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Contents

Value and limitation of meta-analysis

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K-words: meta-analysis, pooling, clinical trials, cumulative meta-analysis.

Meta-analysis is a valuable method of aggregating data sets of different trials which are inadequate or unconvincing on their own. There are strict rules on the retrieval and selection of data which are crucial in terms of the validity of a meta-analysis. Many so-called meta-analyses are flawed because of lack of a protocol or non adherence to it. Also underreporting of clinical trials is haunting the validity of meta-analysis. This hidden information is not a random process but is affecting mainly trials with negative results. To avoid this publication bias all clinical trials should enter an international online database.

Meta-analysis can be defined as the combination of results from several randomized controlled trials of similar design to produce a single estimate of the effect of a treatment which is more precise than the estimate of outcome of single trials. This systematic review tends to overcome the subjective and often biased traditional narrative reviews which most often do not specify the source of information and fails to perform a standardized assessment of the methodological quality of studies (1, 2).

Meta-analysis have received a mixed reception from the outset as meta-analyses of small trials were later contradicted by a single large randomized trial on the same topic. Well known examples are the effects of nitrates (3,4) and magnesium (5,6) on mortality in acute myocardial infarction, comprehensive in-hospital assessment on mortality in the elderly (7, 8) and the effect of aspirin on the risk of pre-eclampsia (9, 10).

Obviously the quality of component trials is of crucial importance: if the raw material is flawed, so will the resulting meta-analysis ("garbage in, garbage out"). Several experts reviewed the numerous biases that threaten the validity of meta-analysis (11, 12). These may relate to differences among component trials in patients' characteristics (selection bias), provided care (performance bias), assessment of outcome (detection bias) and exclusion of randomized patients (attrition bias).

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Also underreporting of trials is haunting the validity of narrative reviews and meta-analysis. It appears that only about half of abstracts presented at conferences are later published in full (13). Based on research proposals approved by ethics committees of four leading medical schools, only 49 to 67% are fully published in medical journals (14, 15). Of trials funded by the National Institutes of Health 20% are still unpublished several years after completion (14, 16). This hidden information is unfortunately not a random process but is affecting mainly trials with negative results. A review of published papers could thus identify a spurious beneficial treatment or miss an important adverse effect. To avoid the publication bias (unpublished or duplicate publication) it has been proposed to enter all trials in an (inter)national online data base (17). In addition to the Cochrane controlled register there is Pub Med Central, a free electronic archive of biomedical research launched by the US National Institutes of Health (18).

Meta-analysis is much more than pooling of data of individual trials

A meta-analysis will not provide the same quality of information about the efficacy of an intervention as a single large randomized trial if the standards are less stringent.

Current standards emphasize the importance of several qualitative features such as the development of a protocol before starting the meta-analysis, inclusion of only truly randomized studies, and the collection of complete outcome information of all randomized patiens. (11,19,20). Many so-called meta-analyses are flawed because of lack of a protocol or non adherence to it. Another important shortcoming is that meta-analyses are done when the outcome results of individual trials are known. To circumvent this problem one should, in selecting randomized trials for uptake in a meta-analysis, study each trial with concealed outcome events.

Thus, the retrieval and selection of data are crucial matters in terms of the validity of a meta-analysis. The criteria set forward by Chalmers et al (19) should be strictly adhered to:

Proper double-blind randomization. Central procedures are important whatever the scheme, because they minimize the possibility of biased treatment allocation.

Complete availability of data in line

with "intention to treat" principles.

Full consideration of any patients "lost to follow-up", and any other missing information (e.g., percentage of missed visits, number and reasons for withdrawals from the treatment, etc.).

Procedures for outcome validation

No rules to calculate the sample size of a given meta-analysis.

One of the major roles of meta-analysis is to provide reliable estimates of typical treatment effects when randomized clinical trials themselves are not of sufficient size. However, how shall one define when a meta-analysis is itself of sufficient size? How should the statistical reliability of the evidence within a meta-analysis be assessed? It is reasonable to assume that the sample size should be at least as large as that of the single well-designed and optimally powered randomized controlled trial. Considering the heterogeneity in various features of study design and other possible biases in individual studies included in a meta-analysis, a larger total number of patients may be needed compared to a single randomized trial. Pogue and Yusuf (20) proposed a formula for an optimum information size (OIS) which provides a first approximation of the minimum sample size required.

In practice, calculation for a power analysis is rarely done prospectively which may explain why the results of meta-analyses and corresponding large trials do not necessarily agree (21).

The risk of meta-analysis based on small trials

Small trials with nominally significant p values tend to overestimate the size of treatment effect, since the treatment effect must be large if statistical significance is to be reached with small sample size. This bias is amplified by the fact that negative trials are often not published. Thus a meta-analysis including mainly small trials is more likely to overestimate treatment effects. Larger trials, even if the results are negative, are known to a broad group of international investigators and are more likely to be published. Meta-analyses of larger trials should thus be less susceptible to this publication bias (20).

There is another reason why even large differences in outcome, based on a meta-analysis of small trials, should be interpreted cautiously (20). Sample variability exists even in studies performed in the same way in identical populations causing different treatment effect estimates. The smaller the study, the larger will be the sampling variability which is another argument to concentrate meta-analyses to large trials (15).

Heterogeneity of treatment effect within meta-analyses might be related to the order of publication of individual trials

Rothwell and Robertson (22) studied 26 meta-analyses of 241 trials and found that when the trials within each meta-analysis were ordered according to year of publication, there was a significant variation in the proportion of trials in which treatment was better than control with a significant excess of positive outcome in the earlier trials. This variation is independent of trial size. Early trials overestimated the treatment effect in comparison with subsequent trials in 20 of 26 meta-analyses studied.

If an initial trial is positive, it is likely to be published — and sooner — than if it is negative. However, once a treatment is considered to be effective and established, a negative trial becomes interesting. Thus meta-analyses done early in the evolution of published trials overestimate a positive treatment effect.

Can heterogeneity be avoided in meta-analysis?

Meta-analysis usually try to convince the reader that the data are homogeneous to justify combining them for a focused question. Diversity in clinical trials is unavoidable. Trials may target different populations of patients and even populations defined by the same eligibility criteria change overtime. Indeed, patients enrolled in comparable trials may belong to the same basic population, but even small differences in the criteria for diagnosis, coexisting conditions, severity of disease, and age will produce very different groups of patients. Differences in doses, time to onset, and duration of therapies can also produce substantial disparity among trials that are included in meta-analyses. The choice of concomitant treatments can also affect the results. Summarizing all the information contained in a set of trials into a single odds ratio may greatly oversimplify an extremely complex issue (23).

Can meta-analysis predict the outcome of a single large trial?

Many meta-analyses do provide a correct understanding of a given treatment or procedure. A glaring example is shocking this confidence. A meta-analysis of 1,266 patients in seven randomized trials showed that intravenous magnesium therapy reduced serious arrhythmias and death after myocardial infarction (odds ratio 0.44, 95% CI 0.27-0.71) (5). The subsequent LIMIT-2 study in 2,300 patients confirmed this result (24% relative reduction in mortality) (24). However, the ISIS-4 study (6) in 58,050 patients showed a slight excess of deaths in the magnesium group. The 30 day mortality in the recent MAGIC trial was the same in the two treatment groups (15.2%) but no harm was observed in eight prespecified subgroups analyses (25).

These conflicting results were tentatively explained by a publication bias of never published trials (26).

A Canadian group studied the results of 12 large (> 1,000 patients) randomized, controlled trials with the results of 19 meta-analyses published earlier on similar topics (23). The outcomes of 12 large trials were not predicted accurately 35% of the time by corresponding meta-analysis. If there had been no subse-

quent randomized trial, the meta-analyses would have lead to the adoption of an ineffective treatment in 32% of cases and to rejection of a useful treatment in 33% of cases. Argentinian investigators evaluated the ability of meta-analysis to predict the results of a single large trial (> 1,000 patients). There were 30 meta-analyses covering 185 randomized controlled trials. The largest of these trials was then removed and compared to the recalculated relative risk of the meta-analyses (27). In 24 of 30 comparisons the meta-analysis had good predictive ability of the direction of the treatment effect of the largest trial. However, in the other six (20%) the meta-analysis failed to do this, which is casting doubt on the usefulness of this approach other than as a hypothesis — generating tool. The meta-analysis tended to demonstrate stronger protective effects than the largest trial did.

Cumulative meta-analysis

Each time a relevant trial is reported, evidence on the effects of a given intervention accumulates. In a cumulative meta-analysis a previous meta-analysis is repeated each time the results of a new randomized controlled trial is published (28,29). The obvious goal of this process is to identify the benefit of an intervention as early as possible. This updating should not be continuous but rather periodic — for example when the increment in new information is at least 20 percent of the projected optimum information size (OIS).

A cumulative meta-analysis of controlled trials of beta-blockers in secondary prevention of myocardial infarction was done (Figure 1) (30). Combining the results of 13 trials published by the end of 1981, the. relative risk of mortality in patients treated with beta-blocker versus placebo is 0.78 (95 CI 0.69-0.88, p < 0.001). Subsequent trials in a further 15,000 patients confirmed this result and could be considered superfluous (31). However, there are no guidelines on the interpretation and reliability of such repeated analyses but the principles of the Optimum Information Size (OIS) and application of formal monitoring have been proposed (20).

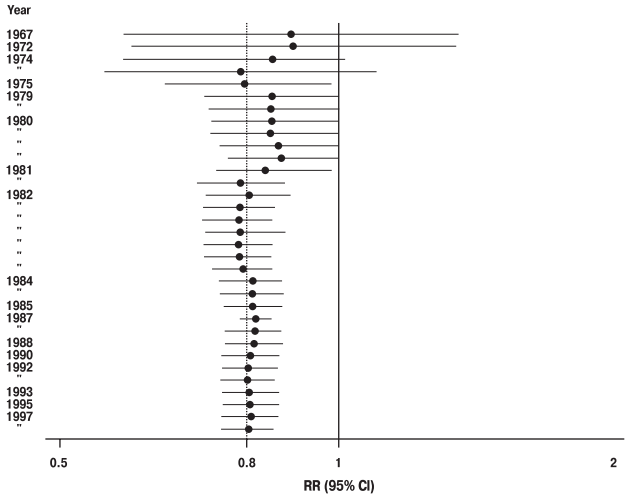

Figure 1. Cumulative meta-analysis of controlled trials of beta-blockers in secondary prevention after myocardial infarction.
A clear (p < 0.001) reduction of mortality was evident by 1981 (Freemantle et al. Br. Med. J. 1999; 318: 1730-1737, reference 30)

Conclusion

Assuming that there are no problems of internal or external consistency and that the pooled estimate is clinically meaningful, then:

If a meta-analysis of several trials of which one ore more reach statistical significance leads to positive findings, the meta-analysis would strengthen the overall evidence.

If meta-analysis of several trials of which none reach statistical significance leads to a positive result, it would be unadvisable to recommend a therapy on the sole basis of the meta-analysis. Larger clinical trials would probably be required.

If meta-analysis of several trials of which one or more reach statistical significance leads to a significant overall result, selection criteria for the trials can be reconsidered and/or further clinical trials be undertaken.

Thus the positive results of a meta-analysis alone do not provide an absolute recommendation for a treatment, other evidence is required.

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Does myocardial reperfusion influence left ventricular contractile function after chronic coronary occlusion?

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Introduction: prolonged, or the so-called "chronic" occlusion of at least one coronary artery has been found in 20-40 percent of CHD patients as described in the literature. According to the results of various authors, successful endovascular restoration of blood flow in obstructed coronary arteries is achieved in 60% to 90% of cases (1-2). It is also known, that, unfortunately, restenosis and re-occlusion following endovascular procedures on those arteries is seen more often, than in occlusion-free patients. One of the major indications for recanalization in chronic coronary occlusion is the evidence, in the territory of obstructed artery, of potentially viable myocardium with transient or persistent ischemia.(1-4) Restoration of blood flow in these arteries also provides donor artery, which can be used if other coronary arteries are stenotic. However, there is another problem of similar importance to be solved: whether left ventricular function is improved by restoration of antegrade flow through the site of chronic occlusion, and, if yes, what is the mechanism of this effect. These questions have stimulated our study.

Purpose of the study: Assessment of general and regional left ventricular (LV) contraction following successful endovascular restoration of the blood flow in the occluded coronary artery.

Materials and methods: We studied records of primary and repeated medical examinations of 112 patients, who underwent successful surgical recanalization for chronic coronary occlusion followed by percutaneous transluminal balloon coronary angioplasty (PTCA) and/or stenting in Moscow City Center of Interventional Cardioangiology from November 1999 till January 2003. Repeated examination of patients, which included coronary angiography and left ventriculography, was performed at least six months after following the procedure.

Criteria of inclusion were: history of coronary occlusion with 0-1 TIMI antegrade flow and i 2.5 mm arterial diameter with minimal duration of 1 month.

Of the patients studied 92 (82.1%) were men, mean age was 52.3±1.8 years.

Selective coronary angiography and left ventriculography were followed by quantitative assessment of the results. TIMI 2-3 flow was considered a satisfactory outcome. Restenosis was defined as > 50% narrowing of vascular diameter revealed by repeated examination in the long term. Re-occlusion was defined as complete obstruction of blood flow through the artery with TIMI 0 or 1 antegrade flow.

Left ventirculography was performed in right oblique view. Contour of the left ventricle was divided in 5 segments: 1 — anterobasal, 2 — anterolateral, 3 — apical, 4 — diaphragmatic and 5 — inferobasal. Regional contractile function of the LV (area and length) was measured taking into account the territory of obstructed artery. In patients with LAD occlusion the contractile function of the first, the second and the third segments was evaluated. Contraction of the second, the third and the forth segments was assessed in patients with CA occlusion. Patients with RCA occlusion were assessed for regional contraction of the third, the fourth and the fifth segments.

All patients underwent mechanical recanalization and PTCA of the occluded artery, with subsequent stenting in some cases. Successful endovascular procedures were performed in 117 coronary arteries of 112 patients. In 9 (8.0%) patients two-vessel occlusion was revealed, among these there were four (44,6%) cases of unsuccessful recanalization of the second artery.

Coronary stents were implanted in 85 arteries of 78 (69.6%) patients. With this, 5 (4.5%) patients had two stents and one (0.9%) patient — three stents implanted in one artery.

The following complications were observed during endovascular procedures: acute occlusion of the lateral branch — 1 (09%), ventricular fibrillation — 1 (0.9%), threatening intimal dissection — 1 (0.9%), perforation of arterial wall with the guidewire while attempting mechanical recanalization for reocclusion — 1 (0.9%).

The hematoma at the site of arterial sheath was seen in some cases. In-hospital period after the procedure was uneventful in all patients, there were no serious complications.

Table 1 summarizes the rate of revascularization procedure in concrete coronary arteries and their segments.

Statistical analysis of the results was performed using SPSS 10.0 for Windows (Russian version).

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Table 1

Artery	Segment			Total:
	Proximal	Middle	Distal	
LAD	32	26	1	59
CA	4	18	1	23
RCA	16	14	1	30
Other:				4

Results:

The results of control follow-up coronary angiographic study are shown on the Diagram 1.

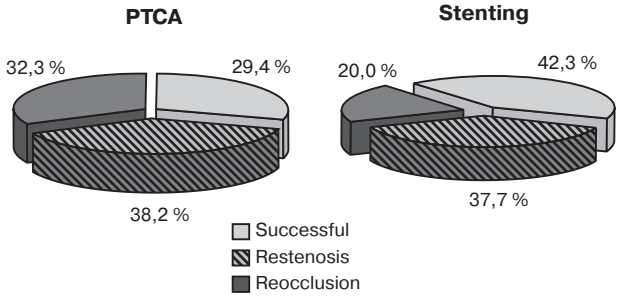

Diagram 1. State of arteries in late follow-up

As shown on the diagram, the effect of antegrade flow restoration in previously occluded artery persisted in the late follow-up in 84 (75.0%) patients, whereas in 43 (38.4%) of them there was a restenosis of varying degree. Late reocclusion was seen in 28 (25.0%) patients.

Clinical state of patients was evaluated by the degree of angina and the results of exercise testing (Diagrams 2 and 3).

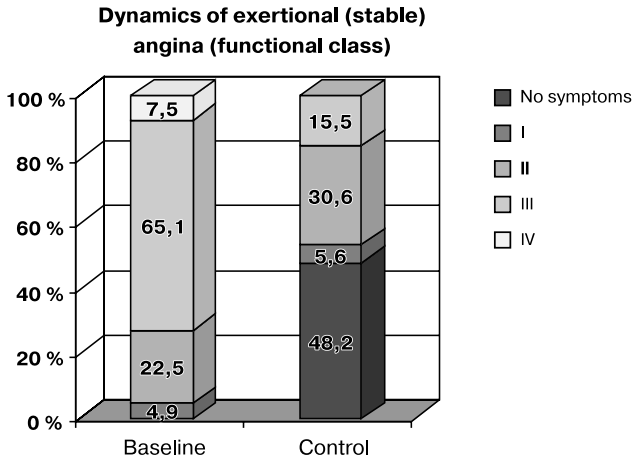

Diagram 2.

The Diagrams show a long-term positive trend in the clinical state of patients, with the disappearance or significant decrease of anginal episodes and the increase of exercise tolerance in certain patients.

Before the procedure total left ventricular ejection fraction was in average 56.29±1.35%, and at control study 59.76±1.34% thereafter (p<0.01), suggesting its reliable increase in the long-term follow-up after the procedure. A comparative assessment of LVEF

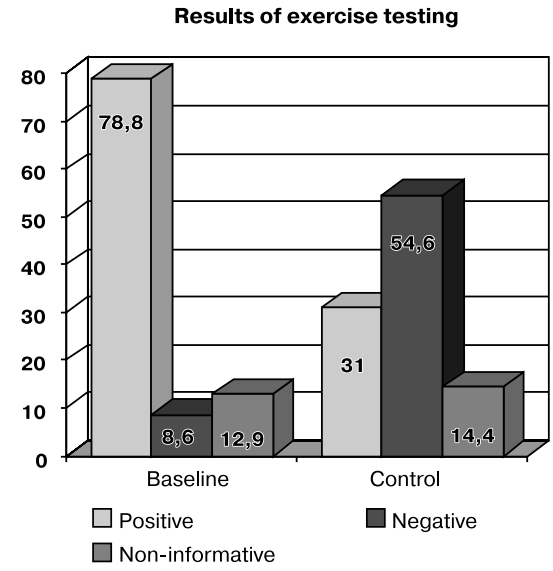

Diagram 3.

changes depending on the state of treated coronary arteries late after the procedure showed, that with good late results (absence of restenosis) total LVEF increased in average from 55.54±2.50% to 60.71±2.80% (p<0.015); restenosis was also associated with reliable, but less significant increase in LVEF from 58.70±2.14% to 61.89±1.80% (p<0.002), whereas re-occlusions were associated with only non-significant LVEF increase from 55.20±2.30% to 57.05±2.55% (p=0.34).

The analysis of regional contractility consisted in determination of the summary changes in three LV segments corresponding to the treated artery's pool. The results of this analysis are shown in Tables 2 and 3).

Table 2. Analysis of regional contractility in patients with preserved antegrade flow

Recanalized artery		LAD	CxA	RCA
Length of segments	Baseline	70,14±5,95	67,5±4,22	41,81±4,8
	Control	79,82±5,89	70,26±5,52	47,9±6,37
Total area of segments	Baseline	118,09±7,9	116,81±6,72	83,19±7,51
	Control	135,76±7,12	122,37±7,98	93,68±9,35

Statistical significance: Length (p<0.02), area (p<0.002)

The analysis of the data on regional LV contractility, shown in Tables 2 and 3, suggests, that the increase in regional contraction, as well as the rise of total LV ejection fraction, is due to segments, supplied via previously obstructed artery, where antegrade

Table 3. Patients with re-occlusion

Recanalized artery		LAD	CA	RCA
Length of segments	Baseline	70,84±5,75	65,52±4,62	41,22±4,65
	Control	72,22±5,69	67,24±5,58	43,31±6,05
Total area of segments	Baseline	116,39±7,93	113,81±6,55	81,19±7,32
	Control	119,66±7,12	120,47±7,91	86,08±9,15

The increase of contractile function in re-occlusion patients wasn't statistically significant

blood flow has been restored by endovascular procedure. The results suggest the beneficial effect of myocardial reperfusion in the territory of "chronic" occlusion on the total LV function, and is also an indirect evidence of the viability of the myocardium, which had been functionally suppressed during "chronic" occlusion.

Figures 1 and 2 show the time course of regional LV contraction in the pool of different arteries, treated with endovascular methods (mechanical recanalization and subsequent PTCA).

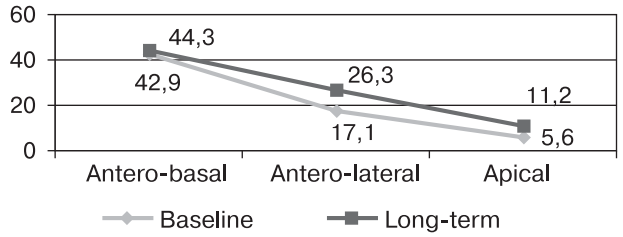

Figure 1. Time course of contractile function of the anterior segments of LV myocardium (LAD pool)

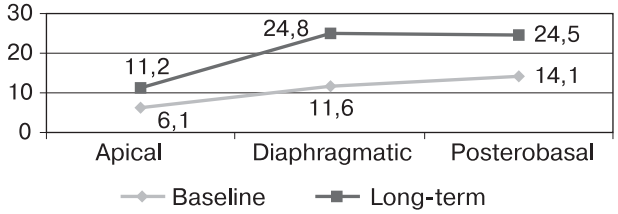

Figure 2. Time course of contractile function of posterior segments of LV myocardium (RCA pool)

Discussion

Therefore, our results confirmed the existing opinion that successful restoration of antegrade flow can be achieved in a large number of patients with chronically occluded coronary arteries using mechanical recanalization with subsequent balloon angioplasty and/or stenting. This effect also persists for the long-term period in about 2/3 of patients. Meanwhile it is worth noting, that after the stenting of a "chronically" occluded coronary artery the late good result is preserved far more commonly, than after the PTCA alone. It is mainly due to the reliably lower rate of re-occlusion seen with stenting. The rate of restenosis in both groups is approximately the same. Those results are encouraging, as total restoration of the blood flow can be achieved easier and more commonly in a restenosed vessel as compared with the re-occluded one. It also suggests that, when possible, the recanalization of a "chronically" occluded artery should be performed with stenting, and not with balloon angioplasty alone

Restoration of blood flow in arteries with long-standing occlusion is, in the majority of cases, accompanied by substantial improvement of clinical state of patients with the decrease of complete disappearance of angina episodes, as well as of the transient myocardial hypoxia (as judged by the results of exercise testing and 24-hour ECG monitoring). Myocardial function in the pool of previously occluded artery improved reliably, and this was more pronounced in cases with persisting good the effect of the procedure as compared with the cases of restenosis (8-9)

We didn't reveal any significant increase of LV function over baseline in patients with coronary re-occlusion. One has to emphasize that almost any patient with good and satisfactory results of endovascular procedure didn't receive additional medications which could improve his/her contractile capacity. Moreover, after the restoration of the blood flow in the occluded coronary artery medical therapy was significantly reduced.

The results are consistent with the existing concept of "stunned" myocardium, still viable, but deprived of full-value functional activity due to chronic hypoxia.(5-7) Thus, the restoration of adequate blood supply in such regions improves their function, as confirmed by our results. This improvement of regional and general LV myocardial function can be considered the true effect of antegrade flow restoration in the pool of "chronically" occluded coronary artery, because, in contrast to reperfusion in acute myocardial infarction, where with time the reparatory-compensatory mechanisms from the preserved myocardium of other LV regions are induced, the improvement of LV function after the reperfusion of "chronically" occluded coronary artery occurs only at the expense of previously hybernating, "stunned" myocardium.

All this confirms the opinion of both clinicians and researchers concerning the advisability of antegrade flow restoration in chronic coronary occlusions (11-15). This is also true for the cases, when the occluded arteries receive blood from collateral pathways originating from other coronary arteries, because these pathways, for the most part, can not provide complete compensation of compromised antegrade flow. This is confirmed by the fact, that 98% of the patients studied had angiographic signs of collateral pathways leading to the occluded artery, and, nevertheless, after the restoration of the antegrade blood flow we saw a reliable improvement of myocardial function in LV segments supplied from these arteries.

Thus, our data confirm once again the advisability of restoration of the antegrade blood flow in so-called "chronically" occluded coronary arteries. It produces a beneficial influence on clinical course of CHD by relieving or eliminating the episodes of angina. The coronary reserve is increased and, what is not less important, the functional heart capacity improves. The aforesaid applies, primarily, to the cases, when the occluded arteries supplies the viable, but "stunned" hypoxic myocardium. In order to determine the myocardial viability in the occluded artery's pool it is worth using exercise myocardial scintigraphy and/or exercise echocardiography. At the same time we

believe, that even in cases presenting with is a scar in the occluded artery's pool, but with sufficiently big diameter and length of the vessel, it is advisable to try to restore the antegrade blood flow with the purpose of receiving a donor artery in the event of progress of stenotic and occlusive lesions in other coronary arteries.

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Clinical and economic analysis of optimization of antithrombotic therapy in coronary heart disease patients undergoing coronary angioplasty with stenting

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Introduction

Percutaneous transluminal coronary angioplasty (PTCA) with stenting is becoming increasingly important as an alternative therapy for severe coronary heart disease (CHD). Over 1.2 million endovascular coronary interventions are performed in the world annually, 70% of these imply stenting (1, 10, 11, 16, 17, 19).

Development of potent antiplatelet agents, which significantly decrease the risk of ischemic events during and following endovascular procedures, has also been crucial in the improvement of PTCA results (5, 12, 15, 18, 20, 21, 22, 23, 27, 29, 32, 33).

However, many available methods of antithrombotic therapy (ATT) in CHD patients undergoing PTCA with stenting are expensive and commonly rival the cost of the procedure itself.

Clinical and economic aspects of ATT for PTCA with stenting have been poorly investigated (7, 8, 9, 12, 26, 30, 33).

Purpose of the study

Comparative efficacy assessment of various ATT techniques for PTCA with stenting from the position of clinical and cost-effectiveness analysis (CCEA).

Study objectives

1. To compare the efficacy of various ATT techniques for PTCA with stenting.
2. To perform CCEA of these techniques on the basis of cost/effectiveness ratio.
3. To determine the optimal ATT technique on the basis of CCEA.

Materials and methods

The study enrolled male patients with CHD (n=290), who underwent PTCA with stenting in the cardiological center of Vishnevsky Central Military Clinical Hospital from January 1998 through December 2003 after clinical examination, which included laboratory investigation of systemic hemostasis, lipid metabolism, electrocardiography (ECG), echocardiography (EchoCG), bicycle ergometry test (BET), coronary angiography (CAG). A total of 317 stents were implanted.

Depending on the ATT technique used for endovascular coronary intervention, the patients were divided between three groups.

The first group (n=100) included CHD patients who received ATT with ticlopidine (Ticlid, Sanofi-Synthelabo, France) 500 mg daily and acetylsalicylic acid (Aspirin cardio, Bayer, Germany) 100 mg daily 3 days prior to stenting; intra-arterial bolus injection of 10.000 IU heparin was performed immediately before PTCA; 1000 IU heparin was administered in a drip over the entire PTCA with stenting and within the first 24 hours postoperatively to obtain activated partial thromboplastin time between 60 and 80 sec, followed by the combination of ticlid and aspirin in the above listed dosage for 4 weeks.

In the second group of patients (n=140) ATT was performed with ticlid 500 mg daily and aspirin cardio 100 mg daily during 3 days prior to stenting and 4 weeks thereafter; intra-arterial bolus injection of 15.000 IU heparin was administered during PTCA followed by 0.3 ml s.c. nadroparin (fraxiparin, Sanofi-Synthelabo, France) over 12-72 hours after the procedure.

The third group included patients who received ATT with glycoprotein (GP) IIb/IIIa platelet receptor antagonists: abciximab (ReoPro, Lilly, Switzerland) or eptifibatide (Integrilin, Schering-Plough, USA). Patients of this group received intra-arterial bolus injection of 1000 IU heparin 30 min before PTCA, intermittent dosing of heparin during the procedure to obtain activated partial thromboplastin time between 60 and 80 sec. In addition, 30 patients received 0.25 mg/kg ReoPro 10 min before the intervention (injection time 3-5 min) followed by 12 h dropwise infusion of 10 mg/kg and subsequent administration of 7 IU/kg/min heparin during 12 h. Introducer was removed from the femoral artery 24 h following PTCA. Twenty patients received bolus injection of Integrilin in a dose of 180 mg/kg followed by continuous i.v. administration of 20 mg/kg/min. Ten minutes after the first bolus injection another bolus administration of 180 mg/kg Integrilin was conducted. The infusion duration was 24 h. Introducer was removed from the femoral artery 24 h following PTCA.

The results of physical, instrumental and laboratory studies are summarized in Table 1.

The first group included 100 male patients (mean

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Table 1. Clinic-laboratory and instrumental values for three patients groups

Indices	Gr.1	Gr. 2	Gr. 3
Age (years)	51,3	52,2	54,1
Primary angina	11 (11 %)	10 (7,2 %)	11 (22 %)
Progressive angina	16 (16 %)	28 (20,0 %)	26 (52 %)
Q-wave myocardial infarction	2 (2 %)	4 (2,8 %)	3 (6 %)
Non Q-wave myocardial infarction	6 (6 %)	5 (3,6 %)	3 (6 %)
Stable exertional angina,	65 (65 %)	93 (66,4 %)	7 (14 %)
II class NYHA	28 (42,8 %)	27 (29,4 %)	—
III class NYHA	32 (49,3 %)	55 (58,5 %)	5 (71,4 %)
IV class NYHA	5 (7,9 %)	11 (12,1 %)	2 (28,6 %)
Hypertensive disease	58 (58 %)	106 (75,1 %)	39 (78,0 %)
Diabetes mellitus	10 (10 %)	27 (19,1 %)	7 (14,0 %)
History of myocardial infarction	39 (39 %)	47 (33,6 %)	21 (42,0 %)
History of CABG	3 (3 %)	3 (2,1 %)	3 (6 %)
History of PTCA	13 (13 %)	19 (13,6%)	7 (14 %)
Lipid metabolism troubles	47 (47 %)	67 (49%)	26 (53 %)
Hypo-, dis-, akynesia of the LV (EchoCG)	47 (47 %)	43 (60 %)	37 (79 %)
Ejection fraction <50% (EchoCG)	6 (6 %)	9 (6,4%)	1 (2 %)
LV EDD > 5,5 cm	10 (10 %)	8 (5,7 %)	1 (2 %)
Low exercise tolerance (VEM)	32 (32 %)	49 (35 %)	17 (58 %)
ST depression (ECG VEM)	51 (51 %)	66 (46,7 %)	19 (67 %)

age 51.3 years). Stable angina (SA) as determined by the Classification of the Canadian Cardiological Society was diagnosed in 65 patients, unstable angina (UA) — in 27 patients, 8 patients had an ongoing myocardial infarction (MI). Hypertension was revealed in 58 patients, and diabetes mellitus — in 10 patients. Three patients had a history of coronary artery bypass surgery, 13 underwent PTCA, 39 had a history of MI. Lipid metabolism disorders were found in 47% of cases, mostly Frederickson type 2B — 4. Instrumental assessment of cardiovascular system (EchoCG) revealed myocardial hypo-, dys- or akinesia in 47 patients, 6 subjects had ejection fraction below 50%, in 10 patients the left ventricular end-diastolic diameter (LV EDD) was over 5.5 cm. Bicycle stress test showed decreased exercise tolerance in 32 patients (exercise level not exceeding 12.5-50 Wt), ECG revealed ST segment depression over 1.5 mm from baseline in 51% of cases, 8 patients exhibited hypertensive reaction to exercise.

The second group (140 subjects) consisted of male patients with a mean age of 52.2. In 27.2% (38) CHD patients UA was present, 66.4% (93) patients had SA, and MI was found in 9 subjects (6.4%). Forty-seven subjects (33.6%) had a history of MI, 3 of these (2.1%) underwent coronary artery bypass grafting (CABG), PTCA was performed in 19 subjects (13.6%). In 75.1% CHD patients concomitant hypertension was present (106 patients), 27 (19%) subjects had diabetes mellitus. Lipid metabolism disorders was revealed in 49% (67) of the participants, of these 60% were classified as type 4, 30% — type 2B, 10% — type 2A (Frederickson scale). EchoCG revealed left ventricular hypo-, dys- or akinesia in 60% (43) of subjects, 9 patients (6.4%) had left ventricular ejection fraction (EF) below 50%. In 35% (49) subjects bicycle stress test showed decreased exercise tolerance, ST segment depression over 1.5 mm from baseline was found in 46.7% (66) subjects, 24% (17) of subjects exhibited hypertensive reaction to exercise.

The third group (50 subjects) consisted of male patients with CHD (mean age 54.1 years), among these 37 (74%) patients had UA, 6 (12%) patients — MI, 7 patients (14%) — stable angina (SA). Twenty-one (21) patients (42%) presented with a history of MI, 3 of these (6%) underwent CABG, PTCA was performed in 7 patients (14%). Comorbidities included hypertension in 75% of cases (38 subjects), diabetes mellitus in 14% of cases (7 patients). Lipid metabolism disorders was revealed in 53% of patients (n=26), among these 80% were Frederickson type 4 disorders, 12% — Frederickson type 2B. Left ventricular hypo-, dys- or akinesia was found on EchoCG in 79% of patients (n=37), left ventricular EF was below 50% in one patient. Bicycle stress test revealed decreased exercise tolerance in 58% of patients (n=17), ST segment depression over 1.5 mm from baseline — in 67% of patients, hypertensive reaction to exercise — in 34% of patients.

Clinical, laboratory and instrumental profile of the three groups is presented in Table 1, while Diagram 1 summarizes the percentage of different CHD forms in the groups.

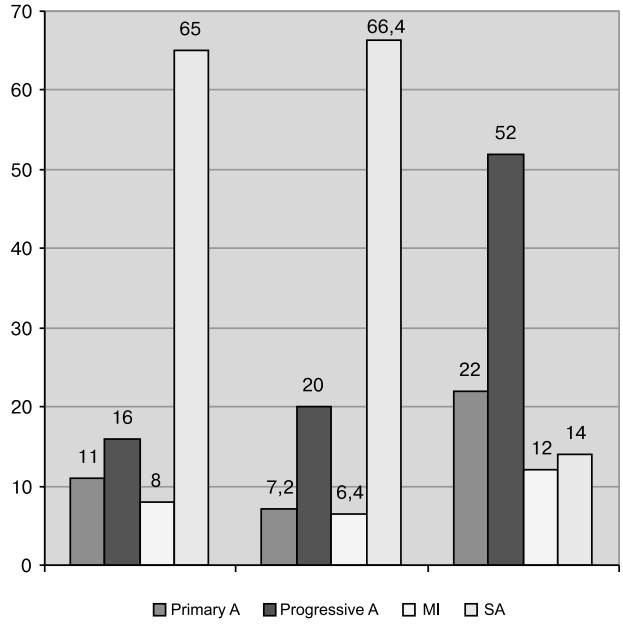

Diagram 1. Prevalence of different CHD forms (%) in the three patient groups

Acute coronary syndrome (ACS) was found in 35% of patients (n=35) in the first group, 33.6% of patients (n=47) in the second group, and in 86% of patients (n=43) in the third group. The rate of stable angina was

65% in the first group, 66.4% in the second group, and 14% in the third group.

Coronary angiographic changes are presented on Diagrams 2 and 3.

Analysis of angiographic images defined i50%

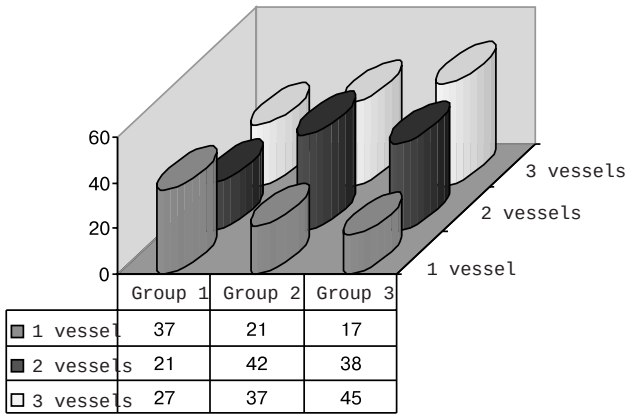

Diagram 2. Prevalence of the amount of damaged coronary arteries (%) in three groups of patients

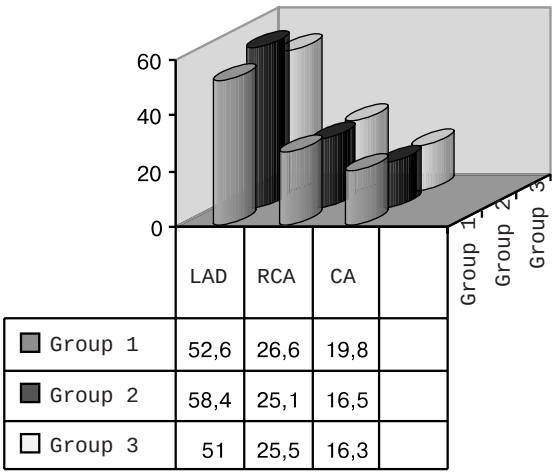

Diagram 3. The prevalence of damaged coronary arteries (%) in the three groups of patients

stenosis as hemodynamically significant. Single artery stenosis was found in 37% of patients (n=37) in the first group, in 21% of patients (n=29) in the second group, and in 17% of patients (n=9) in the third group. Two-artery disease was revealed in 32 patients (32%) of the first group, 59 patients (42%) of the second group, and 19 patients (38%) of the third group. Three-artery disease was found in 31 patients (31%) of the first group, 52 patients (37%) of the second group, and 22 patients (45%) of the third group.

Prevalence of the affected coronary arteries in the three groups is presented on Diagram 3.

Overall prevalence of LAD stenosis was over 50%, RCA stenosis — over 25%, CA stenosis — over 16%.

Pharmacological and Cost-Effectiveness Analysis/CEA — was used to compare various approaches to ATT techniques during PTCA with stenting and define the least expensive one. The price for the drug is divided by the nonprice efficacy index, expressed in specific units (46,47,48,93,216).

Clinical and economic analysis of various ATT techniques for PTCA with stenting consecutively included the following stages:

- clinical efficacy assessment of ATT techniques used; rates of acute and subacute thrombosis, nonfatal and fatal MI were used as efficacy criteria (Table 2);
- calculation of ATT costs (Tables 3,4,5,6);

Table 2. Rate of cardiac complications in the three patient groups

Group number	Acute myocardial infarction (nonfatal)	Acute myocardial infarction (fatal)
1	1 (1 %)	1 (1 %)
2	2 (1,4 %)	—
3	—	—

- calculation of cost-effectiveness ratio for the studied drugs from the formula:

$$CER=C:Ef,$$

where: CER — cost-effectiveness ratio: cost required to achieve clinical effect;
C — cost of the procedure;
Ef — efficacy of the procedure expressed in corresponding units.

The State costs registry of vitally essential and major drugs of the Russian Federation Ministry of Health and The stock of pharmaceutical data (2000) were used to calculate the cost of antithrombotic therapy.

Results and discussion

The rate of successful PTCA with stenting and type 1 ATT was 98% in the first group, while the costs reached 607640.0 rubles. The rate of successful PTCA and type 2 ATT was 98.7% in the second group (140 subjects), while the costs reached 445144.0 rubles. The rate of successful PTCA with stenting and ATT in the third group (50 subjects) was 100%, while the cost of therapy in patients receiving ReoPro was

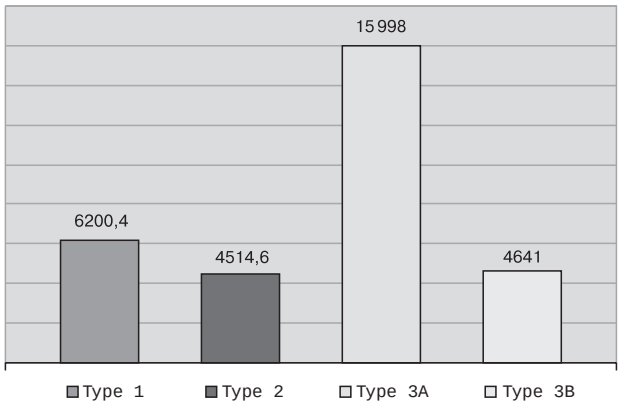

Diagram 4. Cost-Effectiveness Ratio for different types of antithrombotic therapy

Table 3. Cost of antithrombotic agents

Drug name, mg/U	Form of production/ amount per pack	Price per pack, rbl.	Mean price of 1 tablet/ bottle, rbl.	Recommended daily dose, mg	Cost of the daily dose
Aspirin cardio, 100 mg	Tablets, 20	101,26	5,06	100 мг	5,06
Ticlid, 250 mg	Tablets,20	623,20	31,16	500 мг	62,32
Heparin, 5000 U/ml	Bottle. 5x5 ml	60,0	12,0	15 000 ЕД, 40 000 ЕД	12,0-24,0
ReoPro 2 mg /ml	Bottle. 10 mg/5 ml	17200,0	17200,0	29,4 mg(with body weight up to 90 kg)	51083,0
Integrilin 0,75 mg /ml	Bottle. 10 mg/ml for bolus, 75 mg/ 100ml for infusion	1923,0 5678,0	923,0 5678,0	291,6 mg(with body weight up to 90 kg)	22778,4
Fraxiparin	Syringe-ampoule, 10x0,3 ml	1150,0	115,0	0,6 мл	230,0

Table 4. Cost of antithrombotic agents used in the three groups

ATT type/drug name	Recommended daily dose	Daily dose cost, rubles	Course dose cost, rubles
Type 1: Ticlid Aspirin cardio Heparin	500 mg 100 mg 34,000 IU	62,32 10,12 24,0 TOTAL: 96,44	1869,6 333,96 24,0 TOTAL: 2227,56
Type 2: Ticlid Aspirin cardio Heparin Fraxiparin	500 mg 100 mg 15000 IU 0,6 ml	62,32 10,12 12,02 30,0 TOTAL: 314,44	1869,6 333,96 12,0 230,0 TOTAL: 2445,56
Type 3: a) ReoPro+Heparin	0.25 mg\kg i.v. bolus injection, followed by continuous infusion in a dose of 10 mg/min over 12 h; 10000 IU bolus injection; continuous infusion in a dose of 7 IU/kg/min over 12 h following ReoPro infusion	51083,0 12,0 192,0 TOTAL: 51287,0	51083,0 12,0 192,0 TOTAL: 51287,0
Type 3: b) Integrilin+Heparin	Two bolus i.v. injections in a dose of 0.18 mg\kg, followed by continuous infusion is a dose of 2 mg/kg/min over 24 h. 7500-10000 IU bolus injection	22778,4 12,0 TOTAL: 22790,4	22778,4 12,0 TOTAL: 22790,4

Table 5. Cost of laboratory study in the three patient groups receiving different ATT

ATT technique	List of studies	Study cost(rbls)	Number of studies	Total cost of all studies (rbls)
Type 1: Ticlid Aspirin cardio Heparin	Total blood count Coagulation study APTT	90,76 326,65 67,71	3 1 48	272,28 326,65 3250,08 TOTAL: 3849,01
Type 2: Ticlid Aspirin cardio Heparin Fraxiparin	Total blood count Coagulation study APTT	90,76 326,65 67,71	3 1 2	272,28 326,65 135,42 TOTAL: 734,35
Type 3: a) ReoPro + Heparin	Total blood count Coagulation study APTT	90,76 326,65 67,71	1 1 24	90,76 326,65 1625,04
Type 3: b) Heparin + Integrilin	Total blood count Coagulation study	90,76 326,65	1 1	90,76 326,65 TOTAL: 417,41

1599882.0 rubles, and in patients receiving Integrilin 464156.0 rubles.

Cost-Effectiveness Ratio (CER) values in the three groups are presented on Diagram 4.

Cost-Effectiveness Ratio in the first group was: CER-1 = 607640,0 : 98= 6200,4. In the second group the Cost-Effectiveness Ratio was: CER-2 = 445144,0 : 98,6 = 4514,6. The Cost-Effectiveness Ratio in the subgroup of patients receiving ReoPro (the third group) was: CER-3A = 1599882,0 : 100 = 15998,8, and in the subgroup of patients receiving

Table 6. Costs of ATT for PTA with stenting per patient and per group

Group of patients	Cost of medica-tions (rbls)	Cost of laboratory study (rbls)	Total cost per patient (rbls)	Total cost per patient group (rbls)
First group	2227,6	3849,0	6076,4	607640,0
Second group	2445,6	734,4	3179,6	445144,0
First subgroup of the third group (ReoPro)	51287,0	2042,4	53329,4	1599882,0
Second subgroup of the third group (integrilin)	22790,4	417,4	23207,8	464156,0

Integrilin was: CER-3B = 464156,0 : 100 = 4641,0.

Due to the fact, that all major complications of PTCA with stenting in the first and the second groups occurred in ACS patients, whereas in patients of the third group with similar condition no such events were present, calculation of ATT and CER costs was performed to make the data for clinical and economical analysis more objective and comparable.

Financial costs of ATT and PTCA with stenting in ACS patients are summarized in Table 7, and the proportion of Cost-Effectiveness Ratios — on Diagram 5.

The value of Cost-Effectiveness Ratio in ACS

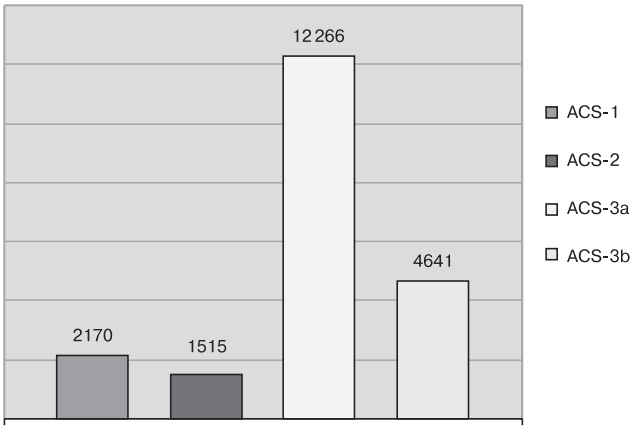

Diagram 5. Cost-Effectiveness Ratio in ACS patients from the three groups

patients of the first group was:

CER-1 = 212674,0 : 98 = 2170,1.

The value of Cost-Effectiveness Ratio in ACS patients of the second group was:

CER-2 = 149441,0 : 98,6 = 1515,6.

The value of Cost-Effectiveness Ratio in the subgroup of ACS patients (third group) receiving ReoPro was:

CER-3A = 1226576,2 : 100 = 12265,7;

and, in the subgroup receiving Integrilin:

CER-3B = 464156,0 : 100 = 4641,0.

Conclusions

1. In the study groups of CHD patients, who underwent PTCA with stenting, ATT with oral aspirin and ticlid, intra-arterial bolus injection of heparin and s.c. administration of fraxiparin was most cost-effective.

2. In the group of ACS patients receiving ATT with platelet GP IIb/IIIa antagonists, Integrilin therapy was least expensive among techniques of equal efficacy.

Table 7. Costs of ATT for PTA with stenting in ACS patients

Group of patients	Cost of medications(rbls)	Cost of laboratory study(rbls)	Total cost per patient(rbls)	Total cost per patient group (rbls)
Group 1 — 35 subjects	2227,6	3849,0	6076,4	212674,0
Group 2 — 47 subjects	2445,6	734,4	3179,6	149441,0
Group 3a (ReoPro) — 23 subjects	51287,0	2042,4	53329,4	1226576,0
Group 3b (integrilin) — 20 subjects	22790,4	417,4	23207,8	464156,0

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The place of angioplasty in the treatment of femoral artery occlusion over 10 cm in length

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Femoral artery is the most common location of peripheral arterial disease (PAD) involving lower extremities. This localization is responsible for symptomatic PAD in general population aged over 50 in 1% of cases, and in patients with peripheral atherosclerosis — in 55% of cases (1).

This group of patients is clinically beneficial and around 78% of those with claudication remain stable for 6 years on medical therapy alone (2). Disabling claudication and limb-threatening ischemia are the indications for revascularization (surgical reconstruction or angioplasty). To date bypass grafting has been the method of choice.

Percutaneous transluminal angioplasty (PTA) has been extensively implicated as a therapy for femoral artery occlusions for almost 40 years. The potential for recanalization of prolonged occlusions, good immediate results, easy performance, minimal rate of complications have gradually extended indications to PTA and, currently, this procedure is performed even in patients with severe and disseminated disease of peripheral arteries.

Despite the development of techniques and instruments, the wide acceptance of stenting and the enthusiasm of investigators, the long-term outcome of PTA in the 90-s was not consistent with the results of reconstructive surgery.

Clinical trials showed 2-year patency rate after angioplasty to be 46 to 79% and 5-year patency — 36 to 45% (3-8). Similar results restricted the wide use of PTA in femoropopliteal segment (8-10).

These results substantially differ from those with aortoiliac segment, where the role of angioplasty is significantly higher and the long-term results are similar to reconstructive surgery (10-11).

Nevertheless, multivariate studies are being performed to decide when PTA is more beneficial as compared to reconstructive surgery and to determine factors affecting the long-term results. This paper summarizes our experience with angioplasty for femoral artery occlusions (over 10 cm in length).

Materials and methods. Since 1993 through 2002 we had performed 73 endovascular recanalizations of superficial femoral artery (SFA) occlusions in 58 patients (56 men and 2 women). The length of occlusion was over 10 cm (11 to 26 cm, mean 15.5 cm). Eight occlusions in 7 patients involved the entire length of SFA from its origin to the Hunter's channel.

All patients had 10-year history of disease or less. Patient age ranged from 52 to 80 years (mean 61.5 ± 9.8 years). There were 28 smokers (48.3%), 30 patients with hypertension (51.7%), hypercholesterolemia was detected in 24 patients (41.4%) and diabetes mellitus — in 13 patients (22.4%). Coronary heart disease was observed in 27 patients (46.6%). Indications to minimally invasive surgery were determined by the results of noninvasive procedures and angiography.

Clinical signs. Claudication alone was found in 42 limbs (57.5%), rest pain — in 10 limbs (13.7%), ischemic ulcers and necrosis — in 18 (24.7%), and acute ischemia — in 3 (4.1%).

Mean ankle-brachial index (ABI) in patients with claudication prior to surgery was 0.61 (± 0.11) vs 0.39 (± 0.12) in patients with critical ischemia.

However, interventions were relatively often combined with popliteal-tibial angioplasty (9 patients, 14.3%) and, particularly, with the angioplasty of aortoiliac segment (17 patients, 25.4%). Therefore, good inflow and outflow was provided, which partially determined beneficial long-term results of angioplasty.

Technique. Recanalization was performed with "Road Runner" hydrophilic guidewire (COOK) and was successful in 73 (92.4%) out of 79 cases. The following approaches were used: antegrade femoral approach in 65 cases and retrograde popliteal approach in 8 cases.

Antegrade recanalization was performed if the proximal stump of SFA was observed, retrograde popliteal approach was used when no stump was detected. However, the major cause of failure during antegrade recanalization was the absence of SFA stump and the presence of large collateral vessel, originating from the occlusion site.

Guidewire recanalization was followed by balloon angioplasty with "Opta" (Cordis) 5F catheter 5, 6 or 7 mm in diameter and 100 mm in length.

A total of 195 stents were deployed, including COOK ZA-stents (stent index 2.67) 40, 60 and 80 mm in length and 6 to 8 mm in diameter. Stenting was per-

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formed in selected sites of residual stenosis or occluding dissection.

Maximum number of stents deployed in a single SFA was 4.

Anesthesia. Local anesthesia was used in all cases.

Medical therapy: symptomatic therapy + Plavix 75 daily 3-4 days prior to intervention, intraoperatively — heparin 100 MU/kg, postoperatively — heparin 1000 MU/h tapered to lower dose and change to low-molecule heparin (fraxiparine) 0.6 daily during 2 weeks + plavix (6 weeks) + Aspirin-cardio 100 mg daily.

Mean hospital stay was 2.5 days (2 to 4 days).

RESULTS

Immediate results: In all cases good angiographical and clinical outcome was obtained following successful guidewire recanalization with subsequent balloon dilation and stenting. Complications were observed in 4 patients (6.0%). Distal arterial embolization was encountered in 2 cases, in another 2 cases false aneurysm formation at the puncture site was observed. Peripheral macroembolizations causing obstruction of popliteal artery or tibial arteries were the major complications following recanalization of chronic occlusions. In one case the embolus was aspirated through catheter, in the other case it was retracted into the anterior tibial artery and removed by open embolectomy. False aneurysms were treated with ultrasound-controlled compression.

Short-term and long-term results: Assessment of the results was based on primary and secondary patency rates of the operated arteries.

Control follow-up included physical examination and non-invasive studies (ABI measurement and duplex ultrasound) at 3, 6, 12 months and every year thereafter.

Clinical success was defined as the improvement of symptoms, i0.15 increase of ankle-brachial index and/or normal peripheral pulse. Mean ABI increased to 0.86 ± 0.22 ($p < 0.01$) for claudication at baseline and to 0.78 ± 0.14 ($p < 0.01$) for critical ischemia at baseline.

Long-term (36 months and thereafter) follow-up was conducted in 31 patients with 38 recanalization procedures. Restenosis over 50% was revealed in 11 arteries (28.9%), recurrent occlusions — in 7 arteries (18.4%). Repeated angioplasty was performed in all such patients. Femoropopliteal bypass grafting due to the failure of repeated recanalization was carried out only in one patient. Three patients underwent repeated angioplasty within 96 months 3 times each, another patient had 4 angioplasty procedures with patent SFA. Interestingly, patent proximal portion of popliteal artery was associated with most favorable results both immediately and in the long-term follow-up. Restenosis was more common in distal portion of SFA (Hunter's channel) as compared to proximal portions. Recurrent occlusion of superficial femoral artery was not associated with severe symptoms, characteristic for acute occlusion. The 5-year primary patency rate following angioplasty was 76%, whereas secondary patency rate — 84.5%. Complications included arteriovenous fistula formation in one patient due to repeated puncture of popliteal artery. The fistula was separated surgically. No lethal cases were observed. No amputations were performed. Clinical improvement of limb blood supply and, correspondingly, of the quality of life was achieved in all cases.

Cumulative patency rate was calculated using Kaplan-Meier method and compared to log-rank test results as shown on the diagram in figure №1.

The following clinical observation can be given as

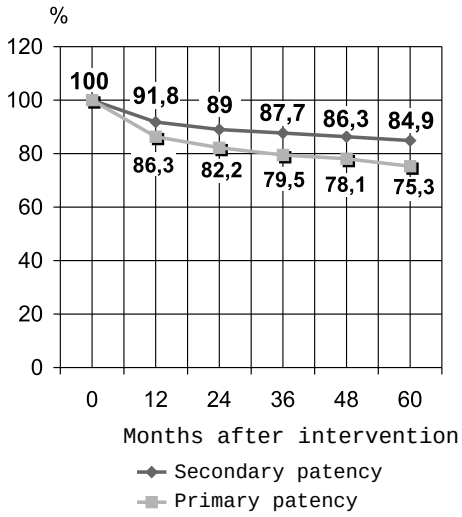

Figure № 1. Cumulative primary and secondary patency rate following PTA of superficial femoral artery

an example:

Patient G., aged 51, presented with 10-year history of bilateral claudication and 150 m pain-free walking distance. On admission both limbs were warm, had normal color, movements and sensitivity, palpation of sural muscles was painful. Pulse was found only on femoral arteries and absent distally. The degree of ischemia was determined as 2B. ABI was 0.56 on either side.

Angiography revealed subtotal stenosis in the distal portion of the right common iliac artery (CIA), 70% stenosis of the right common femoral artery (CFA) bifurcation, 4 cm long occlusion of the right SFA with Hunter's channel, occlusion of the left SFA extending from its origin to popliteal artery, patent popliteal and infrapopliteal arteries without any flow limiting stenoses. See fig. № 2.

The patient underwent balloon angioplasty and stenting of the right CIA and CFA, recanalization of both SFA followed by balloon angioplasty and stenting performed via popliteal approach on either side. Balloon angioplasty of CIA and CFA was conducted with 10 and 7 mm balloon and accompanied with stenting: stent length 10 and 60 mm in CIA, 8 and 40

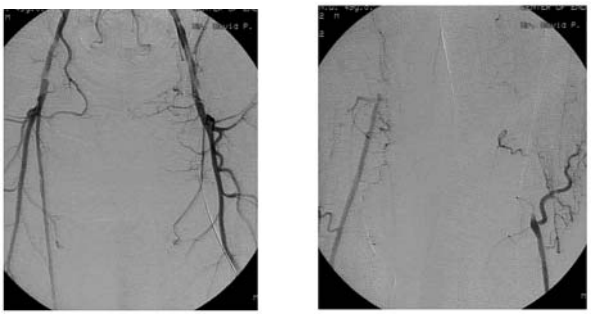

Fig. № 2. Preoperative angiography results

mm in CFA, respectively. Recanalization of SFA was perfomed on both sides using hydrophilic "Road Runner" guidewire with subsequent balloon angioplasty using 6 and 7 mm balloons and stenting. ZA stents of the corresponding diameter and 40 to 80 mm in length were deployed in all arteries. A total of 6 stents were used in the following arteries: right CIA, right CFA, right SFA. Three stents were deployed in the left SFA: 1 in the proximal portion starting from the origin, 2 in the Hunter's channel. See fig. №3.

Distinct pulsation of all arteries was found postop-

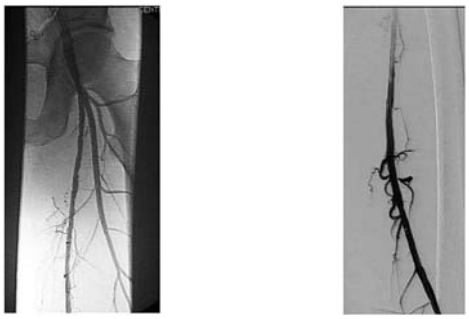

Fig. № 3. Completion angiography following recanalization and stenting of the left SFA

eratively, the patient was discharged 2 days following angioplasty.

Six months later the patient felt numbness of the left foot while walking. Duplex ultrasound revealed 80% stenosis of the left SFA proximal to Hunter's channel. The ABI on the left side was 0.7. Angiography showed stenosis of the left SFA located on the border of middle and distal thirds of the artery just above the stents deployed, no changes were found in other arteries or previously stented portions. Balloon dilation was conducted via popliteal approach and another stent was placed in the left SFA proximally to the previous one. The patient was discharged at day 2 with completely restored blood supply of the left limb and ABI of 0.86.

The patient presented again with left-sided claudication 1.5 years following primary angioplasty and 1 year following the repeated procedure. Pain-free walking distance was 400 m, right limb was normal. Moderate edema of the left foot was also noted by the patient. ABI on the left side was 0.64. Repeated angiography was performed via radial artery approach, which revealed in-stent restenosis in the left SFA origin and restenosis in the middle portion of the left SFA, where stent was not deployed; restenosis within the Hunter's channel. The right limb had no hemodynamic lesions. Arteriovenous shunting of blood between popliteal artery and vein was found in the left limb. See fig. 4a and 4b

Left popliteal artery was exposed via the approach in popliteal region, arteriovenous fistula ligated,

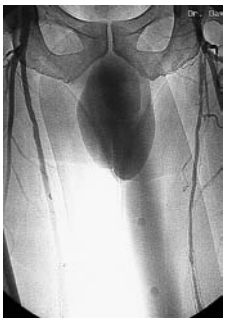

Fig. №4a. Completion transradial angiography at 18 months

Fig. №4b. Preoperative angiography at 18 months showing arteriovenous shunting. Popliteal approach

popliteal artery punctured and balloon angioplasty performed in the left SFA with good immediate outcome, not requiring additional stenting. See fig. №5 .

The patient was discharged at day 4 with clinical recovery and an increase of ABI to 0.89.

This clinical observation is remarkable for the fact,

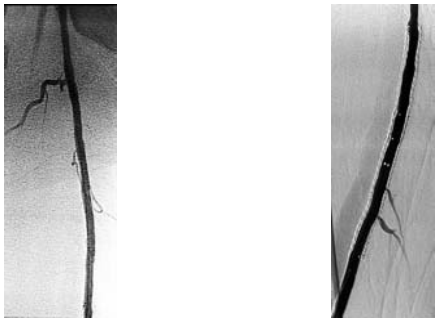

Fig. №5 . Completion angiography following PTA of the left SFA

that the patient underwent multi-level angioplasty of the large limb arteries for occlusion. Repeated puncture of the popliteal artery caused the formation of an arteriovenous fistula, requiring surgery. A total of 7 stents were implanted. Despite the repeated interventions all native large arteries of limbs remain patent, hospital stay was short and the surgery sparing and minimally invasive, leaving a way for another therapies in the future.

DISCUSSION

The use of PTA for the management of SFA occlusions has been reported many times and the results vary greatly concerning both clinical and angiographical indications to this method and the long-term results. As for the surgical technique (methods and mechanisms of recanalization, surgical approach, instruments and stents), in general it is well established. There are

several factors affecting the long-term results of PTA, but the angiographic criteria can be considered the major ones, therefore, they determine long-term patency of the artery (5,6,12,13). Lesion length and location, blood outflow capabilities are the main criteria, which determine success or unfavorable outcome. Till now the common opinion was that PTA can be successfully used for SFA stenosis and short (< 5 cm in length) occlusions with normal distal arterial vasculature, in other patients conventional grafting is indicated (G.Agrifiglio et al, 1999). This fact is consistent with the results of PTA for prolonged femoropopliteal lesions (17, 6). In addition, patency depends on the location of lesion: more distal intervention leads to less favorable results.

PTA with stenting merits special discussion. Residual stenoses after angioplasty (dissections, intimal flaps, elastic recoil) are the indication for femoropopliteal stenting. However, Bergeron et al. reported that stents caused neointimal hyperplasia already 4 months following stent implantation (11). Several other studies concerning long-term results of stenting in this area suggested, that restenosis occurs in 20 to 40% of patients within 6 to 24 months irrespective of the stent type (11). Authors are striving to determine the cause of high restenosis rate, regarding stenting for occlusions as one of them. Thus, stenting after recanalization leads to restenosis in 33-40% of cases, whereas stenting of stenoses is associated with restenosis only in 9-18% of cases. The SFA location of stenting is considered the second cause. Restenosis rate is 40% in the lower third of hip and only 9% in the upper third. The number of stents implanted, i.e. the length of artery covered with stents, affects the rate of restenosis as well: 1 stent gives 3.6% restenosis rate within 6 months and 18% within 4 years, while 2 or more stents give 7.9% and 34%, respectively (25). It is generally believed, that stenting does not improve the long-term results of femoropopliteal segment surgery, as it leads to the increase of restenosis rate. An attempt to use sirolimus-covered "Smart" nitinol stents (Cordis) for SFA angioplasty showed better results with respect to primary patency over the control within 6 months. However, the results became almost similar at 12 months (29).

CONCLUSIONS

According to our experience, "topical" (performed for residual stenosis and occluding dissection) stenting is a method, which gives satisfactory results of angioplasty for SFA occlusion, thus preventing acute thrombosis and early repeated occlusion of the operated artery.

We believe that the improvement of PTA results is only possible due to aggressive redo interventions. Only repeated intervention can lead to the improvement of long-term results and patency rates of the stented portion. This is supported by other authors (11, 24, 27).

How much and how frequent can PTA be performed for restenosis? Our experience suggests, that PTA can be conducted endlessly after recanalization with subsequent implantation of additional stents or without stenting. Is there any reason to fear restenosis and can it be the cause to refuse from PTA for prolonged SFA occlusion? — the answer is NO. What does PTA give to a patient as compared to grafting? First of all, minimum hospital stay without turning away from everyday activities for a long time, minimum number of complications and rapid postoperative recovery due to minor operative injury, the possibility to perform multi-level vascular interventions in order to improve "inflow" and "outflow", allowing for complete restoration of blood supply in the compromised limb or even in both limbs.

If restenosis occurs after stenting, there's always a possibility for repeated PTA, leading to complete restoration of blood flow. The procedure requires periodic medical assessment by vascular surgeon and duplex ultrasound control of the repaired artery, as well as permanent anticoagulation and antiplatelet therapy after surgery. Indeed, after recanalization and stenting the artery requires attention and care from the patient and the doctor, but is it so different from postoperative management in reconstructive surgery? However, dealing with PTA we preserve native artery, giving the patient an option for repeated interventions in case of vascular "catastrophe" in the operated artery, which is utterly difficult and, in most cases, impossible after surgical repair. The only major drawback of PTA for recanalization of prolonged overweighed by the above listed undeniable benefits.

High secondary patency rate after stenting is directly associated with mandatory non-invasive periodic duplex study of the angioplasty site performed for most early diagnosis and treatment of neointimal hyperplasia.

According to the results of the study and published data we consider PTA a method of choice for the treatment of femoral artery occlusions.

Choice of the method in patients with SFA lesions is based on the analysis of patient's general condition (taking into account the age and the comorbidities); investigation methods (length and degree of involvement of the distal arterial branches), as well as the degree of ischemia and the presence of trophic lesions or infection.

Angioplasty is indicated in elderly patients with severe comorbidities — diabetes mellitus, CHD and other diseases associated with local or diffuse SFA changes.

The use of angioplasty and stenting for prolonged occlusions of SFA ensures satisfactory results in the majority of cases, both immediately after surgery and in the long-term period, which is comparable to or, in some instances, superior to the conventional methods.

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Heart Transplantation in Grown-Up Congenital Heart (GUCH) Patients

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Advances in surgical and medical management of congenital heart disease have resulted in the survival of an increasing number of grown-up congenital heart (GUCH) patients. As myocardial dysfunction can occur, some of them require heart transplantation (HTx).

The number of grown-up congenital hearts (GUCH) comparing with adult patients with acquired heart disease is small and accounts for only 6% of adult cardiac medicine and surgery. About 20 % of GUCH hospital admissions are for cardiac surgery, mostly for reoperations and rarely for primary correction of CHD such as congenital aortic stenos, secundum atrial septal defects, and occasionally, Ebstein anomaly, tetralogy of Fallot or more complex anomalies (1). It was estimated that in United Kingdom they need at least another 20 suitably trained cardiologists for adult congenital heart disease. The number of adult patients with congenital heart disease is likely to increase from 110,000 to 140,000 by 2010, therefore even more cardiologists and operations will be necessary (2). The most common cardiological problem in GUCH are the arrhythmias: frequently atrial flutter, followed by complete heart block /pacemaker problems, atrial fibrillation and ventricular or supraventricular tachycardias (3)

Very special group of GUCH patients are the patients in whom heart transplantation is necessary because of advanced heart failure and absence of other surgical options.

In several published series, this subset of patients represented a very small group of candidates for heart transplantation (4-7)

Indications and contraindications

The indications for transplantation in adolescent group (11-17 years) mirror that for the adult population, with cardiomyopathy in 65% of cases and congenital heart disease in 25 % of cases(8). Most frequent indications for heart transplantation in GUCH patients are failed reconstructive or palliative operations for acquired systemic ventricle failure (Mustard, Senning, Fontan) or specific complications such as a protein-losing enteropathy (Fontan). (Table 1) (8-10). Contraindications for heart transplantation include an irreversible pulmonary vascular resistance index greater than 6 units, not responding to vasodilatation tests and transpulmonary gradient more than 15 mm Hg, and pulmonary artery tree hypoplasia. Other contraindications are similar to those for adult heart transplantation (Table 2).

Table 1. Indications for Transplantation in Congenital Heart Disease. (Modified after J.Odim, 2000)

HLHS
Aortic stenosis with LV endocardial fibroelastosis
Unbalanced AV canal with LV hypoplasia *
HLHS equivalent malformations
L-TGA with single ventricle and heart block *
Extensive cardiac tumors
Dilated cardiomyopathy
Ischemic cardiomyopathy (ACAPA) *
Intractable arrhythmias
Dilatated or hypertrophic cardiomyopathy **
Failed reconstructive and palliative operations with acquired myopathy (Mustard, Senning, Fontan) **
Protein-losing enteropathy **

* Controversial indications.
** GUCH Patients

Table 2. Contraindications to Transplantation for Congenital Heart Disease (J.Odim, 2000)

Irreversible PVRI > 6 units/m^2
Irreversible TPG > 15 mm Hg.
Active infection and sepsis
Severe metabolic disease
Severe hepatic dysfunction
Active malignancy (except primary brain tumor)
Multiple congenital anomalies
Advanced multiple organ failure (Artificial heart ?)
Socioeconomic factors (noncompliance).

Waiting list and mortality

As noted by J Somerville: "The glamour for transplantation is understandable, but there are difficult

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issues affecting transplantation in GUCH. The operated complex patients do not so well as other patients group. With increasing recipients and decreasing donors, the GUCH remain at the bottom of the priority list and many become untranslatable by the time an organ is available" (3).

Optimal age for heart transplantation in GUCH

Despite extensive experience with pediatric heart transplantation there is very limited number of publications dealing with heart transplantation in GUCH patients (11). The transplantation anatomy is often very complicated because of previous operations or unusual arrangement of the great vessels and venous anomalies.

It is very difficult to define the optimal age for heart transplantation in GUCH patients.

Many factors should be taken into the account, such as an unnatural history and prognosis, technical possibility to perform heart transplantation, general condition.

GUCH patients are quite sick at the time of transplantation and it is very difficult to recommend transplantation to a patient who feels relatively well, despite obvious complications of advanced operated or non-operated congenital heart disease. Usually transplantation is indicated in end-stage congenital heart defects when all available (or conventional, or standard) medical or surgical measures are ineffective. The following criteria of end-stage congenital heart disease were defined (12):

1. Progressive deterioration of ventricular function or functional status despite optimal medical care.
2. Growth failure attributable to severe congestive heart failure, which is irresponsive to conventional medical treatment.
3. Malignant arrhythmias or survival of cardiac arrest unresponsive to medical or surgical treatment.
4. Need for ongoing intravenous inotropic support
5. Unacceptably poor quality of life
6. Progressive pulmonary hypertension that would preclude cardiac transplantation at a later date.

Individualized approach in complex GUCH

Adult GUCH patients presented for heart transplantation often have complex extracardiac anatomy. Therefore individualized approach is necessary with modifications of the standard technique to fit the anatomical variations of a particular patient. In general, the sickest patients need the best donor hearts. The pre-transplantation evaluation of patients with complex heart defects and often after multiple previous operations must accurately define cardiac and great vessel anatomy and spatial relationships. All venous anomalies as well as all surgical shunts also must be identified. Preoperative planning of the surgical procedure and reconstruction modalities must be discussed with pediatric (GUCH) cardiologist. Preoperative cross-matching as well as avoidance of blood transfusion before transplantation are important to minimize rejection. The preoperative risk may be enhanced by such factors as laborious dissection, increased bleeding, correction of coexisting extracardiac defects, and re-establishment of normal anatomy in positional, arterial and venous anomalies. Extended graft ischemic time and operative time also may play an important role (10, 13).

Donor heart harvesting

The surgeons must have an operative plan in order to know what specific donor tissue will be necessary for surgical reconstruction.

Modification of donor heart harvesting techniques must be considered in details to promote complex reconstruction during heart transplantation. Excess donor tissue is necessary to correct atrial abnormalities. To adopt the graft structures to complex recipient's anatomy and to enable correction of some of the recipient's anomalies, the donor heart should be removed en block including the entire ascending aorta, transverse arch, pulmonary artery bifurcation and both pulmonary arteries (14). The right internal jugular and innominate veins should be harvested in continuity. Donor's pericardium or descending aorta can be used for patch reconstruction of the stenotic pulmonary artery branches or atria abnormalities (15). Cooperation with lung transplantation team is necessary to obtain necessary length of the pulmonary arteries. Coordination between the donor and recipient teams is of critical importance in patients after multiple previous operations, and time should be given for meticulous dissection in re-do patients.

Techniques of heart transplantation

Heart transplantation in GUCH patient frequently represents a technical challenge for the surgeon because of previous palliative operations and complex structural anomalies (16)

Surgical improvisation based on anatomical findings at the time of transplantation may be necessary (10). Growth potential problems of anastomosis don't rise in adults. Therefore in some difficult cases prosthetic conduits can be used (17). Individual modifications should be tailored to patients' great vessels' and atrial anatomy. In some specific situations one should consider the use of modified cannulation technique as well as of deep hypothermia and circulatory arrest. Femoral or rarely neck cannulation is safer in patients after previous operations and calcified homografts beneath sternum. Transesophageal echocardiography is important to evaluate immediate results of surgical reconstruction. Routine use of aprotonin seems to reduce bleeding events. (9, 18)

SPECIFIC SURGICAL PROBLEMS

Position anomalies

Heart transplantation represents the most complex problem in patients with situs inversus (16). Some

anatomic relationships appear to be almost constantly preserved in patients with situs inversus: the left atrium and the main pulmonary artery are midline structures; the aorta is usually to the left of the pulmonary artery as they both exit the pericardium, even in patients with transposition abnormalities (19). Reconstruction of the mirror-image systemic venous inflow tracts remains the operative challenge in such patients, because the left atrium, aorta and pulmonary artery usually are situated near the midline. Opening the donor's left atrium between right superior and inferior pulmonary veins serves the purpose of juxtaposing donor and recipient pulmonary atria near the midline. (20). There are only few reports dealing with this issue in adult patients. (17,20,21). Transplantation technique varies. A simplified technique has been reported by Vricella at all (20).

Donor cardiectomy should be performed with en block removal of the superior vena cava and innominate vein which later will be used for reconstruction of cephalic venous drainage in the recipient . Operation is performed using deep hypothermia with intermittent circulatory arrest for proper exposure. Recipients' cardiotomy is performed leaving a small pulmonary atrial cuff and atrial tissue in continuity with left positioned inferior vena cava. It is important to perform a wide excision of the left pericardium to allow left-sided rotation of the graft after implantation.

Donor graft is then prepared by ligation of the left pulmonary venous orifices and opening the left atrium vertically and horizontally between right pulmonary veins to align donor-recipient's right sided pulmonary atrium for anastomosis which is performed first.

After cardiotomy, the IVC and attached portion of systemic atrium are configured into a rightward rerouting conduit. The pulmonary artery is opened to the left of the midline and partially oversewn to the right, allowing the anastomosis site to be placed to the left of the aorta. The pulmonary venous atrial cuff lies slightly to the right of the midline. The conduit formed by donor SVC and innominate vein is connected to the left-sided native SVC after being positioned in the transverse sinus behind the great arteries. The conduit formed by donor's SVC and innominate vein is connected to the left-sided native SVC, in front of the aortic and pulmonary anastomosis. Transesophageal echocardiography is essential to assess patency of venous connections.

In 1998 Vricella at al (20) reported 15 patients with situs inversus (among them only one adult patient), with 14 immediate survivors.

Surgical complications included obstruction of superior vena cava drainage and rarely phrenic nerve palsy.

Venous return anomalies

Congenital anomalies of the atria pulmonary venous return, and systemic venous return are regarded by some surgeons as anatomical contraindications to orthotopic heart transplantation.

Surgical modifications include atrial septation in patients after Mustard operation, atrial enlargement, inferior and superior reroofing in patients with left superior vena cava draining into the left atrium. These techniques were described by Claude Chatarand in 1991 (5) and allowed to correct most atrial, pulmonary venous and systemic venous return anomalies during orthotopic heart transplantation.

Recipients who have previously undergone a cavo-pulmonary shunt, require reconstruction of the superior vena cava. Side-to-side anastomosis of the donor internal jugular vein and innominate vein will lengthen the donor SVC and permits reconstruction of the SVC with autologous tissue. To connect the left superior vena cava to the right atrium, Gore-Tex conduit, donor's aorta or tunnel formed from recipients left atrial wall can be used (13).

Transposition complexes

The pre-transplantation evaluation of the patients with transposition complex must accurately define cardiac and great vessel anatomy and spatial relationships.

All surgical shunts also must be identified and divided after initiation of CPB. Recipient's great vessels should be divided just above semilunar valves. Extensive mobilization of both great arteries is necessary to prevent distortion of the heart (15). Donor heart preparation should be modified similarly to that for patients with venous return anomalies. Adequate length of recipient's aorta and main pulmonary artery permits correct anatomical orientation of the great vessels. The superior aspect of the donor transverse arch is anastomosed to the recipient's aorta. Added donor great vessels' length will permit proper anatomical orientation of donor and recipient aorta and pulmonary arteries without unnecessary tension and torsion, and use of vascular prosthesis can be avoided. Patients with corrected transposition of the great arteries require additional aortic length.

Post-Fontan patients

Two groups of such patients can be identified: first, the patients after acute failing Fontan circulation, and second, the patients with long-term complications such as an end-stage myocardial failure or protein-losing enteropathy. Nowadays patients with acute failing Fontan circulation are rare, due to established selection criteria and very low mortality after lateral tunnel or extracardiac Fontan operations. The late failure of Fontan operation is difficult to predict (17). It occurs more commonly in high-risk Fontan patients (11), but can also be expected in a substantial number of ideal Fontan candidates during adulthood because of systemic ventricle failure. Failing Fontan circulation was identified as a risk factor for early death (10). Preoperative evaluation of Fontan patients is difficult. They are at risk to develop pulmonary arteriovenous malformations and can have aortopulmonary collaterals which may contribute to cyanosis and heart failure, the passive flow physiology increasing the possibility

of ventilation-perfusion mismatch (10). Evaluation of pulmonary vascular resistance is important, because in the presence of low Fontan flow, calculated resistance can be misleading. In patients with chronically failed Fontan circulation inotropic support is sometimes necessary before transplantation. They should be referred early and followed closely to identify optimal time for listing. Harvesting technique must be modified to obtain maximal length of great vessels. The pulmonary artery and superior caval vein reconstruction is often necessary.

Protein-losing enteropathy (PLE)

Protein-losing enteropathy after Fontan operation is a poorly understood condition. Incidence of protein-losing enteropathy after Fontan operation is 3.7 % (22). Average interval between surgery and the diagnosis of this complication is 2.7 years. If treated only medically, it is associated with very high morbidity and mortality (46%) rate. A wide variety of surgical approaches are described to treat PLE as an optimization of Fontan circulation, Fontan take-down, valve reconstruction, fenestration, VSD surgery with 62, 5% mortality and relief of PLE in only 19 % of patients. Even heart transplantation appeared to have high mortality rate (40%) with persistent PLE in some surviving patients (10,22). Recently Gamba and co-workers reported reversibility of protein-losing entheropathy in 7 patients (23). Reversal of protein-losing enteropathy after heart transplantation correlates with a decrease in the inferior vena cava pressure (24).

Pulmonary artery deformations

Pulmonary artery deformations, including left and right pulmonary artery stenosis cannot be considered as a contraindication for heart transplantation if peripheral pulmonary arteries are well developed. We found it very useful to calculate lower lobe cross-sectional area as an index of peripheral pulmonary arteries' development (normal — 120±30 mm/m2). Stenotic right or left pulmonary artery can be enlarged with a patch of native or donor pericardium, pulmonary artery or descending aorta can be used. In general, the more distal are the lesions, the less amenable they are to satisfactory reconstruction. Successful cardiac transplantation was reported even in the absence of the left pulmonary artery (9)

Major Aorto-Pulmonary Collaterals

Aorto-pulmonary collateral vessels may be present in some adult patient even after reconstructive operation and should be identified during preoperative evaluation, because they may contribute to high output heart failure after transplantation (10). Coil embolisation of collaterals is the most effective method and prevents unnecessary dissection and danger of life-threatening bleeding. Large arteriovenous or veno-venous collaterals also must be identified and managed interventionally or surgically.

Postransplantation management

Post-transplantation management of adult patient with GUCH is similar to the management of other transplanted adults(13,20). Patients with asplenia should be placed on prophylactic antibiotic regimen (20). After complex reconstruction, residual hemodynamically significant defects , anastomoses' stenoses, residual shunts, collaterals must be promptly recognized and corrected. Despite that, some authors do not consider elevated pulmonary vascular resistance as a contraindication for heart transplantation even in complex CHD (10). To prevent donor right heart failure by the means of manipulation of the PVR it is important to use the most modern methods including nitrous oxide or sometimes mechanical support (8).

Results and late survival after heart transplantation in GUCH patients

It is difficult to evaluate results of heart transplantation in GUCH patients because of small series and accidental case reports (25,26). Reported mortality varies from 0 to 44% with bleeding as a main cause of mortality in patients after multiple previous operations (15) (Table 3).

The rate of rejection episodes as well as of late survival is not different from adult patients with non-congenital heart diseases (9,27-29). Lamour et al. (10)found no difference in survival rate as compared with controls matched for age, sex, race and year of transplantation.

Our experience

Fourteen GUCH patients (6 male, 8 female, mean age 31.9, range 16-58 years) underwent HTx between April 1986 and December 2003 at our institution (Table 4). These patients comprised: four with single ventricle, two with d-transposition of the great arteries and previous atrial switch operation, one with l-transposition of the great arteries, three with Morbus Uhl, and four others after multiple complex valve surgery and

Table 3. Results of Heart Transplantation in GUCH

Source	Year	Number of Patients	Early deaths	Late survival	
				1 year	5 year
Hasan	1993	9	4 (44 %)	—	—
Carell	1994	14	0	100 %	100%
Mace	1994	3	0	—	—
Fullerton	1995	5	0	—	—
Hsu	1995	8	1 (12,5 %)	—	—
Speziali	1998	13	0	86%	—
Carey	1988	4	2	50%	—
Lamour	1999	24	5 (20,8 %)	79%	60 %
Pigula	2001	8	4 (50 %)	—	—
Gamba	2004	14	2 (14,2 %)	86 %	77 %
Our data	2004	14	1 (7,1 %)	91 %	76 %
Total		116	17 (16,3 %)	—	

Pts No.	Sex	Diagnosis	Prior to Surgery	Age at surgery Years	Ageat HTx Years	Mech.support prior HTx	Follow-up Years	Status
1	f	DILV, L-TGA, PS, MI, TI, AF	MKR,TKR	16	16	ECMO	11 days	dead
2	m	d-TGA, TI	Blalock-Hanlon Atrial switch (Senning)	1 1	16	—	3,9	dead
3	m	VSD	VSD closure	5	20	—	10,6	alive
4	f	DORV, l-TGA, TA, PS, MI	Waterston shunt	2	20	—	7,5	alive
5	f	AS, sub- and supravalvu-lar	AVR Resection of sub-valvu-lar AS Konno-OP	16 25 25	25	ECMO	10,3	alive
6	m	d-TGA, VSD, ASD, TI,	PA banding Atrial switch (Mustard)	1 3	27	ECMO	5,3	alive
7	f	VSD, AI, MI, TI	VSD closure AVR Re-AVR, MVR, TVR	15 24 31	31	BVAD	11,3	alive
8	f	DILV, d-TGA, PS	BT Shunt Waterston shunt Shunt revision	4 10 19	33	—	8,4	alive
9	f	Single Ventricle, d-TGA, CAVSD, Polysplenia	BT Shunt Shunt revision TVR	10 17 37	38	—	1,7	alive
10	m	L-TGA,PI	None	—	53	—	6,1	alive
11	m	L-TGA, MI	MKE 1981	40	58	—	3,1	alive
12	f	M.Uhl	None	—	16	—	8,1	alive
13	m	M.Uhl	None	—	46	—	8,2	alive
14	f	M.Uhl	None	—	47	—	17,6	alive

Table 4. *Legend:* DILV = double-inlet left ventricle, TI = tricuspid valve insufficiency, AF = atrial fibrillation, VSD = ventricle septum defect, DORV = double-outlet left ventricle, TGA = transposition of the great arteries, TA = tricuspid valve atresia, AS = aortic stenosis, AI = aortic valve insufficiency, MI = mitral valve insufficiency, PS = pulmonary valve stenosis, CAVSD = complete atrio-ventricular septum defect, BT = Blalock-Taussig, AV= aortic valve, AVR = aortic valve replacement, MV = mitral valve, TV = tricuspid valve

biventricular failure. Refractory heart failure (NYHA IV) was present in all of them. Four patients were transplanted after mechanical circulatory support (three with extracorporeal membrane oxygenation, one with biventricular assist device Berlin Heart). Nine patients had a mean of two previous cardiac operations (Fig.1).

Results

There was one early death caused by infection. The Kaplan-Meier survival rate was 93% at 1 year, 84% at 5 years and 84% at 10 years (Fig.2). No anatomic or surgical risk factor was predictive of death. Outcome was compared with matched (age, gender, time of HTx) control group consisting of 70 patients with dilated cardiomyopathy (DCM) and 28 with ischemic heart disease (IHD). Survival rates of the control groups did not differ significantly from those of the GUCH patients: the Kaplan-Meier survival rate was 92% at 1 year, 88% at 5 years and 84% at 10 years in DCM patients and 93% at 1 year, 89% at 5 years and 75% at 10 years in IHD patients.

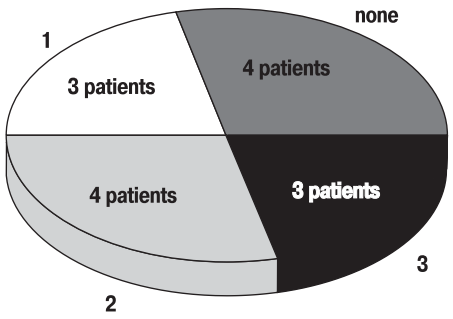

Figure 1. Number of previous operations in transplanted patients with congenital heart defects

Conclusions

1. In adults with various complex congenital heart defects and end-stage disease heart transplantation offers the possibility of excellent short- and medium-term survival.

2. The pre-transplantation evaluation of the patients with complex heart defects and often after multiple previous operations must accurately define cardiac and great vessel anatomy and spatial relation-

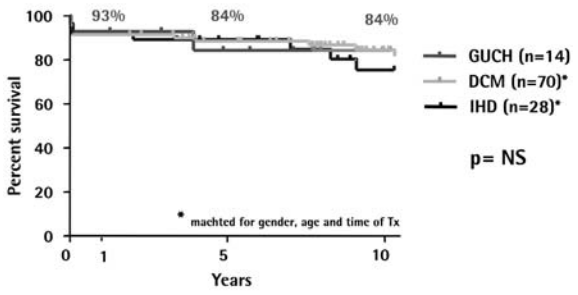

Figure 2. The Kaplan-Meier survival rate in transplanted adult patients with congenital heart defects.
Outcome was compared with matched (age, gender, time of heart transplantation) controls consisting of 70 patients with dilated cardiomyopathy (DCM) and 28 with ischemic heart disease (IHD)

ships. Preoperative planning of the surgical procedure and reconstruction modalities must be discussed.

3. Modification of donor heart harvesting techniques must be considered in details to promote. complex reconstruction during heart transplantation.

4. Individualized approach is necessary with modifications of the standard technique to fit the anatomical variations of a particular patient.

5. Successful heart transplantation can be achieved in patients with GUCH disease, with an outcome similar to that of patients with acquired heart disease.

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Department for Roentgenosurgical Methods of Diagnostics and Treatment

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The department is an independently-working unit within the State institution of public health "Orenburg Regional Clinical Hospital"

There are 3 X-ray operating rooms: 2 rooms with angiographic equipment (Integris H 5000F — Philips and Multistar politron plus — Siemens) and one room for the implantation of cardiac pacemakers (BV-25, Philips).

There are approximately 1100 beds in the multiprofile hospital, among them 40 — in the department of vascular surgery, 10 — in the department of cardiac surgery, 60 — in the department of cardiology, 60 beds — in the rheumatology department and 40 — in the arrhythmia department. There are 15 beds at the department of roentgenosurgical methods of diagnostics and treatment.

Main activity fields

Children. 40 examinations and operations are conducted annually in children over 2.5 years of age suffering from congenital heart diseases (patent ductus arteriosus, coarctation of aorta, valvular aortic stenosis, pulmonary valvular stenosis).

Adults. We perform a full range of angiographic examinations in all vessels and the majority of endovascular procedures (with the exeption of brain vessel embolization and aortic stent-graft implantation). The following procedures are conducted annually: about 150-200 interventions on coronary artery (70% of them with stenting); about 100 interventions on peripheral arteries (30% of them including stenting); 10-15 interventions on brachiocephalic arteries, including internal carotid artery stenting with embolic protection (AngioGard); renal and visceral artery angioplasty and stenting; embolization of visceral, renal and peripheral arteries in patients with arteriovenous fistulas or bleedings; cava-filter implantation; foreign bodies removal from the heart and vessels and other operations.

Moreover, each year we make about 100-110 implantations of cardiac pacemakers.

There is no regular emergency admission.

In 2001 we have performed 2235 diagnostic procedures and in 2002 their amount rose to 2371 examinations.

As for the treating procedures, 562 interventions were performed in 2001 and 531 interventions — in 2002.

The following procedures are applied in practice: rheolytic peripheral artery thrombectomy using AngioJet complex in patients with peripheral artery lesions, recanalization of peripheral arteries with embolic protection, intravascular sonography in congenital heart diseases (patent ductus arteriosus, coarctation of aorta), coronary stent-graft implantation in patients with coronary fistulas and coronary artery ruptures.

The main scientific fields of the activity include the use of intravascular sonographic scan in various vessels, rheolytic thrombectomy using AngioJet complex, various methods of vascular recanalization, concomitant and combined interventions on various segments of arterial system.

ABSTRACTS OF THE 5th INTERNATIONAL SYMPOSIUM "CARDIOVASCULAR AND INTERVENTIONAL RADIOLOGY"

(Center of Endosurgery and Lithotripsy, in cooperation with Russian Society of Interventional Cardioangiology, Russian Society of Angiology and Vascular Surgery, All-Russian Society of Cardiology, Russian Society of Obstetrics and Cynecology, Moscow City Center of Interventional Cardioangiology. Moscow, April 22-24, 2004)

RESULTS OF LEFT MAIN CORONARY ARTERY STENTING

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Objectives: evaluation of left main coronary artery stenting effectiveness.

Forty-three patients with left main coronary artery lesions underwent endovascular intervention at Bakoulev Scientific Centre for Cardiovascular Surgery from 1996 to 2003. Balloon angioplasty was performed in 4 patients; stents were implanted in 39 patients. In 25 cases (64.1%) stenting was performed in patients with stable exertional angina and in 14 cases (35.9%) — in patients with acute coronary syndrome. In the "stable" CHD group 13 patients had "protected" left main coronary artery (at least one patent graft bypassing left main coronary artery) by the time of intervention, 12 patients had "unprotected" left main coronary artery. In the acute coronary syndrome group there were 5 patients with acute myocardial infarction and 9 patients with unstable angina; all the patients had unprotected left main coronary artery. Intraaortic balloon counterpulsation was performed in 4 patients in the acute coronary syndrome group. 11 patients underwent left main coronary artery stenting with "Cypher" stent (among them there were 7 patients with "protected" and 4 patients with "unprotected" artery).

Angiography showed that procedure was successful in 100% of the patients with stable angina. Overall mortality rate in this group was 0%. In acute coronary syndrome group good angiographic outcome was obtained in 13 patients (92.8%). However, overall mortality rate in this group reached 21.4% (3 cases). The deaths were caused by cardiogenic shock (2 cases) and rupture of calcified left main coronary artery.

28 out of 36 patients who underwent left main coronary artery stenting were examined within 6-18 months after the intervention (mean 8.2 ± 1.5 months). Recurrent angina due to in-stent restenosis occurred in 7 patients (19.5%). Control coronarography was performed in 10 patients. In one patient signs of left main coronary artery restenosis were noted 7 months after left main coronary artery stenting with "Cypher" stent.

We concluded that left main coronary artery stenting in patients with stable angina is quite effective and safe method of treatment, particularly in those with "protected" artery. Endovascular method could be an alternative to coronary artery bypass, especially in patients with isolated lesion of left main coronary artery. In patients with acute coronary syndrome left main coronary artery stenting is found to be an effective method of treatment as well. Three deaths were associated with the presence of extremely severe coronary vessel lesions (besides left main coronary artery stenosis), severe left ventricular dysfunction (cardiogenic shock), elderly age and concomitant pathology. Left main coronary artery calcification is a contraindication to endovascular interventions.

PREDICTORS OF DISTAL MICROEMBOLIZATION AFTER PRIMARY CORONARY INTERVENTIONS AND ITS' INFLUENCE ON SHORT-TERM OUTCOMES IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION

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Restoration of blood flow in the infarct-related artery (IRA) not always results in adequate myocardial perfusion because of "no-reflow" phenomenon or bloodstream microembolization (ME) with a clot or plaque fragments.

Angiograms of 92 patients who underwent primary coronary intervention (PCI) within the first 12 hours of acute myocardial infarction were analyzed to evaluate ME and "no-reflow" influence on immediate outcomes of endovascular treatment for acute ST-segment elevation myocardial infarction (MI). In 27 cases (29.3%) angiography revealed signs of ME; in 2 cases (2.2%) — signs of "no-reflow" phenomenon; such patients with angiographic signs of ME formed group I (29 patients — 31.5%). 63 patients (68.5%) without signs of ME formed group II. Both groups were similar in the terms of sex, age, comorbidities, reperfusion time, lesion size and location, antiaggregant and anticoagulant therapy, except for the frequency of integrilin administration: 12 (41.4%) and 6 (9.5%) respectively. Seven patients (24.4%) in the group I and 21 (33.3%) patients in the group II underwent IRA stenting.

Total occlusion before PCI was identified in 26 patients (89.7%) in group I and in 44 patients (69.8%) in group II ($p<0.05$). Post-PCI angiographic success was observed in 20 patients (69%) and in 54 patients (85.7%), respectively ($p<0.05$); left ventricular aneurysm was identified in 10 patients (34.5%) and 6 patients (9.5%), respectively ($p<0.05$); postinfarction angina — in 2 patients (6.9%) in group I and 2 patients (3.1%) in group II ($p<0.05$). On discharge from the hospital left ventricular ejection fraction averaged 44.6% ± 2.5 in group I and 49.2% ± 1.3 in group II, respectively ($p>0.05$); in-hospital mortality rate was 3.5% (1 patient) and 3.1% (2 patients), respectively.

So, ME was observed in 29.3% of cases with ST-segment elevation AMI, the no-reflow phenomenon — in 2.2% of cases (2 patients). Those cases were associated with higher preoperative IRA occlusion rate, worse angiographic results and higher rate of left ventricular aneurism formation.

ULTRASOUND DUPLEX STUDY: PREDICTION AND MONITORING OF THE RESULTS OF ENDOVASCULAR STENTING FOR ARTERIAL OCCLUSIONS OF THE LIMBS

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To assess the efficacy of ultrasound duplex study (DS) for the selection of patients, prediction and monitoring of endovascular stenting (ES) results, between 2000 and 2003 DS of limb arteries was performed in 422 patients. Technical feasibility and the stent function prognosis were determined. Sixty-four (64) patients were selected for ES, 72 stents were deployed: 35 stents — into iliac arteries, 28 — into superficial femoral arteries, 2 — into deep femoral artery, 4 — into popliteal artery, 3 — into the site of anastomosis after prior surgery. Simultaneous implantation of 2 stents was performed in 8 patients. In 7 cases the ES was accompanied by balloon angioplasty, in 6 cases — by regional thrombolysis or rheolytic thrombectomy. Matrix stents were used in 58 cases, nitinol stents — in 14 cases. Immediate results of ES were assessed at day 1-3, while the long-term results were determined at 1, 3, 6, 12 months and yearly thereafter. The follow-up was 3 months to 3 years.

Sensitivity of preoperative DS was 93.7%. No hemodynamically significant residual stenoses were found at the ES site postoperatively. Long-term complications occurring at 3 months or later were found in 18 patients (28.1%). The prevalence of aorto-iliac restenosis/reocclusion was 11.4%, femoropopliteal — 15.6%, contralateral limb, proximal and distal portions were affected in 14% of cases. This fact emphasizes the need for repeated ultrasound study of the lower limb arterial system.

Hemodynamically significant restenosis was defined as one causing peak systolic velocity gradient >2 within the stent. Repeated endovascular procedures (a total of 15) were performed in 10 patients.

DS is sufficiently effective for patient selection, prognosis and monitoring of ES results.

PERFTORAN EMULSION IN COMBINED TREATMENT OF CRITICAL LOWER LIMB ISCHEMIA

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Comparative analysis of combined treatment in 26 patients with obliterating diseases of the lower limb vessels was carried out for morphofunctional evaluation of perftoran emulsion effectiveness in combined treatment for critical ischemia (chronic lower limb arterial insufficiency, degree III according to A.V. Pokrovsky classification). 17 (65.3%) patients had obliterating atherosclerosis, and 9 (34.7%) patients — obliterating endarteritis.

The patients were divided in 2 groups. The first group consisted of 12 patients who received traditional treatment (control group), and the second group consisted of 14 patients who received traditional treatment accompanied with intra-arterial administration of perftoran emulsion (test group).

Before administration unfrozen perftoran emulsion was oxygenated under sterile conditions by Bobrov method with O2 supply 5. ml/min, exposure time was 25 minutes. We determined saturation of perftoran using gas-analyzer, then once a day we performed single-step closed perfusion of perftoran through femoral artery of involved limb.

Outcomes were noticeably better in the second group. Thus, in the first group 4 (33.3%) patients had good results, in the second group — 7 (50.0%). Minor surgery was performed in 3 (25.0%) patients and 4 (28.6%) patients respectively. High limb amputations were performed in 5 (41.6%) patients in the first group, and in 3 (21.4%) patients in the second group.

Among the patients being treated with perftoran, manifestations of chronic arterial insufficiency reduced in 7 (50.0%) patients, 5 of them (71.4%) were reclassified to the stage IIIA, and 2 (28.6%) patients — to the stage IIB. We managed to perform more distal amputation in 4 out of 7 operated patients.

Compared to the traditional methods complex treatment with perftoran emulsion showed that capillary blood O2 concentration increased by 3.2 ± 0.4%, CO2 level decreased by 2.9 ± 0.2%, and muscle blood flow improved by 7.4 ± 0.2%.

Thus, our provisional data suggest that intraarterial perfusion of perftoran emulsion in addition to traditional treatment leads to improvement in blood gas composition and musclar blood flow. So perfusion of perftoran emulsion helps to improve surgical outcomes in patients of this group, particularly to reduce the rate of lower limb amputation.

SURGICAL TREATMENT OF ARRHYTHMIAS IN PATIENTS WITH CORONARY ARTERY DISEASE IN HEMATOLOGICAL CLINIC

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The purpose of the study was to analyze the application possibilities of various methods of electrical stimulation of the heart in hematological patients with concomitant coronary artery disease (CAD) with arrhythmic events prior to and during the chemotherapy (CT) in case of cardiotoxic events.

The methods of temporary (endocardial, transesophageal, external pacemakers) and permanent (implantation of various pacemaker models) electrical stimulation of the heart were applied in 54 patients with lympho- or myeloproliferative syndrome, pathology of thrombocytic series or coagulopathies in the Center clinics.

Preventive stimulation of the heart was performed prior to PCT in cases of supposed latent combined rhythm and conduction disturbances discovered during the cardiac investigation; in other cases the urgent indications for stimulation of the heart were life-threatening arrhythmias, which were difficult to treat or resistant to the drug therapy.

Temporary electrical stimulation was applied in 19 cases. Permanent implantations of pacemakers with atrial and ventricle electrode location were performed in 25 cases.

Electrical stimulation of the heart helps to reduce polypragmasy caused by combination of CT medication complex and adequate drug therapy in patients with cytostatic disease and multiple organ failure.

Electrical stimulation of the heart allows to extend the contingent of hematological patients receiving complete course of high-dose cytostatic therapy, in whom it otherwise would be impossible due to concomitant rhythm and conduction disturbances. It also helps to reduce the rate of complications and mortality caused by arrhythmias in patients with coronary artery disease.

FUNCTIONAL STATE OF THYROID GLAND IN PATIENTS WITH CHRONIC HEART FAILURE

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The aim of the study was to evaluate functional state of thyroid gland in patients with chronic heart failure (CHF). We examined 70 patients with New York Heart Association functional class (NYHA FC) I-IV CHF and euthyroid state, aged 27-75 years (average age 57.2±11.92 years). The ethiology of CHF was acquired heart disease in 20 patients; combination of CAD and arterial hypertension in 43 patients; dilated cardiomyopathy (DCM) in 7 patients.

We analysed clinical and hemodynamic indices, blood TSH concentration, plasma FT3 and FT4 concentrations, as well as patients' quality of life (The Kansas City Cardiomyopathy Questionnaire, Minnesota Living with Heart Failure Questionnaire). Follow-up period was 1 year.

20 patients had NYHA FC I-II, 34 patients — NYHA FC III, 16 patients — NYHA FC IV. In the FC I-II group syndrome of non-thyroid pathology SNTP (low FT3 level on the background of normal TSH level) was revealed in 5% cases (1 out of 20 patients). In the FC III group SNTP was identified in 20.6% cases (7 out of 34 patients). In the FC IV group — in 56.25% cases (9 out of 16 patients). Mortality rate in FC I-II, FC III and FC IV groups amounted to 0%; 5.9% and 31.25% respectively. Four died patients had SNTP.

SNTP detection rate is significantly higher in patients with severe CHF (NYHA FC IV). Study with more participants is needed to evaluate correlation between SNTP and death risk in patients with CHF.

OUR EXPERIENCE IN TREATMENT OF OBLITERATING DISEASES OF THE LOWER LIMB ARTERIES USING BALLOON ANGIOPLASTY

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Objective of the study was to evaluate results of balloon angioplasty in treatment of obliterating diseases of the lower limb arteries.

Within the period from 1996 to 2003, 28 patients were observed at vascular surgery department. All patients were males aged 34 — 57 years. Twenty patients had chronic arterial insufficiency (CAI) stage III — IV. Twenty one patients had concomitant diseases: CAD, diabetes mellitus, essential hypertension and others. Endovascular interventions were performed on the following arteries: 26 common iliac arteries and external iliac artery in 13 patients, 9 external iliac arteries in 9 patients, external iliac and femoral arteries in 6 patients. 16 various stents ("Wall-stent" (Schneider) and "Palmaz" (Johnson&Johnson) were implanted.

Initial success was achieved in all patients who underwent X-ray guided iliac artery endovascular dilatation and stenting. Within the first 6 months after endovascular dilatation of femoral arteries, thrombosis occurred in 3 patients. They underwent staged thrombectomy and lumbar sympathectomy. At the end of 2 years after endovascular dilatation and stenting of iliac arteries, thrombosis was revealed in 8 patients. They underwent lumbar sympathectomy.

We came to the conclusion that X-ray guided endovascular dilatation and stenting of iliac arteries yield good results in patients with obliterating diseases of the lower limb arteries.

STENTING IN PATIENTS WITH ACUTE CORONARY SYNDROME

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Objectives: to show the effectiveness of up-to-date methods of endovascular surgery for the treatment of patients with acute coronary syndrome.

From January 1998 to January 2004 194 patients with unstable angina and acute myocardial infarction underwent 207 endovascular interventions. Procedure was performed in acute period of myocardial infarction in 101 (52%) patients, 28 (14.5%) patients had new-onset angina, 28 (14.5%) — progressive and 37 (19%) — early postinfarction angina. Patients' age varied from 27 to 74 years (mean 47 ±1.6 years), left ventricular ejection fraction ranged from 25% to 66% (mean 42±2.1%). Fifty-three (27.7%) patients had single-vessel lesions; 136 (70%) patients — multivessel lesions. Left main coronary artery lesions were noted in 5 (2.3%) cases.

Percutaneus transluminal coronary angioplasty (PTCA) with stenting was performed in 113 (58%) patients, direct stenting — in 58 (30%) patients, and PTCA — in 23 (12%) patients. Thus, 88% patients underwent coronary artery stenting. In 62 of 63 patients recanalization of occluded infarct-related artery was successful. In 53 cases recanalization of occluded artery was followed by stenting. In 89 (46%) patients platelet glycoprotein IIb-IIIa receptors' inhibitors were administered with the view of additional antiaggregant therapy of acute coronary syndrome. Among them 20 (10%) patients received RheoPro (abciximab), 69 (36%) patients — integrilin. For the first time in Russia we performed a successful thrombectomy with "AngioJet" system in 2 patients with acute thrombosis of right coronary artery.

In 188 (97%) cases interventions showed good angiographic results. Left ventricular ejection fraction increased significantly from 40±2% to 58±2% after endovascular procedures. Ischemic attacks stopped in 73 (37.6%) patients. After the intervention 55 (28.3%) patients had functional class (FC) I according to CCS classification; 49 (25.3%) patients had FC II; 11 (5.7%) patients — FC III. Eight (7.9%) patients with AMI developed Q-infarction, 38 (37.6%) — microinfarction, 50 (49.5%) patients had no ECG signs of myocardial infarction. Death occurred in 5 patients with acute myocardial infarction, and in one patient with unstable angina, complicated by cardiogenic shock. In-hospital mortality rate amounted up to 3%. In-hospital mortality risk factors were cardiogenic shock, three-vessel disease, decreased left ventricular ejection fraction (<40%), age >70 years, anterior myocardial infarction. Causes of death were severe heart failure and cardiogenic shock following extensive anterior myocardial infarction, as well as rupture of left ventricle posterior wall (one case).

In patients with unstable angina and acute myocardial infarction stenting is a treatment of choice. It is one of the most promising methods of treatment for patients with acute coronary syndrome.

EVALUATION OF IMMEDIATE AND LONG-TERM RESULTS OF "CYPHER" DRUG-COATED STENT IMPLANTATION IN PATIENTS WITH CAD

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Trial objectives were to evaluate effectiveness of cytostatics-eluting stents in patients with CAD.

From June 2002 to February 2004 stenting procedures with 541 "Cypher" stent implantations were performed in 286 patients. Patients were arranged in the following groups: in 34 (12%) patients the procedure was performed in the acute period of myocardial infarction; 26 (9%) patients had unstable angina; stable exertional angina CCS FC IV or III was noted in 206 (72%) patients, and exertional angina FC II — in 20 (7%) patients. Left ventricular ejection fraction ranged from 28% to 62%, on average 46±2.5%. 492 coronary arteries were stented. Stent-per-patient ratio was 1.91±0.6. Reference diameter of the diseased artery averaged to 2.8±0.47 mm, the length of the stented segment averaged to 22±6.2 mm.

In 100% of cases (541 stents) good angiographic results were achieved. Left ventricular ejection fraction increased significantly from 46±2.5% to 56±2.8%. Clinical state of patients after endovascular interventions changed as follows: 203 (71%) patients had no signs of angina; 74 (25.7%) patients presented with angina FC I; 8 (3%) patients — FC II; 21 patients with acute myocardial infarction had no ECG signs of infarction, and 8 patients had ECG signs of microinfarction. Total in-hospital mortality rate amounted to 0.35% (one patient). Subacute thromboses of stented vessels were noted in two (0.37%) patients (28 and 72 hours after the intervention). 246 (86%) patients were examined after long-term follow-up (6 and 18 months). Among all these patients 152 (53%) patients underwent clinical examination, 94 (33%) patients underwent selective coronarography. Two (2.1%) 'in-stent" and 1 (1.06%) "in-lesion" restenoses were revealed.

Our findings demonstrate high effectiveness of cytostatics-eluting stents. The rate of angiographically established restenosis within the first 18 months of follow-up was 3.16%. One-year survival rate in patients without serious complications was 97.9%.

CHOICE OF TREATMENT FOR PERIPHERAL ARTERIAL DISEASE

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Recently the number of patients with peripheral artery disease has increased all over the world. Thus, in the USA up to 730 000 strokes are registered every year with prevalence rate of 4 600 000 and death rate 28%. Up to 500 000 cases of transitory ischemia are registered in the USA every year with prevalence rate of 4 900 000 and death rate 6.3%. The rate of peripheral atherosclerosis comes to 8 000 000 — 12 000 000, death rate — 4%. Mortality rate in patients with critical lower limb ischemia amounts to 25%.

The main goals of treatment for peripheral arterial diseases are: to detect concurrent pathology of coronary arteries and valves, to prevent disease getting worse and limb amputation, to change risk factors for death rate decrease as well as improving of functional state of the ishemic organ and life quality.

Basic treatment is carried out according to the following scheme. For critical ischemia (4-8%) revascularization is required. For intermittent claudication (30-50%) exercise + pharmacotherapy + revascularization are recommended. In case of asymptomatic disease course (40-60%) only exercise is required.

Indications for aortoiliac stenting include extensive lesion, ulcerated plaques, restenoses and chronic occlusions.

Indications for aortofemoral bypass (year 2004) are the following: impossibility of recanalization of occlusion with guide wire, incompetent angioplasty and stenting, stent dislocation and incompetence. However there also are problems concerning iliac stenting, among them there are long occlusions (laser or rotational angioplasty is recommended), aneurisms (intraluminal stent-graft implantation), thromboses (in that case AngioJet or Trombex are used), and at last restenoses within the stent, for which repeated balloon angioplasty, brachytherapy and drug-coated stents are recommended.

Thus, intervention of choice for stenoses and occlusion of iliac arteries are transluminal angioplasty and stenting. The efficacy and safety of these manipulations are already proven.

Still there is a number of problems concerning femoral-popliteal segment pathology to this very day. First of all a lack of instruments with proved efficacy, as well as still unsatisfactory long-term results compared with reconstructive surgery. The main disadvantage of the method is restenosis. There are several methods of restenosis prevention: brachytherapy, topical drug administration (local intravascular drug delivery), drug-coated stents, cryotherapy, genetic therapy. However balloon angioplasty and stenting (self-expandable Nitinol stents) in combination with repeated balloon angioplasty or brachytherapy should be considered the best treatment for femoral-popliteal segment occlusion.

In conclusion it could be stated that at present time treatment for patients with peripheral vascular pathology is at the crossroad. Currently 70% of the procedures are already carried out using endovascular techniques. Surgery modification from "vascular" to "endovascular" is not a painless process. Endovascular surgeons quickly adopt new methods of treating peripheral vascular pathology. Cardiologists have pioneered a number of techniques applying for peripheral vascular disease management. But one should bear in mind that these diseases differ significantly. The patients with peripheral artery disease should receive complex treatment based on the principle of "one stop shop" that will give not only clinical improvement but cost-effectiveness.

APPLICATION OF THE COMPUTER PROGRAM "ANGIO VISION" FOR THE DIAGNOSTICS OF MICROCIRCULATORY BLOOD FLOW CHANGES DURING INTRACRANIAL TRANSLUMINAL LASER ANGIOPLASTY

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The resolving capacity even of the most perfect angiographic equipment does not allow to exactly differentiate the capillary phase. Since 2003 we use the computer program "Angio vision" for the detection of capillary blood flow changes; the principle of its functioning is the estimation of brightness histogram displacement with the automatic determination of the number of black points in selected similar zones of the two separate series of radiograms made prior to and after the operating procedures.

The intracranial transluminal laser angioplasty in combination with the use of program "Angio vision" was conducted in 9 patients, 4 from them had acute middle cerebral artery stroke and anterior cerebral artery stroke, 5 had been suffering from chronic cerebrovascular insufficiency and circulatory encephalopathy accompanied by dynamic cerebral blood flow disturbance. DSA was conducted with shooting speed of 25 frames per second. During angiogram analysis the brain tissue zones without main arteries and veins were marked, after that the level of x-ray density in relative units was determined in the marked zones by use of the program "Angio vision".

The patients underwent transluminal laser angioplasty of middle cerebral artery or anterior cerebral artery, respectively. After revascularization of main and collateral brain vessels the patients underwent repeated DSA according to the study parameters.

During the angiogram analysis the same brain tissue zones were marked and the evaluation of x-ray density was conducted using the program "Angio vision".

The correlation of x-ray density of analyzed zones prior to and after transluminal laser angioplasty was 28%, which corresponded to the increase of capillary blood flow by 28%.

The computer program "Angio vision" allows to determine the x-ray density level of angiographic image at the capillary phase with a high degree of accuracy and at the same time to compare x-ray density prior to and after the operating procedures, that permits to estimate the capillary blood flow changes in the examined area of brain tissue.

IN-HOSPITAL MORTALITY DYNAMICS IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION (MI)

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The purpose of the study was to investigate the factors leading to mortality reduction during the period of hospital treatment in patients with acute MI. We analysed data of 4077 patients with acute MI, who underwent hospital treatment in 1993-2002 at the Cardiology Department №6 of the City Clinical Hospital №15 and in Moscow City Center of Interventional Cardioangiology. The mean age of patients was 58 years; 2759 of the patients (67.8 %) were men. All patients with acute MI received standard commonly used drug therapy with nitrates, b-blockers, antiaggregation drugs and ACE inhibitors. The patients, who were hospitalized within first 6-8 hours after MI onset, underwent emergent coronary artery angiography and in case of stenotic or occlusive coronary artery lesions they underwent endovascular procedure in the infarct-related artery.

During the whole study period we observed significant reduction of in-hospital mortality in patients with acute MI: mortality rate reduced from 16.7 % to 4.7 % ($p<0.01$). A correlation analysis showed significant inverse dependence between in-hospital mortality rate on the one hand, and a number of successful endovascular procedures performed at the early period of acute MI, on the other hand ($R=-0.95$, $p<0.00003$). The hospital stay of patients with acute MI was in average 14.8 bed-days.

There was a significant correlation between the reduction of in-hospital mortality due to acute myocardial infarction and the number of endovascular procedures of myocardial reperfusion, conducted both in the first hours of disease and during the whole period of in-hospital treatment.

PREVALENCE AND ETIOLOGY OF URGENT CONDITIONS DEVELOPED DURING X-RAY GUIDED DIAGNOSTIC AND SURGICAL INTERVENTIONS

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We performed retrospective analysis of patient condition during 10330 X-ray guided diagnostic and surgical interventions carried out from 1996 to 2003. The necessity of urgent treatment because of the patient condition worsening existed in 328 cases (3.2%).

In the first group of patients ("cardio"-group) X-ray guided diagnostic and surgical interventions were performed on the heart (coronare angiography, angiocardiography, coronary angioplasty, valvuloplasty, etc.). The second group of patients ("non-cardio") consisted of patients undergoing interventions on various segments of cardiovascular system except for the heart.

The frequency of conditions needing the emergency aid (EA) during various examinations and interventions is presented in Table 1.

Table 1

TOTAL		Frequency of conditions needing EA (%)		Compli-cations (%)	Mor-tality (%)
10330 observations		3,17		0,7	0,05
"Cardio" 41%	Diagnostic interventions (85%)	4,2	5,3	0,5	0,03
	X-ray guided surgery(15%)	8,0		4,1	0,45
"Non-cardio"	Diagnostic interventions(81%)	1,3	1,9	0,15	—
	X-ray guided surgery(19%)	5,2		1,6	0,1

The frequency of conditions needing EA during the diagnostic intervention didn't significantly change at the analysis period and averaged 4-5 % in the "cardio" group and 1.9 % in the "non-cardio" group. It means that the rate of conditions needing EA in cardiology patients is 3-fold higher than in the other group. For example, the rate of conditions needing EA during the coronary angiography was 4.2 %, there were 0.5 % of complications, and mortality rate was 0.03 %. During the diagnostic procedures in the other regions of cardiovascular system conditions needing EA were observed in 1.3 % of patients, complications were noted in 0.15 % of patients and there was no mortality.

The greatest rate of conditions needing EA was detected during coronary angioplasty and averaged 8.0 %. The complication rate during these operations was 4.1 %, mortality — 0.45 %. The frequency of appearance of conditions needing EA during the X-ray guided surgical interventions in "non-cardio" group was 5.2 %, complications were observed in 1.6 % of patients and mortality rate was 0.1 %.

The rate of conditions needing EA and complications during the X-ray guided surgical operations in the "cardio" group changed with time. After dividing the above-indicated period in two parts — from 1996 to 2000 and from 2001 to 2003 it is possible to note, that the rate of conditions needing EA in the first period was 3-fold higher than in the second period (see the table 2).

Table 2

	1996-2000 гг.	2001-2003 гг.
The rate of conditions needing EA (%)	15,0	5,3
Complications (%)	5,5	2,6
Mortality (%)	0,9	0,2

The most frequent reason for the patient condition worsening in 328 cases of condition needing EA was arterial hypotension and bradycardia, regarded as vasovagal reactions (up to 35 % of all reasons). The other reasons of conditions needing EA and complications developed later are presented in the Table 3.

Table 3.

The reasons of appearance of conditions	Rate
Vasovagal reactions, collapses	35,3
Myocardial ischemia	14,3
Hypertensions, tachycardias	11,4
Pseudoallergic reactions	8,8
Arrhythmias, blocks, asystoles	5,9
Myocardial infarctions	5,1
Pyrogenic reactions	4,4
Ventricle fibrillations	4,0
Acute strokes	2,9
Arterial thromboses	2,6
Hematomas, bleedings	2,6

The rate of conditions needing EA during the X-ray guided surgical examinations does not significantly change and is presented generally with the hemodynamic disturbances, which are easy to correct; as well as pseudoallergic and pyrogenic reactions.

The rate of conditions needing EA during the X-ray guided surgical interventions (especially in cardiology patients) has been changing with the increase of the number of operations, with staff experience accumulation, with the development of technical basis.

Despite quite a little percentage of cases with conditions needing EA (3.2 %) during the X-ray guided surgical examinations and interventions the presence of qualified emergency assistance allows to eliminate the most of unfavorable reactions and reduce the number of complications.

TEMPORARY KAVTELADZE ZA-STENT — CLINICAL STUDY

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To access the possibility, effectiveness and safety of temporary stent implantation in clinical practice 20 patients underwent temporary ZA-stent implantation and retrieval .

Temporary stent represents ZA-stent modification with additional elements for stent retrieval located in the distal end of the stent. 20 patients with stenotic and occlusive lesions of iliac arteries underwent implantation of 20 temporary stents after the preliminary balloon angioplasty. Stents were retrieved percutaneously 7 days later.

Implantation and retrieval of stents were conducted without complications in all cases. Minimal artery diameter in the site of stenosis was increased from 2.3 mm to 7.8 mm. There was no evidence of stent breaking, dislocation or damage as well as arterial thrombosis. Intima dissection was detected proximally or distally from the implanted stent in two cases.

Control angiography performed 6 months later showed that minimal artery diameter (in average 7.8 mm) achieved after the stent removal, was not significantly reduced during the next 6 months. During the 12-month follow-up there was no evidence of arterial restenosis or thrombosis. Repeated revascularization procedures were not conducted. Ankle-brachial index significantly increased from 0.5 to 1.0 after the intervention and was in average 0.9 in 6- and 12-month follow-up. Clinical improvement was observed in all patients. Claudication symptoms were absent in 15 out of 20 patients after the treatment.

5 patients with bilateral lesions of iliac arteries underwent implantation of permanent ZA-stent on the one side and temporary stent on the other side. Control angiography of this subgroup 6 months after stent implantation showed that there were no significant differences in minimal artery diameter between the temporary and permanent stent implantation sites.

Temporary vascular stent application in clinical practice is safe and effective. The most promising field of temporary vascular stent usage may be their application as pharmacologic vectors.

PERIPHERAL ANGIOPLASTY: WHAT'S NEW FOR THE LAST DECADE

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The main benefits of angioplasty are "bloodlessness", quick attainment of desired result, ability to treat multifocal atherosclerosis from the same access, as well as possibility of multiple repeated interventions.

Main disadvantages of the method are restenoses and consequently reocclusions.

Success of angioplasty is only possible in case of careful adherence to strict criteria defined for every step of surgery and patient preparation.

Preoperative examination includes: clinical examination with obligatory measurement of ankle-brachial index; duplex scanning, computed tomography, MRI.

Surgery must be carried out under multifunctional X-ray , CT, MRI or ultrasound guidance.

Access must be standard, following obligatory puncture site care. The antegrade and retrograde femoral, axillary or brachial approaches are used with application of suturing devices for access site.

The main facilities for the passage through the lesion are hydrophilic guide wires as well as various mechanical, electromechanical, hydromechanical, optical, mechanochemical, rotary, laser, high-frequency, vibratory, hydrodynamic, ultrasonic devices and, at last, subintimal recanalization.

Distal embolism protection is one more step to improve immediate results. Different methods are used, such as proximal and distal balloons, distal filters.

Balloon dilatation. Among all the achievements 4F and 5F low profile balloon catheters with high burst pressure as well as cryoplasty and "cutting" balloons should be noted first at all.

Stents are probably the most successful invention for the improvement of immediate and long-term results. At present matrix, self-expandable wire and knitted stents, drug-eluting stents, stent-grafts, bioresorbable and temporary stents are being used.

Drug therapy. Before and after manipulation aspirin and klopidogrel are administered, while during operation heparin and IIb/IIIa glycoprotein inhibitors are used.

In conclusion we could say that all these achievements allowed us to tip the scale significantly from cardiosurgery to interventional cardiology. Though, in view of peripheral angioplasty vascular surgery rather slowly turns to endovascular basis, especially in our country. Administrative resources and the authority of each surgeon among his colleagues are of great importance. But time is implacable and progress couldn't be stopped. Hence all that is better and easier for patients undoubtedly must take priority.

APPROACHES IN ENDOVASCULAR SURGERY

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"Incision must be as long as required and as tiny as possible"

T. Kocher

Puncture site for angiography and endovascular surgery is the smallest incision used in surgery. However at least several dozens of diseases can be treated through that one puncture hole… What else incision allows that? None.

What kind of approaches are used in endovascular surgery? Percutaneous: translumbar, femoral (antegrade and retrograde), axillar, carotid, popliteal, radial, ulnar and at last arteriotomy (femoral, popliteal, brachial).

What criteria are used for approach appreciation: possibility and easiness of puncture and Seldinger catheterization, approach "comfortness", functionality, traumatism, hemostasis, complications and patient rehabilitation. Furthermore, there are some external factors concerning medical business and medical institution interests as well as doctor preferences. Surgeon can use open and closed puncture needles, needle angiography.

Puncture technique and Seldinger's principle. The method significantly differs according to local conditions, especially to artery pulsation and it's adherence to surrounding tissues. So-called "blind" puncture and repeated puncture occupy a particular place. This method is associated with a number of complications, such as spasm, lateral puncture, puncture through the two arteries, puncture through artery and vein, puncture between the arteries.

"Comfortness" of approach depends on manipulation convenience according to doctor's position relative to the surgical table and to the patient. Possibility of easy manipulation with extracorporal parts of guidewires and catheters. However, several obstacles can be mentioned. Spastic "compression" of the introducer and difficulties during introducer replacement. Bleeding from the puncture site due to irritation caused by introducer with or without subcutaneous hematoma formation.

Functionality. Possibility of interventions in various vessels. Easy manipulation with extracorporeal catheters, fast replacement of the introducer.

Traumatism. Subcutaneous, periarterial or intracavitary hematoma formation, nerve damage, arteriovenous fistula formation.

Complications. Medical: large or small subcutaneous, periarterial or intracavitary hematoma, pseudoaneurysm, arterial thrombosis, spasm, distal embolism, arteriovenous fistula, nerve damage. Social: impairment of organ functions — limb weakness, movement discoordination, psychological factor.

Hemostasis: Manual, compressive without control, compressive instrumentally controlled hemostasis. Suturing devices application.

Cost: Puncture kit cost. Medical business and medical institutions' interest: availability of special purpose tools.

Rehabilitation: Early mobilization of the patients. Short hospital stay.

Quality of life: We have studied the most up-to-date radial approach. 100 patients undergoing endovascular surgery through radial approach were observed in January-March, 2004. 52 coronary angioplasty and 48 diagnostic interventions were carried out using right-sided radial approach. 5, 6, and 7F introducers were used. No complications were noted in 87 patients. Six patients required approach through the opposite radial artery which was successfully performed in 4 of them. Three patients required femoral approach. In total the surgeons had to change the approach to another artery in 7 patients (among them were 5 female patients). Radial artery thrombosis was observed in 6 patients. Difficulties during passage through the brachyocephalic trunk were noted in 8 patients. Repeated puncture was necessary in 4 patients. Though the complication rate was low the method requires additional anesthesia, because of significant pain.

Conclusion: at present radial approach is the most acceptable in view of all the above mentioned criteria of approach appreciation. Taking into consideration the comfortness criterion, only retrograde femoral approach with the use of suturing device could compete with radial approach.

CAROTID ULTRASOUND STUDY FOR THE ASSESSMENT OF LIPID-LOWERING THERAPY IN PATIENTS WITH CHD AND HYPERCHOLESTEROLEMIA

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Purpose of the study was to assess changes in carotid artery wall using ultrasound study in CHD patients with hypercholesterolemia taking glirofarm — a lipid-lowering agent prepared from autogenous flora.

A total of 36 patients with grade II-III stable angina (SA) and hypercholesterolemia were evaluated (mean age 52.5±1.06, range 35-55). SA was diagnosed by Rouse questionnaire, general clinical studies and bicycle ergometry.

Intima-media thickness (IMT) of the carotid artery was measured using "Ultramark 9" ultrasound system" (ATL, USA) prior to treatment, at 1, 6 and 12 moths post-baseline. Fifteen (15) patients were administered placebo, 21 patients were taking 150 mg/day gliofarm.

The results obtained suggest, that SA patients with hypercholesterolemia had IMT above the normal range: 1.8±0.2 mm vs 0.99±0.3 mm ($P < 0.05$) in healthy persons. At 1 month only a trend towards the decrease of IMT was observed in both groups. We found no significant IMT changes at 6 months and 1 year in patients taking placebo. In gliofarm patients there was statistically significant decrease of IMT at 6 months, reaching 27.9 % from baseline ($P<0.01$) in the right carotid artery and 23.4% ($P<0.05$) from baseline in the left carotid artery. At 1 year the IMT decreased by 28.7% ($P<0.05$) in the right and by 26.2% ($P<0.05$) in the left carotid artery.

Therefore, the ultrasonic measurement of IMT in carotid arteries is an informative, non-invasive method to assess the efficacy of lipid-lowering drugs.

SUBINTIMAL RECANALIZATION FOR PROLONGED ARTERIAL OCCLUSIONS (PRELIMINARY REPORT)

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The potential of endovascular repair of prolonged atherosclerotic occlusions is restricted by the high long-term rate of restenosis and, therefore, is poorly investigated. Purpose of the study was to assess the efficacy and safety of subintimal recanalization for this type of peripheral arterial occlusive disease.

Subintimal recanalization procedures were performed in 10 patients with chronic peripheral arterial atherosclerosis of the limbs in Regional Clinical Hospital. Mean age of patients was 62.7±6.3 years. Superficial femoral artery occlusion involving the entire length of the artery was found in 6 patients, whereas local lesions less than 10 cm in length were observed in two patients. In all patients the symptoms were critical ischemia with trophic disturbances and mean ankle-brachial index of 0.24 ± 0.08.

We determined technical success, postoperative complications, symptoms of ischemia and the ankle-brachial index in the early postoperative period.

Full antegrade flow through the newly constructed channel was restored in 8 patients out of 10. Stent implantation for significant residual stenosis was necessary in a single patient following common iliac artery recanalization. Mean ankle-brachial index postoperatively was 0.37±0.09.

ASSESSMENT OF LOCAL AND GENERAL HORMONE STATUS IN PATIENTS WITH UTERINE FIBROIDS TREATED WITH UTERINE ARTERY EMBOLIZATION (UAE)

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Purpose of the study: evaluation of ovarian function and hormone status in patients with uterine fibroids treated with UAE. Levels of circulating testosterone, prolactin, FSH, LH, 17b-estradiol (E2), progesterone (P4) in the systemic circulation, and, simultaneously, levels of E2, P4 in local circulation were assessed prior and 6 months following UAE. In addition, the ratios of serum E2, P4 in the blood taken from the left ovarian (renal) vein (LOV) to that in the blood from peripheral vein prior and 6 months following UAE were measured.

The study enrolled 60 patients without endocrine disorders aged 22 to 51, who had symptomatic uterine fibroid. Of these, the hormone status was assessed in 30 women according to the phase of menstrual cycle.

Study patients were divided in 2 groups according to their age — group 1 included 18 women of childbearing age (range 22-43, mean 31.1±1.7 years), group 2 included 12 pre- and perimenopausal women aged 43-51 (mean age 45.2±2.8). In all patients, besides general and special examination, E2, P4 levels in systemic and local circulation, as well as circulating FSH, LH, testosterone, prolactin levels, were measured prior and 6 months following UAE using immune-enzyme assay.

Testosterone and prolactin concentrations were normal in both groups.

Group 1 included 2 subgroups — 12 women with fibroid under 10 weeks of pregnancy (VJ330cm^3) containing J3 nodes up to 40 mm in diameter and another 6 women with multiple myoma over 10 weeks of pregnancy (V>330 cm3). In the first subgroup of group 1 the concentration of steroid hormones in general and local circulation was similar, and reliably (P<0.05) within normal range or slightly above it. In the second subgroup the level of E2 and P4 in local circulation was higher than that in cubital vein (3 patients, p<0.05) or normal (3 patients). Follow-up study performed 6 months following UAE revealed unchanged hormone levels in the first subgroup, while in the second subgroup this level decreased to normal or subnormal values (p<0.05) in 3 patients with local hyperestrogenemia.

According to the same principle group 2 was divided in subgroups: the first subgroup included 8 women, the second subgroup — 4 women. Relative and absolute hyperestrogenemia was found in two women of the first subgroup, the level of E2, P4 was normal in 4 women and corresponded with menopausal values in 2 women, with local and peripheral hormone concentrations being similar (p<0.05). In the second subgroup relative or absolute hyperestradiolemia in local circulation was found in 2 women, menopausal values of steroid hormones and gonadotropins were revealed in another 2 patients. Follow-up study performed 6 months following the procedure showed normal hormone status in 6 patients of the first subgroup and 2 patients of the second subgroup. In 2 patients from the first and the second subgroups, who had menopausal levels of E2, P4, ФСГ, ЛГ at baseline, these parameters remained unchanged (menopause in these patients started with persistent amenorrhea).

The following results were obtained in the study: quantitative level of androgens and prolactin in patients with uterine fibroid was within normal range; moderate relative or absolute hyperestrogenemia without significant difference in local and peripheral circulation was more common in premenopausal and perimenopausal women, than in women of childbearing age; severe local hyperestradiolemia was significantly more common in patients with large multinodular fibroids (over 10 weeks of pregnancy, Vi330 cm^3); 6 months following UAE the levels of steroid hormones and gonadotropins became normal in patients from both groups who had statistically significant local hyperestradiolemia at baseline.

PREDICTIVE EFFICACY CRITERIA OF UTERINE ARTERY EMBOLIZATION FOR THE TREATMENT OF FIBROIDS

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Purpose of the study was the development of predictive efficacy criteria for UAE. The objectives included assessment of UAE efficacy depending in the type of fibroid blood supply and its location.

Blood supply of tumor and fibroid nodes was evaluated using duplex ultrasound, color-coded Doppler ultrasound study and angiography as a predictive efficacy criterion for selection of female patients for UAE.

Local blood circulation was assessed in 40 UAE patients. Of these, 60% had hypoechoic or isoechoic tumor as revealed by duplex ultrasound, which was an indirect evidence of predominantly muscular type of fibroid. The study also showed high circulation (over 10 color Doppler signals), peripheral and central blood flow in the fibroids. Mean values of resistance index (RI) were 0.56±0.02 U, peak systolic velocity (PSV) in intratumoral vessels — 27.75±4.20 cm/s. Low RI values suggested high blood supply of the fibroids.

Another situation was found in 40% of patients: the nodes were hyperechoic (predominantly fibrous structure) and had poor blood supply (less than 10 Doppler signals) with only peripheral circulation. No central color Doppler signals were revealed the tumor nodes. Mean RI values were 0.69±0.01 U, mean PSV in fibroid vessels was 14.11±4.10 cm/s. High values of vascular resistance and low blood velocity were the evidence of poor blood supply of the tumor.

In patients with high blood supply of the fibroids interstitial-submucous and submucous location were significantly more common (79.2%) as compared to interstitial-subserous fibroids with poor intratumoral circulation (43.8%) (p<0.001).

The assessment of circulation in submucous and interstitial-submucous nodes showed low RI (0.55±0.01 U and 0.59±0.02 U) compared to interstitial-subserous nodes, where RI value was 0.67±0.02 U (p<0.05), suggesting higher vascularity of submucous and interstitial-submucous nodes over interstitial-subserous fibroids.

High circulation revealed by color-coded ultrasound Doppler study was confirmed by angiography in 60% of cases. This angiographic pattern was graded as type 1 tumor with characteristically high vascularity. The arteries, which carry blood to the myomatous uterus had indistinctive straightened course without screw-like shape and were located at the periphery of the dominant node.

In 40% of patients with poor blood supply (as shown by duplex ultrasound and color-coded Doppler ultrasound study) angiography revealed type 2 tumor with lower vascularity of fibroids. Parametrium contained single vessels, while the intramural artery was located at the tumor's periphery and gave isolated thin branches with staight course.

The number of branches carrying blood to tumor nodes was 18,91±1,70 in fibroids with high circulation. The territory supplied from a single vessel was 141.67±13.09 mm2. In patients with low circulation the number of branches carrying blood to the nodes was almost twice less (10.36±1.4) (p<0.001). The territory supplied form a single vessel was 329.47±38.10 mm2. (p<0.001).

Predictive efficacy criteria of UAE for the treatment of uterine fibroids include: "high" blood supply of the tumor node; submucous and interstitial-submucous location.

THE RESULTS OF UTERINE FIBROID TREATMENT WITH UTERINE ARTERY EMBOLIZATION

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Purpose of the study: to improve the efficacy of uterine artery embolization (UAE) for the treatment of patients with uterine fibroid.

Study objectives included assessment of regress of fibroid and corresponding clinical symptoms as a response to UAE.

Women were divided between 2 groups depending on the size and location of tumor nodes.

Group 1 comprised 12 female patients with large tumors (14 to 20 weeks of pregnancy) or atypical tumor location. Mean age was 40.41±2.30 years. Tumor nodes were interstitial-subserous in 41.7% of cases and intraligamentous in 33.3% of cases (the type observed only in this subgroup). In 16.7% of cases the nodes were interstitial-submucous, and, in 8.3% — submucous. Most common symptoms included pain (100 %) and signs associated with compression of adjacent organs (91.7 %). In more than half of patients (66.6%) the pain progressed.

Group 2 comprised 28 women with a mean age of 42.25±1.20 years. All patients had fibroids J12 weeks of pregnancy, which were submucous (35.7%) and/or interstitial-submucous (46.4%). Interstitial and interstitial-subserous nodes were similarly and substantially less common (7.2% vs 10.7%). The leading symptoms included hemorrhage (85.7%) and anemia (85.7%).

The profile of general and gynecological disorders was similar between the groups.

Completion angiography was performed in all patients to ensure adequate embolization of uterine arteries. Another angiographic study was conducted at 12 months to assess the blood flow.

Evaluation of clinical symptoms at 2 months showed, that UAE decreased pain in the vast majority of women (93% vs 91%, respectively) and contributed to the relief of hemorrhage in both groups of comparison. In group 1 the menstruation period decreased to 1.5 days (from 6.25±0.5 to 4.7±0.33 days, $p<0.01$), the volume of hemorrhage decreased 1.4-fold (from 134.2 ±12.5 to 97.0±3.66 ml, $p<0.01$), blood hemoglobin level increased from 109.0±5.71 g/l to 114.6±3.95 g/l. In group 2 the menstruation period decreased by 2 days (from 6.8±0.4 to 4.9±0.2 days, $p<0.01$), the volume of hemorrhage decreased 1.5-fold (from 149.4±9.6 to 102.5±4.5 ml, $p<0.05$), blood hemoglobin increased from 105.48±3.5 g/l to 112.8±2.6 g/l.

In the first subgroup tumor size decreased steadily throughout 12 months. Length of uterus declined by 76.5 %, width — by 69.7%, anteroposterior diameter — by 57.9%. In the second subgroup (with smaller tumors) UAE effect was mostly observed within the first 2 months. Length decreased by 89.5 %, width — by 70.3%, anteroposterior diameter — by 65.7%. In general, the rates of tumor size decrease in the second subgroup at 12 months were 93.7%, 90.2% and 65.7% from baseline.

The volume of uterus treated with UAE decreased 2.4-fold in group 1 (from 919.87±127.70 to 383.18±177.50 cm3), and 2.7-fold in group 2 (from 252.99±23.50 to 93.10±7.90 cm3).

The tumor size decreased 6.9-fold in group 1 (from 307.07±51.90 to 44.30±32.60 cm3), and 6.3-fold in group 2 (from 87.40±19.70 to 13.74±5.10 cm3).

Assessment of long-term results of UAE at 12 months postoperatively revealed that the procedure was effective in 97.5% of cases.

THE RESULTS OF ENDOVASCULAR PREVENTION OF PULMONARY EMBOLISM IN PREGNANT WOMEN USING "SHUTTLECOCK" CAVA-FILTER

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Acute venous thrombosis and pulmonary embolism are considered among the most dangerous complications of gestational period. The most reliable method to prevent pulmonary embolism if phlebothrombosis had already occurred is the implantation of cava-filter into the inferior vena cava.

To assess the efficacy of endovascular prevention of pulmonary embolism in pregnant women we implanted "shuttlecock" cava-filter to 36 women with venous thrombosis and embolism occurred in different pregnancy periods. The cava-filter was developed in the Hospital Surgery Department of Altai State Medical University (V.B. Gervasiev et al 1990-1998).

Symptoms of phlebothrombosis extending above the popliteal vein were noted in 35 patients, 11 of which developed pulmonary embolism. In one women pulmonary embolism occurred without any symptoms of phlebothrombosis. The degree of embolism was considered massive in 3 patients, submassive in 4 patients and segmental in 5 patients.

Subclavian approach was used for cava-filter implantation in four patients. The other patients underwent temporal device implantation through femoral approach, 7 of which were performed in primary admission hospitals without fluoroscopic guidance.

There were no cases of pulmonary embolism following cava-filter deployment. Twenty-four (24) women had vaginal birth; another 12 women had caesarian delivery.

After delivery and elimination of increased risk of thrombosis the cava-filters were removed in 14 patients. Seven attempts to remove the filter were associated with the rupture of corrigent wire. In 9 patients the filters were left in location for different reasons (late follow-up hospital attendance, abnormal position of filter in inferior vena cava, etc.). Four women were lost to follow-up, therefore the type of delivery and the fate of antiembolic device remained unknown.

Three patients died from massive pulmonary embolism at baseline. Postmortem examination revealed retained embolus in the antiembolic device.

Our experience of permanent and temporary implantation of "shuttlecock" cava-filter to prevent pulmonary embolism suggests that the device can be used in pregnant women with thrombosis of inferior vena cava territory and pulmonary embolism.

THE FIRST EXPERIENCE OF TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOUSUS AND ATRIAL SEPTAL DEFECT

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To assess the immediate results of transcatheter endovascular closure of patent ductus arteriosus (PDA) and atrial septal defect II (ASD II) 20 procedures of transcatheter patent ductus arteriosus closure and 6 procedures of ASD II closure were performed in the Interventional Radiology Department of SRCCD from December 2002. PDA patients were aged 2 months to 18 years (mean age 3.6 years). Of these 12 were female patients and 8 were male patients. ASD II patients were aged 3 to 51 years (mean age 9 years). Of these 4 were female patients and 2 were male patients.

All PDA patients underwent endovascular closure with fluoroscopic guidance: "Flipper" coil (COOK, Denmark) was used in 18 patients, AmplatzerT Duct Occluder system (AGA Medical Corporation, USA) — in 2 patients. In one patient coil occlusion was performed after recanalization of previously ligated ductus arteriosus.

All 6 procedures of ASD II closure were performed with AmplatzerT Septal Occluder system (AGA Medical Corporation, USA). The device was implanted under fluoroscopic and sonographic guidance to ensure proper positioning of occluder with respect to orifices of superior and inferior vena cava, pulmonary veins, coronary sinus, atrioventricular valves. No complications were observed during the procedures.

PDA and ASD II occlusion confirmed intraoperatively by completion angiography and sonography 10 minutes after the procedure was achieved in 19 cases (73%). In 5 (19.2%) patients with insignificant residual flow sonography performed next day after surgery revealed occlusion and the absence of pathological shunting. The long-term results were unavailable in one patients with residual shunting after device implantation. In one patients with large ASD II we failed to deploy the occluder properly inside the defect, therefore the occluder was removed from the heart and open surgery performed.

The first experience of transcatheter PDA and ASD II closure suggests that the method is highly effective for the repair of heart diseases. It has almost no complications, provided that the indications and operation technique are closely observed. The hospital stay substantially decreased from 12-14 to 3-4 days.

EFFECTIVENESS OF IMPAIRED MYOCARDIAL BLOOD SUPPLY CORRECTION USING ANGIOPLASTY IN RELATION TO EXERCISE TOLERANCE IN PATIENTS WITH CORONARY ARTERY DISEASE (CAD)

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The purpose of our study was to determine the effectiveness of PTCA for impaired myocardial blood flow correction in CAD patients with variously located coronary artery lesions. The efficacy of PTCA was evaluated by means of exercise tolerance testing performed in the long-term period (6 months after the endovascular intervention).

450 patients were enrolled in the study; they were arranged in 2 groups: 234 patients with implanted stents formed the 1st group, and 216 patients, who underwent percutaneous transluminal coronary angioplasty (PTCA), formed the 2nd group. Mean age of the patients was 53.48±17.1 years. All patients underwent control coronary angiography 6 months after the intervention. Exercise tolerance was evaluated using bicycle stress ECG test prior to and 6 months after the procedures.

In the stent group mean exercise tolerance increased significantly from 69.5 Watt to 91.57 Watt ($p<0.05$) independently of long-term outcomes. In the PTCA group we did not observe this tendency ($p<0.05$): the tolerance increased only in case of good results of endovascular procedure. The test was significantly more sensitive in stent patients with restenosis of the anterior interventricular artery (70.2 %), whereas in case of right coronary artery and circumflex artery restenoses the sensitivity was almost identical. In average 43 % of restenoses were silent. The decrease of exercise tolerance in patients with instable angina pectoris and acute myocardial infarction (MI) as a result of restenosis (prior to procedure — 69.6 Watt, control test — 46.5 Watt) was significant in both groups.

The percent of patients with good blood flow in the target artery as well as exercise tolerance in the long-term period were significantly higher in the stenting group compared to the PTCA group. Bicycle exercise or clinical signs may help to diagnose restenosis only in 57 % of patients with angiographically proved restenosis.

RADICAL TREATMENT OF VARICOSE VEIN DISEASE WITH MINIMALLY INVASIVE TECHNOLOGIES

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Over almost 100 years the principle of radical treatment of leg veins varicose disease (VD) is a determining one in evaluation of all surgical techniques being used to deal with the mentioned pathology. As a rule radical treatment means total and non-recurrent treatment of superficial varicose veins. To achieve this goal length and direction of incisions were selected in that way, which would enable to identify and then to remove the trunk vein and all its tributaries as a single whole (Madelung). Later, only the tributaries were excised, while the trunk vein was removed using phlebectomy probe (Babcock). Subsequently the varicose surgery was developed on the basis of incision shortening, but increasing in the number. Concurrently with the surgical techniques sclerotherapy of varicose veins was developed. However rather soon it became clear that in many patients it could not be an alternative to surgical treatment. Sclerotherapy more often resulted in the recurrence and progressive VD. Pathogenetic studies of VD have shown that there are factors which would inevitably lead to the recurrence independently of treatment. These factors are well known today: valvular incompetence of the origin and trunks of greater and lesser saphenous veins as well as perforators. Up-to-date principle of radical treatment reads as follows: it is essential not only to remove varicose veins patients have at present, but to eliminate factors necessarily resulting in appearance of new varicose veins in the future.

Is it possible to achieve the radical cure of varicose disease with minimally invasive technologies today? The results of recent 15 years of work allows us to give an affirmative answer. The largest experience have been gained from combinations of surgical techniques and sclerotherapy. Most often the treatment included 2 steps. The first — surgery: crossectomy, trunk vein sclerotherapy, ligation of incompetent perforator veins. This step is aimed at elimination of pathogenetic mechanisms of VD. The second — postsurgical sclerotherapy of remained varicose tributaries. This step brings the principle of radical cure to its maximum. The follow-up analysis has shown the low efficacy of trunk sclerotherapy in case of trunk vein diameter over 1 cm and poor conditions for leg compression. Therefore currently surgeons often use combination of crossectomy, leg vein short stripping, trunk vein sclerotherapy and perforator ligation. Taking into consideration difficulties and long duration of postsurgical sclerotherapy we added Muller mini-phlebectomy to the above mentioned combination.

So what are the advantages of all listed combinations? Firstly — minimal incisions and therefore — good cosmetic and esthetic outcome. Secondly — minimally traumatic operations, hence painlessness of postoperative course and quick rehabilitation. Thirdly — cost-effectiveness and social significance.

Thus, radical cure of VD today can be achieved using minimally invasive technologies.

APPLICATION OF TEMPORARY VENOUS FILTERS IN TREATMENT OF ACUTE THROMBOPHLEBITIS OF DEEP AND SUPERFICIAL VEINS

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Pulmonary embolism (PE) due to floating clot migration is the most dangerous complication of acute deep veins thrombosis (DVT). Until recently the problem has been solved by installation of permanent vena cava-filter and anticoagulant drug administration.

Another pathology resulting in PE is ascending thrombophlebitis (AT) of major saphenous vein in patients with varicose disease. Migration of thrombotic masses during crossectomy and clot removing from the saphenofemoral junction, that is particularly complicated in case of "old" process, can cause grave and even fatal intraoperative PE.

Temporary vena cava filter (TVCF) is a device that allows surgeon to carry out the most active drug therapy of DVT and safe surgery in patients with AT.

Our first experience in TVCF insertion included 12 interventions in patients with floating DVT and 3 interventions in patients with AT, with proximal thrombus margin at the level of saphenofemoral junction and dilatation of this area up to 2 cm or more. Before treatment all patients underwent ultrasound Doppler color flow mapping, which helped to establish the diagnosis and determine indications for insertion of temporary vena filter. Temporary filter was introduced from the contralateral femoral vein, then under fluoroscopy it was advanced through delivery catheter (6F) to the external iliac vein and then expanded. We used "Basket" filter of 8-10 mm in diameter. The filter remained in the vein for 3 days. In cases when prolonged treatment was necessary we replaced the filter and put it more proximally to avoid endothelium damage.

Floating clot measuring 1.5-6 cm in length and 4-7 mm in diameter was located within the superficial femoral vein or popliteal vein. While treating patients with DTV, temporary filter remained in the vein up to 8 days.

The patients were treated with direct and indirect anticoagulants.

As a result complete dissolution of floating clot occurred in 12 observed patients, in 2 patients the clot adhered to the vein wall. In 2 cases the treatment was noneffective, so the patients underwent permanent vena cava filter implantation.

During crossectomy in patients with AT clots measuring 1.5-1.8 cm in width were removed. In one case the clot was easily removed by traction of its proximal part with fenestrated forceps through the vein incision located 3 cm distally to the junction. In 2 other cases the incision was extended proximally across the ostial valve because of the clot adherence to the junction and only after that the clot head was completely removed. We did not register any clinical embolic episodes.

We can not draw definitive conclusion concerning this question because of little TVCF application experience, though safe conservative treatment for DVT and easy surgical management of AT allows us to highly appreciate this method of DVT prevention.

THE ROLE OF EFFECTIVE LIPID-LOWERING THERAPY IN THE IMPROVEMENT OF DIRECT MYOCARIAL REVASCULARIZATION RESULTS

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The need of dislipoproteinemia (DLP) correction in CHD patients after coronary artery bypass grafting (CABG) as a method to prevent restenosis is doubtless. Important issues include the elaboration of standards for lipid-lowering therapy prior to CABG and the rationale for the time to postoperative therapy. To assess the effect of effective lipid-lowering therapy prior to surgery and postoperatively on CABG outcome in CHD patients with severe DLP at baseline we examined 37 patients with grade III-IV angina (56.3+5.6 years), allocated for CABG with cardiopulmonary bypass (CPB). Serum levels of total cholesterol (TCh), of the low density lipoprotein cholesterol (LDLP Ch) and triglycerides (TG) were determined using "Cormay" kits. Simultaneously we investigated haemorheology and microcirculation parameters. The patients were examined prior to CABG and within 13 months postoperatively every 4 weeks. The main study group was comprised of 15 patients with severe DLP (TCh>7.8 mmol/l; TG>2.3 mmol/l), who received atorvastatin (Liprimar, Pfizer) during one month prior to surgery and one year postoperatively as part of adjuvant medical therapy for CABG. The initial dose was 10 mg/day with further 2-fold decrease at 4-6 months postoperatively. Control group included 12 patients, who were nor taking any lipid-lowering agents.

Marginal changes of serum lipids one day before CABG (TCh < 5.7 mmol/l, TG < 2.0 mmol/l) were diagnosed in patients in the study group. These parameters remained unchanged in the control group. At days 1-3 postoperatively we observed severe decrease in TCh and TG, associated with hemodilution performed during cardiopulmonary bypass procedure. These parameters increased at day 10 postoperatively, which required continuation of lipid-lowering therapy. Our results suggest that continuous, prolonged, and effective lipid-lowering therapy facilitates both DLP elimination and hemorheological and microcirculatory parameters. One year following CABG the results were significantly more favorable over control group as to the presence of angina (0%), nitrates intake (13.3%), ischemia progression (0%) (vs 18.8%, 39.6% and 18.8% in control group, respectively).

ENDOVASCULAR LASER COAGULATION OF SUBCUTANEOUS VEINS FOR THE TREATMENT OF LOWER EXTREMITIES VARICOSE VEINS

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To assess the potential of high-energy laser for the combined treatment of lower extremities varicose veins we determined the degree of morphological changes of venous wall after different types of endovascular high-energy laser procedures performed in vitro in subcutaneous veins after their surgical removal. Laser energy of 150 J/cm^2 was found to cause coagulation necrosis of endothelium in the vessel wall. The damage involves 1/2 of the wall thickness.

We also evaluated clinical results of venous stem laser coagulation performed in 41 patients with lower extremities varicose veins. Surgical closure of the upper and the lower venovenous reflux was the first step in all cases. The second step included introduction of light guide into the greater and the lesser saphenous veins using the probe. After the wounds were closed and elastic compression applied we performed laser emission, at the same time the light guide was gently pulled to the proximal direction. Sarplan Nd: Yag system was used as a source of laser emission. Power density of the laser emission was 15-20 Wt/cm2. We used continuous emission with scanning rate of 1 cm/sec and laser energy of 120-150 J/cm2,

The following conclusions can be drawn from the combined assessment of high-energy laser for lower extremities varicose veins:

1. Endovascular use of defocused laser with certain power is associated with homogeneous distribution of heat along the inner surface of vein, causing coagulation necrosis of certain depth and aseptic thrombosis.

2. Intraluminal laser coagulation of veins improves the results of varicose veins therapy through the elimination of certain complications, characteristic for chemical scleroobliteration and conventional methods of phlebectomy.

COMPARISON BETWEEN THE PROFILE OF COMPLICATIONS IMMEDIATELY AFTER CORONARY BYPASS SURGERY IN PPATIENTS WITH TYPE 2 DIABETES MELLITUS AND PATIENTS WITHOUT DIABETES

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Purpose of the study was to compare the profile of complications immediately after surgery in patients with coronary heart disease (CHD) with and without type 2 diabetes mellitus using retrospective analysis.

A total of 295 coronary bypass procedures were performed between 1997 and 2001 in the Vascular surgery Department of Arkhangelsk Municipal Clinical Hospital No.1. Thirty-seven (37) (9.4%) patients had type 2 diabetes mellitus as a concomitant disease. Total mortality rate was 1.3%, with 5,4% in diabetic patients and 0,8% in non-diabetic patients. Causes of death in diabetic patients were: cerebrovascular accident, acute intreoperative myocardial infarction, ketoacidosis, and, in patients without diabetes — acute intraoperative myocardial infarction causing cardiogenic shock.

Two groups of 30 patients each were selected for the comparison of early postoperative complications: CHD patients with type 2 diabetes mellitus and CHD patients without diabetes, which were comparable by the age and the profile of coronary atherosclerosis. Mean age of patients in diabetes group was 53.20±1.14 years. Mean age of patients without diabetes was 54.37±1.22 years. Mean number of affected coronary arteries in diabetic patients was 3.33±0.11, in patients without diabetes — 3.47±0.15.

In non-diabetes mellitus group 28 out of 30 patients were males. Of these there were 21 smokers. Grade 2 angina was found in 2 patients, grade 3 — in 25 patients, and grade 4 — in 3 patients. Nineteen patients had a history of myocardial infarction. Hypertension was found in 24 patients. Concomitant obesity was observed in 17 patients. Elevated cholesterol (> 5.2 mmol/l) was seen in 21 patients. Thirteen patients had decreased ejection fraction.

Diabetes group included 26 men and 4 women, of these there were 25 smokers. The history of diabetes mellitus was 5.13±0.64 years by the time of surgery. Diabetes was judged as mild in 20 patients, moderate — in 6 patients, and severe — in 4 patients. Mean basal glucose was 6.69±0.18 mmol/l, mean postprandial glucose — 8.55±0.28 mmol/l. Hypercholesterolemia was found in 21 patients. As compared to non-diabetic patients, those with type 2 diabetes mellitus had higher rates of hypertension and obesity — 27 patients vs 24 patients, respectively, and a higher rate of grade 4 angina (6 patients). Decreased ejection fraction was also more common in diabetic patients, despite similar profile of coronary atherosclerosis and almost identical rate of myocardial infarction (17 patients in diabetes group).

In non-diabetes group early postoperative myocardial infarction was found in 2 patients, atrial fibrillation — in 5 patients, cerebrovascular accident — in 1 patient, pericarditis — in 2 patients, hemorrhage requiring repeated sternotomy- in 1 patient. In diabetes group there were 2 patients with rhythm disorders, 1 patient with perioperative myocardial infarction, 3 patients with mediastinitis.

We concluded that patients with diabetes mellitus had higher rates of mortality and inflammatory complications after coronary bypass surgery.

CROSSOVER BYPASS FOR UNILATERAL BRACHIOCEPHALIC VEIN OCCLUSION

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Superior vena cava syndrome occupies a particular position among all venous diseases. Development of this syndrome results in hemodynamics impairment associated with serious complications that attracts particular attention of surgeons and morphologists. Several publications concerning brachiocephalic vein occlusions after pacemaker implantation (Inoue T., Otaki M., Nakamoto S., Zang Z., Oku H., 2001) appeared recently. According to the publications, right brachiocephalic vein occlusion is observed in 17.7% of patients with superior vena cava syndrome, and left brachiocephalic vein occlusion is observed in 13.7% of patients.

We have introduced a method of surgical correction aimed at venous decompression in case of unilateral brachiocephalic vein occlusion. Functional effect of the suggested operation was studied in 12 mongrel dogs in chronic experiment. External jugular vein on the contralateral side to the occlusion was separated, and cranial vein segment was transected at the origin of the vein. Then venous angle at the occlusion side was separated, cranial end of the external jugular vein was conducted subcutaneously to the venous angle and end-to-side anastomosis was formed.

So, experimental studies have shown that external jugular veins can be successfully used for a crossover bypass in the treatment of circulatory impairment caused by brachiocephalic vein occlusion.

TRANSHEPATIC ENDOBILIARY PROCEDURES FOR OBSTRUCTIVE JAUNDICE

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Prolonged cholestasis may cause severe morphological and functional homeostatic changes of the human body. The most dangerous consequences of bile flow obstruction include hepatorenal failure, cholangitis, thrombosis or hemorrhage.

Transhepatic endobiliary procedures, which include various types of bile drainage, balloon dilation for strictures of common hepatic and common bile ducts, as well as hepatic-ileal bypass, endoprosthesis placement, lithotripsy.

Follow-up included 56 patients with obstructive jaundice. The age ranged from 23 to 78 years (25 men and 31 women). The history of jaundice was 15 to 90 days. The level of serum bilirubin ranged from 230 mmol/l to 672 mmol/l. The causes of jaundice as a syndrome were as follows: choledocholethiasis — in 20 patients, common bile duct strictures (including those of iatrogenic origin) — in 15 patients; cancer of pancreas head — in 11 patients, stricture of choledochojejunoanastomosis — in 4 patients; cholangiocellular carcinoma of proximal common bile duct — in 2 patients; papillitis, chronic pancreatitis — in 2 patients; hepatic hilus cancer — in 2 patients.

Transhepatic drainage of bile ducts was performed according to Wichel's method under ultrasonic and endoscopic guidance. The period from the admittance to the hospital until the drainage was below 24 hours in 24 patients, below 48 hours — in 12 patients, over 48 hours — in 13 patients, postoperative drainage was performed in 7 patients.

Decompression by percutaneous drainage of bile ducts decreased bilirubin level, cholangitis symptoms and other homeostatis parameters.

Elective surgery after percutaneous drainage of bile ducts was performed in 35 patients. Transhepatic endoprostesis placement was performed in 21 patients.

Self-expanding WALLSTENT metal mesh biliary prostheses were deployed in 9 patients, Kary-Kuns prostheses — in 12 patients. No cases of mechanical jaundice were observed in the long-term period.

The rate of complications during endobiliary procedures was 9.8%.

Endobiliary prosthesis placement, which ensures frame-like shape of common bile duct and facilitates internal bile drainage, is a method of choice for strictures and tumors of hepatobiliary region.

CLINICAL AND ANGIOGRAPHIC RESULTS OF DIRECT MYOCARDIAL REVASCULARIZATION IN THE INTERMEDIATE PERIOD AFTER THE OPERATION

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The purpose of our study was to investigate the influence of bypass function and degree of revascularization in the intermediate period on the clinical course of coronary artery disease (CAD) in patients underwent surgical revascularization.

The study included 89 patients (82 men and 7 women), who underwent coronary artery bypass graft (CABG) surgery in Moscow City Center of Interventional Cardioangiology in January 2001 — March 2004. The patients underwent control examinations including clinical status evaluation, stress tests, coronarography, ventriculography and bypass angiography in average 7.2±0.8 months after the operation. Mean age of the patients was 57.4±4.1 years (from 32 to 72 years). By the time of CABG surgery 3 patients had functional class (FC) II exertional angina, 72 (80.9 %) patients had FC III-IV (Classification of the Canadian Cardiovascular Society), 9 (10.1 %) patients — unstable angina pectoris, 5 (5.6 %) — acute myocardial infarction (MI). 33 (37 %) patients had left main coronary artery lesions, 67 (75.2 %) patients had three-vessel lesions, 22 (24.8 %) patients — two-vessel lesions. Total myocardial revascularization was performed in 59.2% of cases. A total of 269 coronary arteries were operated using 173 (64.3 %) arterial and 96 (35.7 %) venous grafts. A total number of mammary-coronary artery anastomoses was 116 (67.05 %); the mammary arteries were used as a free graft in 32.9 % of cases.

Clinical improvement was observed in 74 (83.1 %) patients at the medium- and long-term period after bypass surgery: 62 (69.6 %) patients had no evidence of angina pectoris symptoms, angina functional class decreased by 2 classes in 12 (13.5 %) patients. Clinical effectiveness of the operation was noted in 91.1% of cases of total revascularization. Two (2.2 %) patients had acute MI, 13 (11.2 %) patients had recurrent angina pectoris FC III-IV. Bicycle exercise test was negative in 82.5 % of patients. The exercise tolerance increased significantly from 59.0±6.0 Watt to 91.0±10.0 Watt ($p<0.05$). The administration of b-blockers and nitrates was significantly reduced from 92 % to 80 % and from 97 % to 42 % respectively.

There were the following causes of clinical worsening: bypass malfunction — in 5 (5.6 %) patients, incomplete revascularization — in 4 (4.5 %) patients, hemodynamically significant coronary artery lesions below the distal anastomoses — in 4 (4.5 %) patients. Bypass angiography showed that 251 (93.3 %) bypass anastomoses were patent. There were 8 (8.3 %) venous graft lesions and 10 (5.7 %) arterial graft lesions. 14 procedures of transluminal angioplasty and 8 stenting procedures with good immediate angiographic result were conducted because of detected lesions.

Coronary artery bypass graft surgery showed high clinical effectiveness in the intermediate period. Venous graft lesions in the intermediate period after direct myocardial revascularization were observed more often than arterial graft lesions. Angiographic control in the intermediate period after the operation allows to perform endovascular correction of pathologic changes in the grafts and native arteries that helps to improve the results of CAD treatment.

ANGIOGRAPHY AND ENDOVASCULAR EMBOLIZATION OF MAXILLARY ARTERY BRANCHES DURING PREOPERATIVE PREPARATION OF PATIENTS WITH JUVENILE ANGIOFIBROMES IN NASOPHARYNX

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Rich vascularity of juvenile angiofibromes is a serious obstacle to radical surgical treatment due to the high rate of massive intra- and postoperative hemorrhages.

The aim of this work was to define the nature of juvenile nasopharyngeal angiofibrome vascularity as well as efficacy of preoperative embolization for intraoperative hemorrhage reduction.

External carotid artery angiography and embolization of maxillary artery branches was performed in 10 male patients aged from 10 to 23 years. Bilateral occlusion was performed in 6 patients, unilateral occlusion at the side of the tumor — in 4 patients. We used polyvinyl alcohol particles of 200-400 micron in size and finely cut collagen hemostatic sponge as emboli. The interval between intravascular procedure and surgical intervention varied from 3 hours to 4 days.

Angiograms demonstrated blood supply pattern and allowed to identify the dominant maxillary artery. Bilateral embolization was performed in patients with signs of contralateral circulation in the lesion site as well as in case of medially located tumor. In all cases the tumor was removed using radical Denker rhinotomy with minimal surgical trauma and without significant hemorrhage. Two patients with coagulation impairment and extended tumor lesion required hemotransfusion. There were no recurrent tumors and bleedings, as well as no complications of intravascular and surgical procedures. Preoperative devascularisation did not influence the time of postoperative wound healing.

PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF LOWER LIMB ARTERIES

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The aim of the study was to evaluate immediate results of percutaneous transluminal angioplasty (PTA) for obliterating atherosclerosis of lower limb arteries.

During 2002-2003 forty-two patients underwent 50 PTA procedures. 79% of them were male; the mean age was 62±7.5 years. Indications for PTA were claudication in 10 patients and critical ischemia in 32 patients. 18 PTA procedures were performed in the iliac segment and 32 procedures — in the femoropopliteal segment. In the iliac segment predominant lesions were stenoses (89%); occlusions prevailed in the femoropopliteal segment (83%). The mean length of occluded segment was 10.4±5.3 cm.

Technical success was achieved in 84% of cases (in 94% of procedures in the iliac segment and in 78% of procedures in the femoropopliteal segment). PTA of stenoses was effective in 95% of cases; PTA of occlusions — in 76% of cases. The mean length of successfully recanalized occlusion was 8.6±2.4 cm; in cases of failed recanalizations — 14±8 cm. Clinical improvement was observed in 72% of cases, deterioration — in 14% of cases, patient condition did not change in 14% of cases. Complications of PTA required surgical correction were noted in 10%. In 4% of patients thrombectomy was performed, in 4% — bypass surgery and in 2% — amputation of the lower extremity.

So, PTA is a rather effective method of lower limb revascularization in patients with obliterating lesions of main arteries more than 10 cm in length. PTA is significantly more effective in case of stenoses as compared to occlusions, in short occlusions as compared to long occlusions, as well as in iliac segment as compared to femoropopliteal segment. PTA of peripheral arteries requires obligatory surgical standby.

PERCUTANEOUS INTERVENTIONS IN PATIENTS WITH NON-Q MYOCARDIAL INFARCTION

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The aim of the study was to evaluate the efficacy of PTCA and stenting of coronary arteries in patients with microinfarction.

Urgent and elective interventions were performed in 84 patients with non-Q myocardial infarction. "Nonpenetrating" MI in all patients was diagnosed on the basis of clinical and electrocardiographic findings. Anterior MI was diagnosed in 69 patients, posterior (inferior) and/or lateral MI — in 15 patients. In 73 patients non-Q myocardial infarction developed as a result of progressive CAD; 11 patients were transferred to the clinic from other hospitals after successful systemic thrombolysis. In 44 patients urgent intervention was indicated because of unstable angina resistant to drug therapy. According to the coronary angiography blood flow TIMI I-II in the infarct-related artery was identified in 75 patients; occlusion of infarct-related artery (TIMI 0) with significant collateral blood flow originated from other arteries was noted in 9 patients.

PTCA was performed in 23 patients (27.4%), stenting — in 61 (72.6%) patients (direct stenting — 26 cases). Initial effect was observed in 80 (95.2%) patients. Intervention was ineffective in 4 (4.8%) patients: in 2 cases with occlusion we failed to restore perfusion in the infarct-related artery, and two patients with manifested unstable angina died. Stress tests performed before the discharge showed that 63 patients (78.7%) were angina-free.

Clinical course in the long-term period was studied in 53 patients. 11 patients (20.8%) were operated due to restenosis; 9 of them (16.9%) underwent interventional treatment, and two patients (3.9%) were referred for coronary artery bypass surgery.

Non-Q myocardial infarction is extremely dangerous since its anatomic substrate is critical impairment of coronary perfusion in the infarct-related artery. Immediate and long term results of percutaneous interventional methods of coronary blood flow restoration allow us to conclude about high efficacy of this method of CAD treatment.

X-RAY GUIDED ENDOVASCULAR INTERVENTIONS IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION AND EARLY POSTINFARCTION ANGINA

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The aim of the study was to evaluate the possibility of X-ray guided surgical revascularization in patients with acute myocardial infarction and early postinfarction angina.

In 2003, 194 patients of Krasnoyarsk Territorial Clinical Hospital underwent emergent coronary angiography due to acute myocardial infarction or early postinfarction angina.

In case of primary and recurrent infarction the period from the symptom onset till the admission to the hospital averaged to 9.34±19.72 hours. The time from the symptom onset till the patient was transported to the X-ray operating room was in average 5.01±3.56 hours in patients with acute stage of myocardial infarction.

In 26 patients (13.4%) coronary angiography revealed either no changes or moderate changes of coronary arteries. Infarct was caused by single-vessel lesion in 56 patients (28.9%); pathologic changes of more than one artery were identified in 112 patients (57.7%). In addition, in 17 patients (8.8%) extremely severe coronary artery lesions were revealed, so no attempts of recanalization were made.

The attempts to perform PTCA of infarct-related coronary artery were made in 151 patients. Recanalization of the artery failed in 14 patients (9.2%). In 3 patients (2%) it was impossible to pass the guidewire through the occluded segment, so selective intracoronary thrombolysis was performed. In two of those cases selective thrombolysis allowed to perform recanalization, and then — angioplasty of the infarct-related vessel.

"Complete" revascularization was achieved in all patients with single-vessel lesions. In patients with multivessel lesions "complete" revascularization was performed in case of infarction area involving several arteries. "Complete" revascularization was achieved in 63 patients (41.7%). There were 10 fatal outcomes (6.6%) of myocardial infarction among all patients who underwent attempts of infarct-related artery recanalization.

In conclusion one could say that X-ray guided endovascular recanalization of infarct-related artery can be performed successfully in the majority of patients with acute myocardial infarction; this procedure helps to increase the efficacy of infarct treatment and results in decreased in-hospital mortality.

ANALYSIS OF LEUKOCYTE SUBPOPULATIONS IN THE ATHEROMATOUS PLAQUE SAMPLES OBTAINED DURING CORONARY ATHERECTOMY

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Morphologic substrate of acute coronary syndrome is a rupture of atheromatous plaque in the coronary artery wall developed on the background of inflammatory process in the plaque. The main cells participating in this inflammatory process are monocytes and T-lymphocytes. Analysis of various leukocyte subpopulations ratio may help to understand the etiology of acute coronary syndrome.

Atheromatous tissue samples were obtained during directional coronary atherectomy in 13 patients (6 patients with stable exertional angina and 7 patients with acute coronary syndrome). The samples were treated with collagenase to separate the cells and then stained with labeled antibodies to surface antigens CD45, CD14, CD3, CD4, CD8, CD19, CD16+CD56, CD11c, HLA-DR and to chemokine receptors CXCR3, CCR2. Surface antigen expression was analyzed using flow cytofluorometry.

We did not reveal significant leukocyte level in the atheromatous plaque samples in patients with exertional angina. All samples obtained from patients with acute coronary syndrome contained lymphocytes T (CD3+) and monocytes (CD11+ HLA DR+). Lymphocyte/monocyte ratio varied from 1:1 to 1:9. 50-80% of T-lymphocytes were T-helpers (CD4+). From 36% to 66% of CD4+ lymphocytes expressed chemokine receptor CCR2, whereas all T-helpers expressed chemokine receptor CXCR3, showing that instable plaques contained type I T-helpers.

Conclusion. In contrast to atheromatous plaques in patients with stable angina, the plaques associated with acute coronary syndrome development are infiltrated with T-lymphocytes (T-helpers type I) and monocytes.

THE VALUE OF RADIONUCLIDE VENTRICULOGRAPHY IN THE ASSESSMENT OF LEFT VENTRICULAR CONTRACTILE FUNCTION IN PATIENTS WITH HEART FAILURE

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Purpose of the study was to assess left ventricular contractile function in patients with heart failure using radionuclide ventriculography (RV).

We examined 25 CHD with postinfarction cardiosclerosis and grade 2-3 heart failure (NYHA grade 2-3), aged 40 to 60 years (mean age 52.8±1.3 years). The study enrolled patients with a history of myocardial infarction 6 months to 5 years prior to study. All patients underwent electrocardiography, complete set of clinical and biochemical studies, two-dimensional sonography (Toshiba SSH — YOA) and Tc99 TSK RV (E-сам gamma camera, Siemens, Germany) to assess total ejection fraction (TEF) and sectoral ejection fraction (SEF). Left ventricular myocardium was divided between 4 regions (anterobasal, posterolateral, apical and septal) and 9 sectors.

The results showed, that in patients with grade 1 chronic heart failure TEF value was 60.6±1.57 % as determined by sonography and 55.6±3.0% — by RV. In patients with grade 2 chronic heart failure this value was 51.8±0.98% for sonography and 43.0±4.1% for RV, while in patients with grade 3 chronic heart failure the sonographic value was 43.0±21 % and RV value — 34.0±3.5%. The results of sectoral analysis showed, that the decrease in left ventricular contractile function most commonly involved apical and septal regions, which is consistent with the predominant location of postinfarction atherosclerosis.

Therefore, RV with sectoral analysis proved informative for the assessment of left ventricular contractile function in patients with heart failure.

IMMEDIATE AND LONG-TERM RESULTS OF CORONARY STENTING WITH Bx Velocity AND Cypher STENTS

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The use of stents with polymeric drug coating substantially increases the potential of endovascular treatment for CHD. The most widespread type of stents with rapamycin® coating (immunosupressive agent) is Cypher stent (Cordis), designed on the basis of Bx Velocity stent (Cordis). We routinely use both types of coronary stents.

Purpose of the study was to compare immediate efficacy and long-term results of endovascular therapy for CHD using stents without drug coating (Bx Velocity) and Cypher stents.

We analyzed immediate and long-term results of coronary stenting in 697 patients. The patients were divided in 2 groups: group 1 — 376 patients, who underwent coronary stenting with a total of 490 Bx Velocity and Bx Sonic coronary stents. Group 2 — 321 patients with 446 Cypher stents. We assessed the immediate results (angiographic success, immediate clinical outcome) and the presence of complications, as well as the long-term coronary events (CHD aggravation, in-stent restenosis, segmental restenosis, death, MI, coronary bypass surgery, repeated endovascular procedures in the target vessel). The follow-up period in group 1 was at least 12-18 months, and in group 2 — 6-18 months. The diagnosis of restenosis was based on clinical data, positive exercise test and follow-up angiography (FUA). FUA was performed in 34% of patients. Treatment results were analyzed in the following sub-groups: coronary occlusions, bifurcation stenosis, prolonged stenosis, small vessel stenting, angioplasty for restenosis and bypass grafts.

The immediate success of stenting was 100% in both groups. We observed effective delivery, precise positioning and complete controlled expansion of stents. Difficult advancement of the stent system due to arterial tortuosity or calcinosis was observed with stents over 28 mm in length and required predilatation or consecutive implantation of short stents. Clinical efficacy of stenting (relief or decrease of angina, negative exercise test) was 98.4% in group 1 and 99.3% in group 2. There were no intraoperative or postoperative complications (including MI and death) in any group. Angina recurrence or aggravation during follow-up were found in 9.2% of group 1 patients and 1.6% of group 2 patients. The cumulative proportion of patients with no coronary events during long-term follow-up was 88.3% for conventional metal Bx Velocity stents and 96.0% for Cypher stents. Total decrease of risk of coronary events during 18-month follow-up was 34.2% for Cypher stents. The rate of in-stent restenosis was 3.87% in group 1 and 0.2% in group 2; the rate of segment restenosis was 0.67% and 6.5%, respectively. The most significant differences in the long-term results and the rate of restenosis between the groups were observed in the subgroups with diffuse changes in coronary artery requiring prolonged stenting, coronary occlusion, bifurcation stenosis, endovascular procedures for in-stent restenosis, coronary graft stenosis.

The use of both types of coronary stents is safe and effective for endovascular management of CHD. There were no differences in long-term outcome between the groups.

The risk of coronary events declined throughout the 9-18 months of follow-up by 34.2%.

The rate of clinically significant restenosis in Cypher group as compared to Bx Velocity group decreased from 3.87 to 0.2, and for segmental restenosis — from 6.5 to 0.67%. The need for repeated endovascular procedure in the target vessel decreased from 3.6 to 0.4%.

The most significant benefits of Cypher stent from the viewpoint of the long-term outcome were revealed for diffuse changes of coronary arteries, recanalized coronary occlusion, in bifurcations, arteries below 2.75 mm in diameter.

Implantation of Cypher stents with rapamycin coating is a method of choice for the management of restenosis and coronary graft failure.

The use of conventional metal Bx Velocity stents is advisable in "simple" clinical situations with arterial diameter exceeding 3.5 mm and the length of stenosis below 18 mm.

COMPARATIVE EVALUATION OF LONG TERM RESULTS OF STENTING AND CORONARY ARTERY BALLOON DILATATION WITH OPTIMAL (STENT-LIKE) IMMEDIATE ANGIOGRAPHIC RESULT

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For the comparison of long term results of stenting procedure and balloon angioplasty with optimal immediate angiographic effect meeting the "stent-like" criteria, there were selected 2 statistically similar groups of patients (a total of 262 patients) with the lesion of one native coronary artery; during 2000-2003 these patients underwent 154 stenting procedures (1st group) and 108 balloon angioplasty procedures (2nd group) due to stable functional class II-III angina pectoris. All patients were examined again 7.5 ± 1.2 months after the intervention. The examination included control coronarography. The mean age of patients was 54±7.2 years; among all the patients there were 248 male patients (94.7 %). Endovascular procedures were performed on the anterior interventricular artery in 60 % of cases; reference diameter of the target artery averaged 2.8±0.4 mm, stenosis severity — 84±12 %. Initial type of injury was A and B1 (AHA/ACC classification). Modular Multylink (Guidant) protheses were used in all stenting cases. The criterion of optimal procedure result was the absence of dissection and residual artery stenosis not more than 10 % of the vessel lumen (residual stenosis was on average 2.3±0.8 % in the 1st group and 6.2±3.7 % in the 2nd group ($p>0.05$)). Definitive angiographic result was estimated by data of control angiography performed in at least 15 min after the last dilatation.

The frequency of restenoses in the intervention zone was higher in the 2nd group, however the differences were not significant: 28 (18.2%) in the 1st group compared to 24 (22.2%) in the 2nd group ($p>0.05$). Severity of stenoses was significantly less in the 1st group: 61.6±7.5% compared to 66.5±15.8% ($p<0.05$). Diffuse restenoses were significantly more frequent in the 1st group: 78.6% and 35.7% respectively ($p<0.05$). Control angiography revealed no evidence of vascular occlusion in both groups.

The long term clinical and angiographic results of balloon angioplasty in patients with favorable initial lesion morphology (type A, B1) and optimal immediate angiography results correspond to the stenting results.

EQUIVALENCE STUDY: COMPARISON BETWEEN THE NEW TSUNAMI CORONARY STENT (TERUMO) AND BXVELOCITY STENT (CORDIS) FOR ENDOVASCULAR MANAGEMENT OF CHD PATIENTS

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Over 50 types of endovascular stents are currently available in invasive cardiology. For novel stent type an equivalence study is mandatory, i.e. their comparison with the widespread types of stents. Such studies are, in a way, a threshold, regulating the selection of stents for clinical use.

Purpose of the study was to compare new TSUNAMI (TERUMO, Japan) matrix stent and the well-known BxVelocity stent (Cordis, USA) as a reference stent.

The study enrolled 166 CHD patients, in whom TSUNAMI (n=72) or BxVelocity (n=94) stents were implanted. We assessed the long-term (6-month) angiographic outcome.

The results are summarized in the Table below.

Angiographic characteristics of the coronary arteries				P
		TSUNAMI	BxVelocity	
Distal stent diameter, mm		2,9±0,7	3,1±0,6	NS*
Minimum stent diameter, mm		2,8±0.3	2,9±0,3	NS*
Restenosis rate 6 months following stenting				
In-stent restenosis		20 %	18 %	NS*
Restenosis of stent segment		5,1 %	4,7 %	NS*
Total restenosis rate		25,1 %	22,7 %	NS*
% diameter stenosis	Restenosis	63±9 %	62±10 %	NS*
	No restenosis	8±2 %	6±2 %	NS*

* NS — non-significant

The results suggest, that there are no statistically significant differences in the rate of restenosis at 6 months between the new TSUNAMI (TERUMO) matrix stents and BxVelocity stents. TSUNAMI stents can be extensively used for endovascular management of CHD patients.

INVASIVE METHODS OF INVESTIGATION IN VARICOSE ENLARGEMENT OF SPERMATIC CORD VEINS AND PAMPINIFORM PLEXUS IN CHILDREN AND ADOLESCENTS

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Left-sided phleborenotesticulography, bilateral phleborenotensiometry and blood sampling from the right and the left renal veins with blood gases analysis were carried out in 90 children and adolescents with grade II or III varicocele aged 11 to 15 years for profound investigation of renotesticular venous pool aimed at the choice of optimal treatment and prevention strategy.

The study revealed aorto-mesenterial compression of the left renal vein, judged as moderate in 45 patients, severe — in 38 patients and causing stenosis in 7 patients; in 8 patients no compression was found.

Contrast study of the left testicular vein showed its drastic enlargement up to 9 mm in diameter in 31 cases, slight enlargement — up to 3 mm in 37 cases and loose branching of the testicular vein in 22 cases.

Phleborenohypertension (systolic pressure over 9 mm Hg) was diagnosed in 26 children, with the remaining 64 children being normotensive.

Stenosis and severe aorto-mesenterial compression of the left renal vein, left testicular vein enlargement with phleborenohypertension were the indications for proximal testiculoiliac venous anastomosis creation in 21 cases.

Normal pressure, moderate aorto-mesenterial compression of the left testicular vein with a single enlarged vessel and loose branching of the testicular vein were the indications for endovascular closure of the left testicular vein using 3% trombovar solution in 42 patients; 27 patients underwent Ivanissevich operation.

Blood gases analysis showed bilateral hypoxemia in over one half of patients, more pronounced on the left side. Other patients had no pathological changes.

Therefore, the use of invasive methods of investigation allowed for differentiated choice of the method of surgical treatment.

CLINICAL EXPERIENCE OF APPLICATION OF CORONARY STENTS COVERED WITH SILICON CARBIDE (BIOTRONIC, GERMANY)

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The purpose of the study was to evaluate the immediate efficacy of carbide covered (Biotronic) stents as well as long-term clinical results of their implantation in patients with coronary artery disease (CAD).

During the period from 2001 till now 146 stents of this model were implanted, 132 of these were TENAX and 14 — RITHRON. 132 patients with CAD of various severity grades underwent endovascular operations. Postinfarction cardiosclerosis was diagnosed in 114 (86.4 %) postoperative patients. 23 (17.4 %) from them were operated due to angina pectoris recurrence after bypass operation. The indications for stent implantation were considered individually. 22 (15.1 %) stents were implanted in coronary artery bifurcation stenoses, 17 (11.6 %) — in ostial portion of the main coronary arteries, 3 (2.1 %) — in left main trunk.

In all these cases implantation was not accompanied by stent dislocation from the delivery device. The anatomical artery anomalies in 3 (2.3 %) patients did not allow to place the stent in the damaged segment. The stenting was complicated by distal intima dissection in 2 (1.4 %) cases. We couldn't to restore completely the patency of the ostial portion of a lateral branch in 8 (6.1 %) cases of bifurcation stenting. There were no cases of arterial thrombosis at the place of stenting in this study. 78 (59.1 %) patients were examined again after 6 months. The essential evaluation criterion was clinical state of patient with CAD immediately after the operation and after 6 months. 8 (6.1 %) patients had recurrence of angina pectoris during the indicated period and restenosis was verified by angiography.

The conclusion: 1) BIOTRONIK stent application has low risk of immediate postoperative complications; 2) our results show that implantation of carbide covered stents can reduce the rate of repeated endovascular interventions; 3) the first stent generations - TENAX- are quite a hard construction, they are difficult to implant in the kinked parts of coronary arteries; 4) the cell structure of indicated stents allows to recover the normal diameter of lateral artery branch in the bifurcation stenosis area, but not in all cases.

STENTING FOR INTRACRANIAL ARTERIAL LESIONS

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Since 2002 we have performed 6 stenting procedures in 6 patients with intracranial stenoses for the treatment of intracranial arterial lesions and cerebral aneurysm repair. The age of patients ranged from 48 to 55 years, the procedures were performed 1 to 6 months following the episode of transient ischemic attack or reversible ischemic neurological deficit. We performed three stenting procedures in cavernous ICA portion, 2 stenting procedures in petrous ICA portion, 1 stenting procedure in M1 segment of MCA. Coronary stents were used in all patients. Complete reduction of stenosis was achieved in all cases, and substantial decrease of neurologic deficit was observed.

In 2 cases we used stent-grafts for cerebral aneurysm repair. In 1 case a stent-graft was implanted in the neck of a giant aneurysm of subclinoid ICA portion, which had tumor-like clinical manifestations. The ICA patency was preserved and the neurological symptoms regressed. In another patient a wide neck aneurysm of vertebrobasillar junction was treated with the same technique. The right vertebral artery with hypoplasia was closed together with the aneurysm near vertebrobasillar junction using stent-graft, the left vertebral artery was patent and no progression of neurological symptoms was observed.

Often the stenosis can not be completely reduced by percutaneous transluminal angioplasty without stenting. The risk of intimal dissection causing arterial occlusion and brain ischemia is rather high. Stenting of intracranial arteries ensures complete reduction of stenosis with significantly lower risk of complications.

The use of stent-grafts for the repair of giant aneurysms and wide neck aneurysms maintains patency of the artery and reduces the effect of aneurysm on adjacent cranial nerves.

Stenting can be successfully used for the treatment of intracranial stenoses and the repair of cerebral aneurysms when direct clipping is unavailable.