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ANGIOPLASTY AND STENTING OF THE CERVICAL CAROTID BIFURCATION UNDER FILTER PROTECTION: A PROSPECTIVE STUDY IN A SERIES OF 53 PATIENTS

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SUMMARY

The aim of this study is to assess safety, reliability, ease of use and usefulness of filter protection devices during angioplasty and stenting of stenotic lesions of the cervical carotid bifurcation. Over a period of 42 months, 53 patients harboring a cervical carotid bifurcation stenotic lesion were treated, by angioplasty and/or stenting using filter protection devices of different kinds. The stenosis was atherosclerotic in 48 cases, post-surgical in four and post-radiation in one case. In all cases, the treatment was successful, with good restoration of the luminal diameter. There were three major strokes (5.6%) and one minor stroke (1.9%). Two of these (one major, one minor) occurred a few hours after the stenting procedure and both seemed by all evidence due to a hemorrhagic hyperperfusion syndrome. One hemiparesis and dysphasia occurred two days after the procedure, secondary to subacute thrombosis with occlusion of the stent. One patient complained of three episodes of decrease in visual acuity of the eye ipsilateral to the stenting in the two weeks following treatment. In conclusion, in our experience, use of the devices adds only few minutes to the procedure time; direct lesions of the arterial wall, such as dissections or intraluminal thrombi, related to the use of filters were never observed, and spasm of the distal I.C.A. also proved rapidly regressive. The content of all filters, if any, was histologically examined, but plaque material was found only in one case, probably owing to our primary stenting technique without use of pre-dilation. The major technical drawback is in-filter coagulation, which occurred in 16 cases, occluding the membrane of the filter and thus slowing or blocking intracranial flow. Such an event can be counteracted by a more aggressive anti-coagulation protocol, which could, however, be responsible for the two complications with hemorrhagic brain infarction. Furthermore, we observed two other major neurological events, which bring the incidence of neurological complications in this series as high as 7.5%. Therefore, it is our opinion that safety of filters is not yet proven, and consequently great care must be taken in their use.

Key words: angioplasty, carotid artery disease, stents.

RÉSUMÉ

Angioplastie et stenting de la bifurcation carotide cervicale avec filtre de protection : étude prospective de 53 patients

Le but de ce travail est d'évaluer la tolérance, la fiabilité, la facilité d'utilisation et l'intérêt des filtres de protection pendant l'angioplastie et le « stenting » des sténoses de la bifurcation carotide. Sur une période de 42 mois, 53 patients porteurs d'une sténose de la bifurcation carotide ont été traités par angioplastie et/ou « stenting » en utilisant des filtres de protection cérébrale de différents types. Les sténoses étaient d'origine athéroscléreuse (n = 48), post-chirurgicale (n = 4) et post-radiothérapique (n = 1). Les résultats anatomiques étaient dans tous les cas satisfaisants, avec une restauration satisfaisante du diamètre artériel. Il y eut trois cas d'accident cerébral majeur (5,6 %) et un cas mineur (1,9 %). Deux de ces accidents (un majeur et un mineur) sont survenus dans les heures suivant le traitement et correspondaient à un syndrome d'hyperperfusion hémorragique. Une hémiparésie avec dysphasie, survenue 2 jours après le traitement, était liée à un ethrombose subaiguë avec occlusion du stent. Un patient présenta au cours des deux semaines qui suivirent le traitement, trois épisodes de cécité monoculaire homolatéraux à l'endoprothèse. En conclusion, dans notre pratique, la mise en place de filtres de protection cérébrale ajoute quelques minutes à la durée totale du traitement ; des dissections de la paroi artérielle ou thrombi intraluminaux n'ont jamais été observés ; les spasmes distaux de l'artère carotide ont toujours été résolutifs. Le contenu des filtres a été étudié ; du matériel de plaque n'a été observé qu'une seule fois (présence probablement liée à notre technique initiale de stenting sans prédilatation). La principale limite technique est la survenue d'une coagulation au sein du filtre, observée dans 16 cas, responsable d'une occlusion de la membrane du filtre et d'un ralentissement ou d'un arrêt de la circulation. Un tel événement est prévenu par une anticoagulation plus importante qui pourrait être à l'origine de deux infarctus hémorragiques. De plus nous avons observé deux autres complications majeures ce qui porte le taux de complications dans cette série à 7,5 %. À notre avis, la tolérance des filtres n'est pas aujourd'hui démontrée et de grandes précautions sont nécessaires lors de leur utilisation.

Mots-clés : *angioplastie, artère carotide, endoprothèse.*

INTRODUCTION

Carotid artery angioplasty and stenting is becoming a more and more popular tool for treatment of stenotic lesions of the extracranial internal carotid artery (I.C.A.), as an alternative to carotid endarterectomy (C.E.A.), which has proved its efficacy and superiority over medical management for treatment of symptomatic and asymptomatic lesions in large, randomized trials [2, 6, 19]. However, endovascular percutaneous techniques, even if highly appealing for their potential as a safer, less trau-

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matic alternative, remain controversial, owing to lack of such large, controlled, randomized trials and to excessive heterogeneity of patients' cohorts in terms of pathologic processes, lesion sites, indications for treatment or recruitment criteria, and above all in terms of techniques and devices used. Several unresolved issues have prevented their development, the main one being the risk of neurological complications due to brain embolization by plaque fragments during the procedure.

Moreover, agreement on the best procedural technique from the numerous teams performing the procedure worldwide is still lacking. For instance, the use of different types of balloons arresting the flow during deployment of the stent and dilation to protect the brain from possible embolism has been advocated for many years by only a few [12, 29-31], so that the most frequent technical choice of different authors remains that of primary stenting without protection, as classically described [9, 10, 13, 14]. This was our technical choice until recently, when, as already reported [3, 4], we observed one major stroke from middle cerebral artery embolization by atherosclerotic material migration caused by balloon compression of the atherosclerotic plaque.

Since then, we have modified our attitude and we have been looking for a safe protection device. First, we tried a new system needing balloon I.C.A. occlusion, the GuardWire® (PercuSurge) [3, 4]. Only recently, have filter protection systems been developed and tested in ex vivo models [21]; thereafter the filters became available on the market. In July 2000, we started the present, prospective study to assess feasibility of carotid artery stenting under filter protection, safety and usefulness of such devices. The material found inside the filter after retrieval, when present, has always been sent for histopathologic analysis, to better understand its composition and origin.

SUBJECTS AND METHODS

Patient characteristics and lesion morphology

From July 2000 to December 2003, 53 patients with cervical carotid bifurcation stenotic lesions were treated, by P.T.A. and stenting (50 cases) or stenting alone (3 cases). The patients in this series represent 17.5% of the 303 patients treated since our first case in 1986 (114 P.T.A.s, 44 Palmaz stents, 145 self-expansible stents) [4, 18, 23].

Of the patients 35 were male, 18 were female; the mean age was 68 years (range 55-85 years).

All treated patients gave written consent; patients unable to give informed consent were excluded, as were patients disabled because of stroke or dementia.

The carotid bifurcation stenosis was due to atherosclerotic plaque in 48 cases, post-surgical restenosis in four cases, and post-radiation stenosis in one case.

38 patients were symptomatic, with symptoms being congruent with the lesion treated, and 15 were asymptomatic; in these cases, the choice of endovascular treatment was based either on a refusal of surgery by the patient, or to the fact that the patients were considered at high risk for surgery, both for poor general condition, local surgical anatomy (such as high retromandibular bifurcation or in the post-C.E.A. restenosis cases) or contralateral I.C.A. occlusion.

Degree of stenosis, measured according to the NASCET criteria [20], was not less than 70% for asymptomatic patients, 50% or more in symptomatic patients [4].

Imaging evaluation

The pre-treatment angiographic examination always includes a 4-vessel study with intracranial circulation. Furthermore, for all patients a carotid ultrasound (US) examination was performed before and immediately after the procedure [7-17].

Immediately after P.T.A. and stenting, angiographic runs are performed both of the treated cervical bifurcation and of the homolateral intracranial circulation.

Pre-treatment brain M.R.I. and/or C.T. were available for all patients. Before intervention 38 patients also underwent CT angiography, mainly for confirmation of US findings and evaluation of I.C.A. plaque morphology and composition (above all in relation to ulcerations or calcifications).

Intra-procedural trans-cranial-Doppler was not available.

Drug regimen

All patients but one (see below) received for at least 48 hours before the procedure aspirin (100mg twice daily) and one among either ticlopidine (250mg twice daily) or clopidogrel (75mg daily). At the beginning of the study, we used to administer heparin during the procedure, to achieve an activated clotting time of at least two and a half times the baseline; this practice was subsequently modified, as discussed later. From a practical point of view, once the Arrow® sheath or guiding catheter are positioned in the common carotid artery, we start injecting 100 I.U./kg of heparin, subsequently we control ACT and add 2.000 I.U. at a time until the desired ACT value is obtained.

1mg atropine was administered just before balloon dilation of the stenosis for possible bradycardia due to carotid glomus stimulation. Blood pressure and neurological status were carefully monitored during the whole procedure.

Administration of low molecular weight heparin was maintained for at lest 48 hours after treatment (more frequently for 5-6 days, at decreasing doses), ticlopidine or clopidogrel were discontinued after 1 month, while aspirin is maintained life long.

Angioplasty and stenting technique

The endovascular treatment was performed under local anesthesia and mild sedation in most cases, under general anesthesia, owing to lack of cooperation by the sedated patient, in 5 cases.

Percutaneous access was obtained through the femoral route, and a long, armed sheath (Arrow® by Arrow International) or a guiding catheter was posi-