REMOTE RESULTS OF EVERSION CAROTID ENDARTERECTOMY DEPENDING ON THE SUTURE MATERIAL USED

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Background. It is known that namely long-term presence of suture material as the only foreign body in autologous conditions may lead to restenosis in the remote period. Such hypothesis was put forward based on good results of reconstructive cardiovascular operations in case of using absorbable suture material.

Objective. Our study was aimed at comparative analysis of remote results of using absorbable suture material polydioxanone and non-absorbable suture material polypropylene in eversion carotid endarterectomy.

Patients and methods. Over the period from 2002 to 2007, at the Department of Vascular Surgery of the Institute of Surgery named after A.V. Vishnevsky performed a total of 408 carotid reconstructions according to the eversion technique. The study was based on comparative analysis of the remote results of this procedure in two groups of patients: the first group consisted of 121 patients in whom replantation of the internal carotid artery into the common carotid artery was performed using absorbable suture material polydioxanone with the metric sizes 5–0 and 6–0 and the second group comprising 135 patients in whom similar manipulations were performed using non-absorbable suture material polypropylene with the metric size 6–0. In the course of the study it turned out that the remote results might also be influenced by the metric size of polydioxanone, therefore the first group was further subdivided into subgroups: polydioxanone 5–0 – 79 patients and polydioxanone 6–0 – 42 patients.

Results. At baseline, with statistically significant differences by the gender, incidence of unstable atherosclerotic plaque, diameter of the ipsilateral internal carotid artery ⩽4 mm, the groups of patients turned out to be in the remote period statistically significantly comparable by such parameters as frequency of the development of a pseudoaneurysm, restenosis of the internal carotid artery, ipsilateral stroke, restenosis-associated stroke, and by survival. However, when comparing the subgroup of patients wherein polydioxanone 6–0 was used and the second group with the initially statistically significant differences by incidence of unstable atherosclerotic plaque and myocardial infarction, in the remote period there was a statistically significant decrease in the incidence rate of restenosis of the internal carotid artery in the first case.

Conclusions. The obtained findings suggested that the absorbable suture material polydioxanone with the metric size 6–0 might be considered as quite a substantiated alternative to the used in cardiovascular surgery non-absorbable suture material polypropylene. Polydioxanone with the metric size 6–0 made it possible to remove or considerably decrease the incidence rate of the development of restenosis of the internal carotid artery after eversion carotid endarterectomy.

Key words: *eversion carotid endarterectomy, restenosis, absorbable suture material.*

Acute impairments of cerebral circulation (AICC) are currently of both medical and social concern [1]. Suffice it to say that annually in Russia there occur approximately 400 thousand new cases of strokes, of which up to 90% end with permanent disability [2].

Today it is known that amongst all types of strokes dominating are ischaemic ones (80%). Their main cause is considered to be an atherosclerotic narrowing of the extracranial portions of the internal carotid artery (ICA) [3]. According to the data of multicenter studies it was determined that the risk for the development of ischaemic strokes in patients may statistically significantly be decreased by performing carotid endarterectomy (CEA), rather than medicamentally [4–6]. But it should be mentioned that in spite of considerable clinical success, as with any arterial reconstruction, performing CEA may be accompanied by the development of restenosis occurring in a portion of patients during both first days after operation and within months and even years thereafter. Special attention to prevention of this problem is dictated by probability of the appearance or recurrence of neurological symptomatology [7].

Today there is evidence confirming that the appearance of these alterations in the arterial wall is mainly associated with high activity of aseptic inflammatory process [8], the final of which is considered to be myointimal hyperplasia [9] or progression of atherosclerosis in the zone of arterial reconstructions [10]. Therefore, the measures on prevention of restenosis should be aimed primarily at decreasing the degree of inflammation. It means that first of all every effort should be made to rule out the use of foreign materials in vascular reconstructive interventions or to maximize their autologous nature [11, 12]. The latter in due time served one of the reasons

why many vascular surgeons of the world's leading clinics use eversion carotid endarterectomy (eCEA) [13, 14]. As a result, the risk for the development of restenosis decreased, not however disappearing completely – according to the latest data the incidence rate of restenosis development at 7 years amounts to 5% [15]. Along with it, it is known that namely long-term presence of suture material as the only foreign body in conditions of autologous reconstruction may lead to restenosis in the remote period. Such hypothesis was put forward based on the reports of good results of reconstructive cardiovascular operations in case of using absorbable suture materials.

Absorbable suture materials in cardiovascular surgery started to be used since the 1950s [16]. Nevertheless, this trend received rapid development after the appearance in 1980 of synthetic absorbable suture material polydioxanone (PDS) principally differing from other absorbable suture materials by slower destruction: it preserves after use more than 85% of its original tensile strength during 14 days, 60% by day 28, with complete absorption thereof occurring within 180 days [17].

In a series of experimental studies on laboratory animals, carried out since 1984, when comparing the results of using PDS and widely used in cardiovascular surgery non-absorbable suture material polypropylene (PPL) for creation of vascular anastomoses while using the latter, the recipient beds demonstrated statistically significantly more pronounced inflammatory reaction [18, 19] maintained by both the presence of a foreign material [20] and marginal ischaemia of tissues of the central and peripheral ends of vessels due to relatively prolonged tightening with a dense cord [21, 22]. The described inflammation, in its turn, resulted in migration of smooth-muscle cells, coarse sclerotic alterations, hyaline degeneration, calcification, retraction of tissues and deformation of the anastomosis in the zone of vascular reconstruction [23]. But the negative consequences of using PPL are not confined thereto. In an experimental study comparing the results of using PDS with PPL, implantation of non-absorbable material was accompanied by impaired compliance of the parts in the anastomosis at the expense of a rigid line of the suture [24], which along with the previous events, in the long run, increased the risk for the development of restenosis [25–27].

Relying upon the results of experiments of implantation of PDS into vessels of animals, researchers began using this suture material in vessels of volunteers, in autologous reconstructions, since the transplant does not have

Table 1

Clinical studies of using absorbable suture material in cardiovascular surgery

Author	n/age*	Type of reconstructions	Follow-up duration	Incidence of restenosis	Incidence of pseudoaneurysm
Arenas J.D., et al., 1991 [31]	15/3.7 years	resection of aortic coarctation with formation of an end-to-end anastomosis	23 months	0	0
Spector M.L., et al., 1991 [32]	18/9 months	resection of the common carotid artery with formation of an end-to-end anastomosis	6 months	0	not mentioned
Merrell S.W., Lawrence P.F., 1991 [33]	21	infrainguinal bypass procedures, thromboembolectomy, formation of an arteriovenous fistula for haemodialysis and disunion of post-traumatic arteriovenous fistula	7.2 months	0	0
Ikeda S., et al., 1993 [34]	7	formation of an extra-intracranial anastomosis	8.5 months	0	0
Wang Z-G., et al., 1994 [35]	21 35	arterial reconstructions: thromboembolectomy via the femoral artery, femoral-distal bypass procedures, profundoplasty, arterialization of superficial veins of the foot, repair of popliteal artery, grafting of the brachial artery and reconstruction of the carotid artery venous reconstructions: cava-atrial, jugular-atrial, innominate-atrial, meso-atrial, spleno-atrial, mesocaval, sapheno-jugular bypass grafting, Palma's operation, Hussni's operation, inferior cavatomies, iliofemoral thrombectomy, transplantation of venous valves	42 months	0	0
Sarioğlu T, et al., 1996 [36]	53/3.7 years	indirect isthmoplasty	34 months	0	0
Yetkin U., et al., 2007 [37]	1	classical CEA with primary suture	2 months	0	not mentioned
MacIver R.H., et al., 2008 [38]	114/1.6 years	formation of bi-directional cava-pulmonal anastomoses	31 months	0	not mentioned
Yaşa H., et al., 2009 [39]	5	classical CEA with primary suture	3 months	0	not mentioned

** – age indicated for children only*

Table 2

Clinical comparative studies of using absorbable and non-absorbable suture material in cardiovascular surgery

Author	n/age	Type of reconstructions	Follow-up duration	End point	Result	Statistical significance, p
Hawkins J.A., et al., 1995 [40]	32 with PPL/54 days	formation of an anastomosis between the pulmonary confluence and left atrium	60 months	frequency of occlusion of pulmonary veins	17%	< 0.05
	35 with PDS/15 days				3.2%	
Yoshimura N., et al., 1998 [41]	41 with PPL/3 months	bypass operations according to Blalock-Taussig (formation of a subclavian-pulmonary anastomosis)	12 months	average inner diameter of the subclavian-pulmonary anastomosis	3.1±0.2 mm	< 0.001
	40 с ПДС/ 1,8 мес.				4,6±0,2 мм	

the function of cohesion with live tissue. The history of using PDS in cardiovascular surgery stems from 1984 when Harjola P.T., et al. reported performing 10 femoropopliteal bypass graft procedures, 5 aortoiliac endarterectomies and 5 coronary aortic bypass grafting (CABG) procedures, while Tuchmann A. and Dinstl K. reported 3 femoropopliteal (tibial) bypass grafting procedures using the same suture material. During the follow-up from 3 to 5 months, all except those subjected to CABG underwent angiography whose findings showed no evidence of either restenosis or aneurysms in the reconstruction zone [28, 29].

Five years later, the first group of authors reported as many as 50 CABG procedures (including 33 mammary-coronary bypass grafts) using PDS. The duration of the follow-up period amounted to 2.5 years, based on clinical findings, in recurrence of angina pectoris observed in 6 cases, they performed control coronarography revealing only in one case occlusion of the distal portion of the sequential autovenous shunt [30].

Further foreign studies within the framework of studying the results of using PDS in cardiovascular surgery are presented in Tables 1 and 2.

2003 saw the publication of the first work on using PDS in vascular surgery in Russia, including 34 arterial reconstructions (28 interventions on the carotid arteries, 5 femorodistal bypass graft procedures and 1 carotid-brachial bypass grafting). That work demonstrated the world's largest experience of using this suture material in surgery of carotid arteries at that time. Having examined the results of 11 interventions on the internal carotid artery (9 eCEA procedures and 2 reconstructions for kinking of the ICA) by means of colour Doppler scanning (CDS) over a six-month period, the authors demonstrated only one case of restenosis of the reconstruction zone with competent anastomoses in all cases by the moment of complete resorption of suture material [42].

Hence, proceeding from the findings of experimental and clinical studies of using PDS in cardiovascular surgery, it seems that the choice of PDS instead of PPL might play an important role in respect of possible prognosis of the risk for the development of ICA restenosis. However, this cannot so far be affirmed, since statistically correct comparative studies of PDS with PPL in cardiovascular surgery have hitherto been carried out in children only. Wide application of PPL in cardiovascular surgery and at the same time lack of data of remote comparative results of using PDS and PPL in adults hampers implementation of absorbable suture material into clinical practice. Bridging this gap was the purpose of our study, for which we selected eversion CEA due to lack of the necessity of using plastic (foreign) material in its application.

PATIENTS AND METHODS

At the Department of Vascular Surgery of the Institute of Surgery named after A.V. Visnevsky over the period from 2002 to 2007 carried out a total of 408 carotid reconstructions according to the eversion technique. Of these, there were 171 cases of replantation of ICA into the the common carotid artery using PDS with metric sizes of 5–0 and 6–0 and 237 cases of using PPL sized 6–0. The present work contains a comparative analysis of the outcomes of eCEA depending on the suture material used. Since PDS by the moment of discharge (averagely 8 days after surgery) retains nearly original (more than 85% during 14 days) initial strength, while the reaction of tissues to various types of suture materials begins to manifest itself only after 10–15 days [43], we purely hypothetically consider it inexpedient to study the immediate comparative results, because the effect of these suture materials on vascular walls would hardly differ from those for PPL. In this connection, we concentrated our attention on studying and comparing the remote results of eCEA. In so doing, as the basic end criterion we assumed the state of reconstructed carotid arteries, evaluated by means of CDS. We concentrated our attention only on haemodynamically meaningful lesions which were considered to be restenoses ⩾70% of the overall diameter. The genesis of a restenosis was interpreted as atheroscletrotic if an eccentric and local structure was revealed, more resembling by CDS a heterogeneous atherosclerotic plaque (ASP) with predominance of a hypoechogenic component, or as

a consequence of myointimal hyperplasia, if revealed was a concentric homogeneous, echonegative, as a rule, prolonged formation, with smooth intraluminal surface.

Mention should be made that of the 408 patients, in the remote period we knew the fate of only 256 (63%) patients. To compare the results of eCEA depending on the suture material used in this type of intervention these patients were divided into two groups:

The first group included 121 patients subjected to eCEA with the use of absorbable suture material PDS. The obtained results of eCEA were also compared with regard for the metric parameters of the absorbable suture material used, for which purpose this group, depending on the metric size of the suture material, was further subdivided into a subgroup of PDS 5–0 comprising 59 patients and subgroup PDS 6–0 consisting of 42 patients.

The second group was composed of 135 patients subjected to eCEA with the use of nonabsorbable suture material PPL.

This work was approved by the Medical Ethics Committee on clinical trials, with the informed consent being obtained from all patients.

The choice of a particular technique of carotid reconstruction was determined by intraoperative indications. Thus, to perform the eversion technique required an "anatomical accessibility" of the ICA, tolerance of the brain to ICA cross-clamping, determined by measuring retrograde pressure (the borderline one considered to be 1/3 of the direct one, but not less than 40 mm Hg), lack of pronounced calcification and combination of stenosis and tortuosity of the ICA [44].

In the early postoperative period, all patients of both groups received treatment according to the standard algorithm. At discharge, all patients who survived were given recommendations to undergo CDS of the BCA annually, to give up smoking, to receive permanent antiaggregant therapy, control the lipid profile and arterial pressure, and those with diabetes mellitus to additionally control glycaemia with drug correction, if necessary.

The obtained results were statistically processed with the help of the mathematical package "Statistica 7" manufactured by the Company "StatSoft, Inc" (USA) for the operating system "Windows 7". Continuous data were expressed as means ± standard deviation, as well as in absolute numbers and percentage. The comparative analysis was made using the Mann–Whitney U test, Pearson's chi-squared test, Fisher's exact test, and Wilcoxon signed-rank test. Differences were regarded as statistically significant if $p<0.05$.

RESULTS

At baseline, in the studied groups we analysed the demographic parameters (age, gender), CDS results (degree of stenosis of the ipsilateral ICA, length of ASP, type of ASP, dissemination of the lesion), intraoperative data (pathological tortuosity of the ICA, diameter of the ICA), manifestations of cardiovascular insufficiency, a medical history of accompanying diseases (arterial hypertension, coronary artery disease, diabetes mellitus, hyperlipidaemia, lesion and reconstruction of other arterial basins), as well as harmful habits (smoking).

Table 3

Baseline clinical parameters of patients of the first and second groups

Parameter	Result (first group PDS – 121)	Result (second group PPL – 135)	Statistical significance, p
Gender: males females	 88 (73%) 33 (27%)	 82 (61%) 53 (39%)	0,04
Unstable ASP (CDS)	76 (63%)	102 (76%)	0.02
Diameter of the ipsilateral ICA ≤4 mm (intraoperative findings)	19 (16%)	10 (8%)	0.05

Table 4

Remote results of eCEA in the first and second groups

Parameter	Results (first group PDS – 121)	Results (second group PPL – 135)	Statistical significance, p
Mean duration of follow up (CDS)	60±38 months	61±40 months	0.88
False aneurysm	0	0	1.0
ICA restenosis including ICA occlusion	10 (8,3%) 3 (2,5%)	12 (8,9%) 5 (3,7%)	0,86 0,58
Ipsilateral stroke	6 (5%)	2 (1.5%)	0.12
Restenosis-associated stroke	2 (1.65%)	1 (0.75%)	0.51
Survival	98 (81%)	113 (83.7%)	0.53

The initially statistically significantly differing parameters for the first and second groups are shown in Table 3.

In both groups, superiority was on the men's side, but in the first group it turned out to be so high that men statistically significantly more often, and women less often, were encountered in the first group as compared with the second group.

In the first group, the number of patients with an unstable-pattern ASP in the ICA was statistically significantly less than that of analogous patients in the second group.

The diameter of the ipsilateral ICA measuring ⩽4 mm turned out to be encountered statistically significantly more often in patients belonging to the first group.

In the remote period, in both groups we analysed the results of the respective end points – frequency of the development of a false aneurysm in the reconstruction zone, ICA restenosis, ipsilateral stroke, restenosis-associated stroke and survival.

The remote results of eCEA for the first and second groups are shown in Table 4.

Table 5

Remote results of eCEA in the PDS 5–0 subgroup and PDS 6–0 subgroup

Parameter	Result (PDS 5–0 subgroup – 79)	Result (PDS 6–0 subgroup – 42)	Statistical significance, p
Mean duration of follow up (CDS)	53±37 months	70±37 months	0.02
False aneurysm	0	0	1.0
ICA restenosis including ICA occlusion	10 (12.7%) 3 (3.8%)	0 0	0.02 0.20
Ipsilateral stroke	6 (7.6%)	0	0.07
Restenosis-associated stroke	2 (2.5%)	0	0.30
Survival	60 (76%)	38 (90.5%)	0.05

Table 6

Baseline clinical parameters of patients for the PDS 6–0 subgroup and the second group

Parameter	Result (PDS 6–0 subgroup – 42)	Result (second group PPL – 135)	Statistical significance, p
Unstable ASP	22 (52%)	102 (76%)	0.003
Myocardial infarction	4 (10%)	47 (35%)	0.002

Table 7

Remote results of eCEA in the PDS 6–0 subgroup and in the second group

Parameter	Result (PDS 6–0 subgroup – 42)	Result (second group PPL – 135)	Statistical significance, p
Mean duration of follow up (CDS)	70±37 months	61±40 months	0.13
False aneurysm	0	0	1.0
ICA restenosis including ICA occlusion	0 0	12 (8.9%) 5 (3.7%)	0.05 0.22
Ipsilateral stroke	0	2 (1.5%)	0.44
Restenosis-associated stroke	0	1 (0.75%)	0.57
Survival	38 (90.5%)	113 (83.7%)	0.28

As can be seen from Table 4, the groups with PDS and PPL did not statistically significantly differ by the remote results.

We then compared the remote results of eCEA depending on the metric size of PDS, which are shown in Table 5. The baseline clinical characteristics of the examined subgroups turned out comparable by all parameters.

As can seen from Table 5, the use of PDS 6–0 for eCEA was in the remote period associated with statistically significantly longer follow up, decreased incidence of ICA restenosis, improved parameters of survival, as well as a tendency toward decreased incidence of the development of ipsilateral stroke as compared with the use of PDS 5–0 for this intervention.

The final comparison was carried out between PDS 6–0 and PPL.

The initially statistically significantly differing parameters for the subgroup of PDS 6–0 and the second group are shown in Table 6.

In the PDS 6–0 subgroup compared with the second group, the patients with signs of an unstable ASP, as well as those suffering from myocardial infarction were encountered statistically significantly less often.

The remote results of eCEA for the PDS 6–0 subgroup and the second group are shown in Table 7.

As can be seen from Table 7, the patients subjected to eCEA with the use of PDS 6–0 had statistically significantly fewer risks of ICA restenosis compared with the patients in whom PPL 6–0 was used for this operation.

DISCUSSION

Before entering into a discussion, mention should be made that in the available literature we came across no studies dedicated to comparing absorbable suture material PDS with nonabsorbable PPL in cardiovascular surgery amongst adult patients. It is noteworthy that comparative analyses of the results of PDS with PDL were carried out on amplitudinous clinical material and in the long-term period.

To date, preference to PDS is usually given in formation of vascular anastomoses in a growing body, i.e., in children [31, 32, 36, 38, 40, 41], because as the body grows, simultaneously with other organs also grows the vessel itself. This means that formation of a rigid line of suture with any nonabsorbable thread in the area of an anastomosis may entail formation of restenosis [40, 41]. In adults, these threads are, mainly, a subject of choice in infectious complications of anastomoses, because after their resorption the infectious focus is no longer maintained [45, 46]. In other cases, many surgeons refrain from using them in cardiovascular surgery. So restrained attitude to absorbable suture materials, with the exception of the surgeon's habit to use PPL, is primarily connected with fear of dehiscence of the sutured tissues to be followed by formation of a false aneurysm of the anastomosis because of thread resorption. But this has turned out to be unsubstantiated, since in an experimental study on animals during which the authors compared PPL and one of the types of absorbable suture material with the time of biodegradation less than that of PDS demonstrated that the integrity of an anastomosis was dependent on healing rather than on the permanent strength of the suture material and that the absorbable suture maintained vascular integrity long enough to permit this healing to occur [47]. Moreover, the currently available clinical studies reported not a single case of formation of a pseudoaneurysm [28, 29, 33–35, 42]. Analogous data were obtained in our study: amongst

the examined patients of either the first group, or in the second group, there were no cases of a false aneurysm revealed in the remote period.

Although there was evidence of no danger of suture stitch dehiscence in using PDS in carotid reconstructions, according to the analysis of using absorbable suture material, in our study the assessment of competence of anastomoses was not the main task. Put in the forefront was the effect of absorbable suture material on the development of restenosis of carotid arteries, since efficacy of carotid reconstructions is based on remote patency and its interrelation with the risk for the development of ipsilateral stroke and survival. Absence of inflammatory reaction of tissues around the suture and optimization of compliance in a vascular anastomosis in using PDS made it possible to decrease in previous clinical studies the incidence rate of ICA restenosis in the remote period [35, 37, 39, 42]. In our study, examining patency of the zones of carotid reconstructions from the end of the first month after the operation (because restenosis starts to develop approximately from this period on with extremely high incidence during the first 6 months) we noted statistically significantly comparable incidence of the development of ICA restenosis in the remote period in both groups, contrary to the anticipated advantage in the group with the use of absorbable suture material. And, as a consequence, the frequency of ipsilateral stroke, restenosis-associated stroke and survival in both groups turned out to be statistically significantly comparable.

In the course of our study it appeared that apart form the fact of using absorbable suture material the remote results may be influenced also by their metric parameters. In this connection it was decided to perform a comparative analysis of the remote results of eCEA with the use of PDS 5–0 and PDS 6–0. In this case it turned out that PDS 6–0 versus PDS 5–0 statistically significantly during longer terms decreased the incidence of the development of ICA restenosis. Moreover, using PDS 6–0 versus PDS 5–0 demonstrated a tendency towards decreased incidence of ipsilateral stroke, and, consequently, a statistically significant increase of survival.

The revealed differences in the remote results of the subgroups, in their turn, opened new perspectives in studying the problem of influence of absorbable suture material on the remote results of eCEA. In particular, we carried out a comparative analysis of the remote results of the subgroup PDS 6–0 versus the second group, according to which the advantage was on the side of the former at the expense of statistically significantly less often revealed ICA restenosis as compared with the latter.

Thus, in our study, the remote results of eCEA in the first and second groups turned out comparable owing to using in the majority of cases in the first group threads with metric sizes 5–0.

Why do we concentrate attention on the suture's diameter? The thing is that the larger metric size of suturing material the greater damaging effect it exerts on the vascular walls, and, consequently, creating prerequisites for blood retention in these needle-insertion sites [48]. In this case, blood acts as an "endogenous" foreign body. Apart from a direct traumatic effect, the use of large-size suture materials implies leaving in tissues of vascular wall a larger in mass foreign body, although temporarily, both in ligature channels and nodes thus meaning prolongation of the process of biodegradation [49]. The mentioned circumstances, eventually, lead to enhancement (layering of inflammatory reaction to the thread on wound inflammation) and widening of the zone of the inflammatory process of tissues around absorbable suture material, and this, in turn, increases the risk of restenosis after arterial interventions.

Why then in the majority of cases in the experimental group did we use PDS 5–0? Taking into consideration the fact that we had previously had no experience with using this suture material and only empirically supposed that the larger the diameter of suturing material the stronger it is, and in this connection we initially used during carotid reconstruction only PDS 5–0, hoping that such metric size was safer and decreasing the risk of suture dehiscence. However, having analysed the immediate results (6 months after surgery), we were convinced of sufficient strength of this suture material and gradually began using 6–0 sutures [42].

In conclusion, we may state that the choice of absorbable suture material PDS with metric size 6–0 instead of PPL is quite substantiated and makes it possible to eliminate or considerably decrease the frequency of ICA restenosis after eCEA.

Conflict of interest: none declared.

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