientific Center of the Russian Academy of Medical Sciences N. V. Sklifossovsky Emergency Research Institute Sechenov Moscow Medical Academy Municipal Clinical Hospital No. 15 Federal Roentgenosurgery Center Research and Practical Center of Radiology Central Clinical Hospital of the Federal Security Service of the RF United Hospital of Administration of the President Affairs of the RF Russian Scientific Center of Surgery of Russian Academy of Medical Sciences Scientific Research Institute of Pediatry and Pediatric Surgery A. V. Vishnevsky Institute of Surgery Vishnevsky Central Military Clinical Hospital A. N. Bakoulev Scientific Center for Cardiovascular Surgery of Russian Academy of Medical Sciences
Murmansk	
Nizhniy Novgorod	Nizhny Novgorod Center of Cardiac Surgery
Nizhniy Tagil	
Novosibirsk	Clinical Cardiologic Dispensary
Obninsk	
Odintsovo	Hospital of Rocket Troops
Omsk	
Oryol	
Orenburg	Orenburg Clinical Hospital
Pavlov	
Penza	
Perm	Municipal Clinical Hospital No. 4
Pskov	
Ryazan	Clinical Cardiologic Dispensary
Samara	Clinical Hospital
Saratov	
Sarov	
Saint Petersburg	
Solnechnogorsk	
Stavropol	
Syktyvkar	Cardiologic Dispensary
Tomsk	Tomsk Research Institute of Cardiology
Tyumen	Tyumen Cardiologic Centre
Ulyanovsk	Ulyanovsk Clinical Hospital
Ufa	Cardiologic Dispensary
Khabarovsk	S. I. Sergeyev Clinical Hospital No. 1
Khanty-Mansiysk	Clinical Hospital
Tcherepovets	
Chita	
Yakutsk	

[1] Russia, 101000, Moscow, Sverchkov per., 5.
Moscow City Center of Interventional Cardioangiology
(for the Secretary of the Society)
Phone.: (7-095) 924-96-36, 924-47-18
Fax: (7-095) 924-67-33
e-mail: info@noik.ru

cities of Russia and hospitals and institutions, which have taken part in the Congress.

The Moscow City Center of Interventional Cardioangiology (director – Professor D. G. Iosseliani) and Moscow Center of Endosurgery and Lithotripsy (director – Professor A. S. Bronshtein) presented the biggest amount of reports.

During the Congress, many specialists from different countries have dedicated their lectures to the most urgent topics of interventional cardioangiology: "The Future of Interventional Cardioogy" by David Holmes (Rochester, USA); "Comparative results of Taxus versus Cypher Stents " by Bernhard Meier (Switzerland); "The Status of Carotid Angioplasty" by Gerald Dorros (Phoenix, USA); "Present and Future of Percutaneous Interventions on Heart Valves" by Alec Vahanian (Paris, France); "Stem Cells in the Treatment of Acute Myocardial Infarction" by Helmut D. Glogar (Vienna, Austria); "Treatment of In-Stent Restenoses in Native Coronary Vessels with Drug-Eluting Stents under "Real-World" Conditions" by Werner Haberbosch (Suhl, FRG); "Current Status and Perspectives of Carotid Stenting" by Michel Henri (Paris, France) and "Update of Strategies with Stent-Graft Interventions for Aortic Dissection" by Christoph Nienaber (Rostok, Germany). Andreas Benhauer (Austria); Matyas Keltai (Hungary); Rьdiger Simon (Germany); Rainer Rienmьller (Austria); Maciej Lesiak (Poland); Tyrone Collins (USA) and Issam Moussa (USA) also have presented interesting reports.

Within the framework of the Congress, the most urgent problems of different branches of interventional radiology were discussed during the "Round Table" meetings held with participation of the leading specialists in these fields of research and practical activity. Thus, the Round Tables were held dedicated to the following urgent matters of endovascular surgery: "Treatment of cardiovascular diseases with the use of stem cells: State of the art and perspectives", "Complications of the interventional procedures ", "Endovascular interventions in valvular heart diseases", "Transradial approach: advantages and drawbacks; can it become an alternative to transfemoral approach?", "Stenting of small coronary arteries: are there any changes in the last years?", "Informative and communicational technologies in interventional cardiology and radiology".

Furthermore, the Satellite Symposia of medical companies have taken place within the framework of the Congress: "New technologies from Abbot Vascular Devices: Trimaxx coronary stent — new stent platform, and Starclose vessel closure device " by Jomedica; "Thrombolysis and endovascular procedures in AMI: Separately or in combination?" by Boehringer Ingelheim (Germany); "Atherothrombosis. Treatment and prevention of clinical manifestations" by Sanofi (France); "Problems of visualization and nomenclature in Interventional Cardiology and Radiology" by Siemens (Germany); "What's new in coronary stenting" by Guidant (USA); "Use of Simdax (levosimendan) in the treatment of patients with acute myocardial infarction complicated by left ventricular failure following endovascular procsdures" by Orion-Pharma (Finland); "Actual state and perspectives of carotid stenting" by Cordis and Johnson & Johnson (USA); "New horizons in PTCA. Drug-Eluting cobalt stent. Results of ENDEAVOUR study " by Medtronic (USA); "Optimization of interventional procedures in high-risk patients" by "Nycomed/ General Electric; "Drug treatment of patients with CAD after endovascular and surgical interventions" by Pfizer (USA); "Experience of Polish cardiologists with modern methods of treatment of cardiovascular diseases. Examples of the use of Balton cardiac instruments (Balton, Poland)" by Balton, Poland and "Drug treatment in patients before, during and after surgical intervention on coronary arteries. Time-tested classics" by Bayer (Germany).

D. Holmes (Rochester, USA) opened the first Plenary Session with the interesting lecture "The Future of Interventional Cardiology" where in his peculiar manner underlined the immensity of achievements and prospects of development of interventional cardioangiology. Today, the potentialities of this 30-years old method that even yesterday seemed to be fantastic have become real and are determining the profile of both the present and the near future of contemporary medicine.

Further, the meeting was dedicated to the results of clinical implementation of drug-coated stents and was entitled: "Drug-eluting stents: the solution for the problem of in-stent stenosis or just a reduction of its rate?". This part was started with the lecture of Professor Bernhard Meier (Switzerland) "Comparative Results of Taxus versus Cypher stents"; summing up the lecture it is possible to conclude that the results of use of these stents are generally similar to those in all-metal stents and appeare to be much preferable. Further, quite a number of reports was dedicated to evaluation of clinical and angiographic results of use of drug-coated stents; the reporters were resuming the experience of use of Cypher stents (Cordis, США) emphasizing high efficacy of drug coating for prevention of neointimal hyperplasia in the stent lumen which results in significant improvement of clinical results of stenting and reduces the necessity of repeated surgical interventions. Use of drug-eluting stents allows obtaining perfect results of treatment of in-stent stenosis; this was the subject of the lecture of Professor Haberbosch (Suhl, Germany).

The session "PTCA in patients with High Risk of Complications of Interventional Procedures" demonstrated that technical provision of invasive procedures together with professional skills of specialists performing them allows to provide effective and safe medical aid to high-risk patients, which until recently were considered as incurable. The presentations: "Coronary angioplasty in patients after heart transplantation" by E. V. Merkulov et al. (Moscow); "Partial revascularization in geriatric patients" by D. A. Korotkov et al.

(Syktyvkar); "Endovascular manipulations in multivessel coronary artery disease" by V. V. Korobov et al. (Kazan), "Endovascular coronary interventions in patients with diabetes mellitus" by D. G. Iosseliani et al. (Moscow) and others aroused a great interest of the audience. Therefore, the contemporary invasive cardiology declares itself the method of choice for quite a number of severe somatic patients, whose primary disease is accompanied by other severe conditions.

The organizers of the Congress have isolated the session dedicated to treatment of bifurcational stenoses. Despite development of a spectrum of technical solutions of this problem (Crash, Cullot, Y- and T-stenting) and implementation of special bifurcation stents, the rate of recurrent stenoses at the site of intervention remains considerably high. I. Moussa (New York, USA) in his presentation emphasized that using the aforementioned techniques of stent grafting is justified only at the condition of using drug-eluting stents with subsequent optimisation by means of kissing balloons. However, he considers it promising to develop a special bifurcation stent with drug coating. Some authors let in the possibility of main artery stenting without significant impairment of blood flow in the lateral branch, emphasizing the initial type of bifurcation lesion and diameter of the lateral branch, as well as that stenting increases the possibility of restenosis (A. M. Babunashvili et al. (Moscow); D. G. Gromov et al. (Moscow); V. I. Ganyukov et al. (Novosibirsk)). The results of use of ML Frontier bifurcation stents were reported by M. Lesiak (Poznan, Poland), which possesses large experience of work with the aforementioned stent. Immediate clinical and angiographic results of the use of this stent serve as an example of "elegancy" in invasive cardioangiology. However, being all-metal, this stent-graft is unable to compete in its long-term results compared to stents, which are not adapted for treatment of bifurcation lesion, but have drug coating.

The session dedicated to angioplasty of unprotected left main artery included seven reports from different leading centres of Moscow and the Russian Federation (V. V. Chestukhin et al. (Moscow); Iosseliani et al. (Moscow); A. V. Protopopov et al. (Krasnoyarsk); V. A. Porkhanov et al. (Krasnodar) and others). As it results from all reports, the present joint experience of Russian invasive cardiologists exceeds 500 operations of that type; this give evidence of dynamics in choice of therapeutic approach in patients with the left main artery lesions. The leading centres have overcome the point of view, according to which the left main artery lesions are always subject to coronary surgery. The use of drug-coated stents has already guaranteed improvement of long-term prognosis in such patients; however, the problem of the absence on the market of special stents of large diameters persists. It results in necessity of additional (and in such cases — undesirable) manipulations aimed at optimization of stent diameter and even in use of stents developed for application in renal arteries.

One of priority trends in interventional cardioangiology is the treatment of patients with acute myocardial infarction. This problem was the subject of two sectional sessions called: "AMI — optimization of therapy: thrombolysis, PTCA, stenting or combination of those methods?" There is an immense worldwide experience of reperfusion therapy using thrombolytic therapy, primary PTCA and stenting of infarct-related coronary artery. Therefore, a number of conceptual conclusions were made, namely the earliest restoration of antegrade blood flow in the infarct-related coronary artery provides preserving of viable myocardium in the area of infarction and reduces the period of electrophysiological instability of myocardium, thus leading to improvement of in-hospital treatment results and to optimization of long-term prognosis of the disease. In this regard, the transcatheter methods of blood flow restoration appeared to be most safe and effective. However, the reality in Russia is that catheterization performing within the first hours from onset of disease is possible only in an insignificant share of patients. Therefore, it is necessary to seek for a most optimal strategy of AMI treatment under the present conditions. According to D. G. Iosseliani (Chief Cardiologist of Moscow, director of Center of Cardioangiology), the best results are obtained by combining pre-hospital thrombolysis and endovascular methods of treatment performed in a specialized in-patient institution. In general, there were 12 reports from different regions of the country. Of special note is the report of I. E. Galankina (Sklifossovsky Research Institute, Moscow) named "Peculiarities of morphogenesis of acute myocardial infarction in early blood flow restoration", where the author analyses the peculiarities of pathomorphological picture of necrosis focus depending on presence or absence of early reperfusion and on the methods of reperfusion therapy. The great interest was excited by the lecture of H. Glogar (Vienna, Austria) named "Stem Cells in the Treatment of Acute Myocardial Infarction", which deepens us into the problem of one of the most promising trends in contemporary medicine — morphoneogenesis. This topic was discussed during the Round Table headed by H Glogar (Vienna, Austria) and A. F. Tsyb (Obninsk, Russia), which provoked great interest of the audience. The matter of treatment of acute coronary syndrome also was discussed within the framework of satellite symposium of Boehringer Ingelheim Company (Germany).

Two Sectional Sessions were dedicated to application of methods of invasive radiology in oncology. One of those sessions was opened with the lecture of B. I. Dolgushin "Possibilities of interventional radiology in oncology". In general, these two sessions included 14 reports from different clinics of Moscow and the Russian Federation.

The sessions included meaningful spectrum of reports. They were dedicated to the matters as follows: "Neuroradiology" (headed by G. E. Belozerov, Moscow, and V. Yu. Bondar, Khabarovsk), "Interventional Radiology in Obstetrics and Gynecology" (headed by Z. A. Kavteladze, Moscow, and N. I. Tikhomirova, Moscow); "Acute and Chronic Diseases of the Venous System: Tactics of Interventional Procedures: Early and Late results" (headed by V. I. Prokubovsky, Moscow, and S. A. Kapranov, Moscow); "Interventional Radiology in the Treatment of Renal and Hepatic Diseases" (headed by T. Collins, New Orleans (USA), and A. N. Maltsev, Ulyanovsk) and "Endovascular Surgery of the Aorta and Peripheral Arteries" (headed by S. A. Kapranov, Moscow, and V. A. Ivanov, Krasnogorsk).

At the end of the scientific program of the Congress (March 30), a Plenary Session dedicated to the report of the Board and election of the Governing Bodies of the Russian Scientific Society of Interventional Cardioangiologists was held. The report read by of the Chairman of the Society, Professor D. G. Iosseliani repeatedly emphasized the important role of invasive radiologists in contemporary medicine and determined the prospects and objectives of development of domestic invasive cardioangiology and radiology. D. G. Iosseliani desired not to be considered for Chairman in the next term. The elections were held and the new Administrative Board of the Society was formed comprising the leading specialists from all regions of Russia.

V. A. Ivanov (Moscow — Krasnogorsk) was elected as the Chairman of the Society.

Deputy Chairmen: D. G. Iosseliani (chief editor of the International Journal of Interventional Cardioangiology), Z. A. Kavteladze, L. S. Kokov, A. N;. Protopopov, A. N. Samko, S. P. Semitko and A. N. Fedorchenko.

Secretaries of the Society: A. V. Arablinsky (Moscow), S. A. Terekhin (Krasnogorsk).

Presidium of the Society: S. A. Abugov, A. V. Arablinskiy, A. M. Babunashvili, V. I. Ganyukov, D. G. Iosseliani, Z. A. Kavteladze, L S. Kokov, V. V. Kucherov, A. G. Osiev, A. N. Protopopov, A. P. Savchenko, A. N. Samko, S. P. Semitko, S. A. Terekhin, A. N. Fedorchenko, B. E. Shakhov and B. M. Shukurov.

The next Congress is planned in 2008, in Moscow.

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