



■ Original Article

Do we really need patch and shunt for carotid endarterectomy?

Karotis endarterektomide yama ve şanta gerçekten ihtiyacımız var mı?

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Abstract

Aim: The efficacy of carotid endarterectomy (CEA) for stroke prevention in asymptomatic and symptomatic patients is well known. We aimed to share long term follow up results for primary closure technique for CEA without shunting and investigated risk factors for complications in this patient group.

Material and Methods: Between September 2013-2019, 122 patients with isolated CEA with primary closure were enrolled in this retrospective study. Doppler ultrasound (DUSG) scanning was used as the primary imaging tool for the determination of residual and recurrent stenosis. During the follow-up period duplex ultrasonography was performed in the second month, sixth month and annually thereafter. Ipsilateral cerebrovascular events and mortalities were recorded during follow up period.

Results: The mean age was $69,1 \pm 7,1$ (48-90) years. The median follow-up time was 47 (5 to 78) months. Hospital mortality was reported in 1 patient (0,8%). Early postoperative cerebrovascular accident were seen as ipsilateral disabling stroke in 1 patient (0,8%), ipsilateral non-disabling stroke in 1 patient (0,8%), reversible ischemic neurological deficit (RIND) in 1 patient (0,8%) and massive intracranial bleeding in 1 patient (0,8%). Late mortality was reported in 4 (3,3%) patients. 2 (1,6%) were cardiac reasons and 2 (1,6%) were non cardiac reasons. During the follow-up period ipsilateral cerebrovascular accident (CVA) were seen in 3 patients (2,5%) and these were; ipsilateral disabling stroke in 1 patient (0,8%), ipsilateral non-disabling stroke in 1 patient (0,8%), RIND in 1 patient (0,8%). According to the latest duplex scanning during follow up period 4 (3,3%) patients had below 50% restenosis, 2 (1,7%) patients had above 70% restenosis and 1 (0,8%) patient had total occlusion.

Conclusion: Primary closure technique for CEA can be used in selected patients with acceptable early and late complication rates, low mortality and low restenosis rate.

Keywords: carotid endarterectomy; carotid artery disease; carotid artery stenosis

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Öz

Amaç: Karotis endarterektomi (KEA) ameliyatının semptomatik ve asemptomatik hastalarda inmeyi önlemedeki etkinliği bilinmektedir. Biz bu çalışmada şant kullanmadan, primer kapama tekniği ile gerçekleştirdiğimiz KEA operasyonlarının uzun dönem sonuçlarını paylaşmayı amaçladık.

Gereç ve Yöntemler: Ekim 2013 ile 2019 tarihleri arasında şant kullanmadan primer kapama tekniği ile opere olan 122 hasta bu retrospektif çalışmaya dahil edildi. Doppler ultrasonografi (DUSG) rezidüel ve tekrarlayan darlıkların tespiti için primer görüntüleme yöntemi olarak kullanıldı. Takip süresince hastalar ikinci, altıncı aylarda ve sonrasında yıllık olarak yapıldı. Takiplerde ipsilateral serebrovasküler olaylar ve mortalite kayıtları alındı.

Bulgular: Hastaların ortalama yaşı $69,1 \pm 7,1$ (48-90)'ydi. Median takip süresi 47 (5 - 78) aydı. 1 (0,8%) hastada hastane içi ölüm gerçekleşti. Erken dönemde; 1(0,8%) hastada ipsilateral sekel bırakan ve 1(0,8%) hastada da sekelsiz serebrovasküler olay izlendi. Yine 1(0,8%) hastada geridönüşümlü iskemik nörolojik defisit ve 1(0,8%) hastada kafa içi kanama görüldü. Geç mortalite gelişen hasta sayısı 4 (3,3%) olarak kayıt edildi. Bunların 2 (1,6%)'si kardiyak nedenli ölümdü. Geç dönemde 3 (2,5%) hastada ipsilateral serebrovasküler hadise gelişti. Bunların 1 (0,8%)'i sekel bırakan, 1 (0,8%)'i sekel bırakmayan inmeydi. 1 (0,8%) hastada da geridönüşümlü iskemik nörolojik defisit görüldü. Geç dönemde DUSG sonuçlarına göre 4 (3,3%) hastada 50%'nin altında, 2 (1,7%) hastada 70%'in üzerinde darlık görüldü. 1 (0,8%) hastada da total oklüzyon meydana saptandı.

Sonuç: Primer kapama tekniği ile KEA seçilmiş hastalarda kabul edilebilir erken ve geç dönem komplikasyon, düşük mortalite ve tekrarlayan darlık oranlarıyla uygulanabilir.

Anahtar kelimeler: karotis endarterektomi; karotis arter hastalığı; karotis arter darlığı

Introduction

The efficacy of carotid endarterectomy (CEA) for stroke prevention in asymptomatic and symptomatic patients with severe carotid stenosis was shown in many studies. [1-4]

American Heart Association (AHA) defines stroke and mortality rates threshold values for CEA in the light of many clinical studies. Threshold values for stroke are below 6% in symptomatic patients (above 50% stenosis proved by angiography) and below 3% in asymptomatic patients (above 60% stenosis proved by angiography) for CEA. [5]

Today, there is no consensus about two basic subjects for severe asymptomatic or symptomatic carotid stenosis patients. First is which treatment strategy is the right choice CEA or carotid artery stenting (CAS) in this group of patients. Second is which option among primary closure, eversion, synthetic or autologous venous patch is the best choice while performing CEA.

In this study, we aimed to share long term follow up results for primary closure technique for isolated CEA without shunting and investigated risk factors for complications in this patient group.

Material and Methods

All patients were operated by the same senior surgeon in two different centres. Patients who underwent staged, reverse staged and concomittant procedures were excluded from the study.

Clinical and demographic data were obtained from hospital records and office charts. Preoperative data were age, gender, hypertension, smoking, atherosclerotic cardiac disease, diabetes mellitus, peripheral vascular disease, family history, hyperlipidaemia, previous cardiac surgery, chronic

obstructive pulmonary disease, chronic renal failure, atrial fibrillation and history of carotid artery disease symptoms (including disabling and non-disabling stroke, reversible ischemic neurologic deficit (RIND), transient ischemic attack (TIA), amaurosis fugax). Results of preoperative imaging (duplex ultrasonography (DUSG), computerized tomographic angiography (CTA), digital subtraction angiography (DSA) or conventional angiography) were also noted. Perioperative data including carotid artery clamping time, using of shunt, type of surgery (elective, emergent or urgent) were recorded.

Preoperative and postoperative DUSG examinations were performed by using a General Electric Logiq S7 Expert scanner equipped with 9L linear multi frequency transducer. The B-mode settings were adjusted to optimize the quality of the grey-scale images and the pulse repetition frequency used with colour Doppler flow imaging was adjusted according to the flow velocity.

The characteristics of the plaques were described in accordance with the Gray-Weale Classification.[6,7] The degree of stenosis involving the internal carotid artery (ICA) was described in accordance with the Society of Radiologists in Ultrasound Consensus Criteria reported by Grant et al.[8] All stenosis were confirmed by CTA or DSA or conventional angiography.

DUSG scanning was used as the primary imaging tool for the determination of residual and recurrent stenosis. During the follow-up period DUSG was performed in the second month, sixth month and annually thereafter. Restenosis which was found during follow-up period was classified as the same classifying criteria like preoperative period. Ipsilateral cerebrovascular events and mortalities were recorded during follow up period.



Emergent CEA was performed for revascularization of symptomatic patients within 2 weeks from stroke onset. Urgent CEA was performed within 6 hours from stroke onset. All patients signed standard informed consent forms for carotid endarterectomy and were informed about the potential risk of surgery.

All patients had dual anti-platelet (acetylsalicylic acid 100 mg and clopidogrel 75 mg) and anti hyperlipidemic therapy (atorvastatin 20 mg) during follow-up period.

Informed consent was obtained from all the patients participating in the study, and all the researchers signed the Declaration of Helsinki. Approval for the study was granted by the local ethics committee.

Surgical Technique

All procedures were performed under general anaesthesia. After positioning the patient, an incision was made anterior to the sternocleidomastoid muscle and exploration of common (CCA), external (ECA) and internal (ICA) carotid arteries was performed. After heparinisation (weight-based heparin dosing) (85 IU/kg), the vascular clamps were placed and arteriotomy was performed from CCA to ICA. Endarterectomy was applied and then atheromatous plaque was removed. A search for intimal flap was done and tacking sutures (with 7/0 non-absorbable polypropylene) was applied to the ICA if needed. If a large atheromatous plaque was protruding into the ECA, eversion endarterectomy technique was performed to the ECA. Finally the arteriotomy site was primarily repaired by 6/0 monofilament non-absorbable suture with continue technique under proper magnification. Protamine sulphate was not administered at the end of the procedure. After meticulous homeostasis and placement of minivac drain, wound closure and dressing was performed. For all patients conventionally accepted methods of determining the need of shunt insertion, including formal measurement of the ICA back flow and if needed back flow pressure were used. In this series all patients were operated without shunting. The vascular clamping time was recorded during the procedure.

Statistical Analysis

Data analyses were performed by using IBM SPSS Statistics version 17.0 software (IBM Corporation, Armonk, NY, USA). Whether the distributions of continuous variables were normally or not was determined by Kolmogorov Smirnov test. Continuous variables were shown as mean ± SD or median (min-max), where applicable. Number of cases and percentages were used for categorical data. While, the mean differences between groups were compared by Student's t test, otherwise, Mann Whitney U test was applied for not normally distributed data. Categorical variables were analysed by Fisher's exact test. A p value less than 0.05 was considered statistically significant.

Results

Between September 2013-2019, 122 patients with isolated CEA with primary closure were enrolled in this study. All patients were operated by same senior surgeon in two different centres. 75 patients (61,5%) were male and 47 patients (38,5%) were female. The mean age was 69,1 ± 7,1 (48-90) years. Degree of stenosis in contralateral ICA was under 50% in all patients who had bilateral stenosis.

In addition to degree of stenosis, type of plaque and symptomatology of patient were also taken into consideration while deciding surgery. 6 patients with 50-70% stenosis were operated because of their symptoms and type 1 or type II plaques. Preoperative demographic variables, clinical features and preoperative ultrasonographic parameters of the patients listed in Table I.

Table I. Preoperative Demographic Variables, Clinical Features and Preoperative Ultrasonographic Parameters of Patients.	
Variables	Patients n (%)
Age (year)	69,1 ± 7,1 (48-90)
Gender (Male/Female)	75/47 (61,5%/ 38,5%)
Family History	71(58,2%)
Smoking	50 (41%)
HT	91 (74,6%)
HL	71 (58,2%)
COPD	42 (34,4%)
DM	47(38,5%)
CAD	23 (18,9%)
Previous Cardiac Surgery	6 (4,9%)
CRF	9 (7,4%)
PVD	20 (16,4%)
AF	0 (0%)
Preoperative Clopidogrel Usage	44 (36,1%)
Bilateral Carotid Artery Disease	35 (28,7%)
Symptomatic Carotid Artery Disease Symptomatology	45(36,9%)
TIA	17 (13,9%)
RIND	10 (8,2%)
Stroke (non-disabling)	8 (6,6%)
Stroke (disabling)	4 (3,3%)
Amourosis Fugax	6 (4,9%)
Degree Of Stenosis *	
50 – 70 %	6 (4,9%)
> 70%	85 (69,7%)
Near Occlusion	31 (25,4%)
Type Of Carotid Artery Plaque **	
Type I	44 (36,1%)
Type II	52 (42,6%)
Type III	19 (15,6%)
Type IV	7 (5,7%)

* According to the Society of Radiologists in Ultrasound Consensus Criteria
 ** According to Gray-Weale Classification
 (HT: Hypertension, HL: Hyperlipidemia, COPD: Chronic Obstructive Pulmonary Disease, DM: Diabetes Mellitus, CAD: Coronary Artery Disease, CRF: Chronic Renal Failure, PVD: Peripheral Vascular Disease, TIA: Transient Ischemic Attack, RIND: Reversible Ischemic Neurologic Deficit, AF: Atrial Fibrillation)

117 patients (95,9%) were electively operated. 2 symptomatic patients (1,6%) were operated within two weeks of stroke onset and 3 patients (2,5%) were operated within 6 hours of stroke onset. We did not use shunt in any of the patients. We decided not to use shunt by intraoperative electroencephalography, and measuring stump pressure or backflow velocity. The median carotid artery clamping time was 19 (12 to 36) minutes. The median intensive care unit (ICU) stay was 1 (1 to 12) day, the length of median hospital stay was 3 (3 to 12) days and the median follow-up time was 47 (5 to 78) months.

Postoperative complications were reported in 11 patients (9%) and in hospital mortality was reported in 1 patient (0,8%). Early postoperative complications were seen in 11 patients (9%). These complications were; neck hematoma and bleeding (not required re-exploration) in 4 patients (3,4%), recurrent laryngeal nerve dysfunction in 2 patients (1,6%), hypoglossal nerve damage in 1 patient (0,8%), ipsilateral disabling stroke in 1 patient (0,8%), ipsilateral non-disabling stroke in 1 patient (0,8%), RIND in 1 patient (0,8%) and massive intracranial bleeding in 1 patient (0,8%).

Ipsilateral cerebrovascular event was reported in 4 patients and DUSG or CTA were performed. 3 patients had no stenosis or occlusion whereas 1 patient had total occlusion. This patient had RIND. The patient was re-operated. Thrombus was aspirated and arteriotomy was primarily sutured again. Neck hematoma and bleeding were reported in patients who use clopidogrel during preoperative period but this was not statistically significant. Patient with postoperative ipsilateral disabling stroke was the one who was operated urgently within 6 hours of stroke onset.

Late mortality was reported in 4 (3,3%) patients. 2 (1,6%) were cardiac reasons and 2 (1,6%) were non cardiac reasons. During the follow-up period ipsilateral cerebrovascular accident (CVA) were seen in 3 patients (2,5%) and these were; ipsilateral disabling stroke in 1 patient (0,8%), ipsilateral non-disabling stroke in 1 patient (0,8%), RIND in 1 patient (0,8%).

According to the latest duplex scanning during follow up period 114 (94,2%) patients were normal, 4 (3,3%) patients had below 50% stenosis, 2 (1,7%) patients had above 70% stenosis and 1 (0,8%) patient had total occlusion. This patient was the one who had late disabling stroke complication. Operative and the follow-up data are listed in Table II.

Table II. Operative and Follow-up Data of Patients.

Carotid Artery Vascular Clamping Time (min)	19 (12 to 36)
ICU Stay (day)	1 (1 to 12)
Length Of Hospital Stay (day)	3 (3 to 32)
Follow-up Time (month)	47 (5 to 78)
	n (patient) (%)
Type of Surgery	
Elective	117 (95,9%)
Emergent	3 (2,5%)
Urgent	2 (1,6%)
Early Postoperative Complications	
Neck Hematoma and Bleeding	4 (3,6%)
Recurrent Laryngeal Nerve Dysfunction	2 (1,6%)
Hypoglossal Nerve Dysfunction	1 (0,8%)
Ipsilateral Disabling Stroke	1 (0,8%)
Ipsilateral Non-disabling Stroke	1 (0,8%)
RIND	1 (0,8%)
Intracranial Bleeding	1 (0,8%)
Early Mortality	1 (0,8%)
Late Complications	
Ipsilateral Disabling Stroke	1 (0,8%)
Ipsilateral Non-disabling Stroke	1 (0,8%)
RIND	1 (0,8%)
Late Mortality	
Cardiac	2 (1,6%)
Non-cardiac	2 (1,6%)
Degree Of Restenosis *	
< 50%	4 (3,3%)
> 70%	2 (1,6%)
Occlusion	1 (0,8%)

* According to the Society of Radiologists in Ultrasound Consensus Criteria (ICU: Intensive Care Unit, RIND: Reversible Ischemic Neurologic Deficit)

There is no statistically significant difference between preoperative variables and operative data when we compare patients who had late cerebrovascular accidents with had no complications.

When we compare patients who had restenosis after operation with patients with normal control DUSG, we found out that bilateral carotid artery stenosis was statistically significant in restenosis group ($p=0,018$). Also these patients, who had restenosis, had statistically significantly less type 2 plaque preoperatively ($p=0,020$). In addition to this, type 4 preoperative plaque was higher in restenosis group but this is not statistically important ($p= 0,052$). Comparison of the demographic and the clinical features of the patients who were accepted to have restenosis during the follow-up period are listed in Table III.

Patients who had cerebrovascular events during follow up period had higher PVD ratio than the others but this is not statistically significant ($p=0,070$).



Table III. Comparison of Demographic and Clinical Features Of Patients Who Determined Restenosis During Follow-up Period.

Variables	Normal (n=114)	Resteno- sis (n=7)	p- value
Age (year)	68.8±7.0	72.7±8.1	0.167†
Gender			
Male	69 (60,5%)	5 (71,4%)	0.705‡
Female	45 (39,1%)	2 (28,6%)	
Family History	67(58,8%)	3 (42,9%)	0.453‡
Smoking	46 (40,4%)	4 (57,1%)	0.446‡
HT	84 (73,7%)	6 (85,7%)	0.676‡
HL	85 (74,6%)	6 (85,7%)	0.680‡
COPD	39 (34,2%)	3 (42,9%)	0.693‡
DM	46 (40,4%)	1 (14,3%)	0.246‡
CAD	21 (18,4%)	1 (14,3%)	1.000‡
Previous Cardiac Surgery	6 (5,3%)	0 (0,0%)	1.000‡
CRF	9 (7,9%)	0 (0,0%)	1.000‡
PVD	17 (14,9%)	2 (28,6%)	0.302‡
Preoperative Clopidogrel Usage	41 (36%)	2 (28,6%)	1.000‡
Bilateral Carotid Artery Disease	29 (25,4%)	5 (71,4%)	0.018‡
Symptomatic Carotid Artery Disease	40 (35,1%)	4 (57,1%)	0,255‡
Preoperative Carotid Duplex US			
50-70 %	6 (5,3%)	0 (0,0%)	1.000‡
> 70 %	80 (70,2%)	5 (71,4%)	1.000‡
Near Occlusion	28 (24,6%)	2 (28,6%)	1.000‡
Type Of Plaque			
Type I	40 (35,1%)	4 (57,1%)	0.251‡
Type II	51 (44,7%)	0 (0,0%)	0,020‡
Type III	18 (15,8%)	1 (14,3%)	1,000‡
Type IV	5 (4,4%)	2 (28,6%)	0,052‡
Type Of Surgery			
Elective	109 (95,6%)	7 (100%)	1,000‡
Emergent	3 (2,6%)	0 (0%)	1,000‡
Urgent	2 (1,8%)	0(0%)	1,000‡
Carotid Artery Vascular Clamping Time (min)	19 (12-36)	20 (17-28)	0,627¶

† Student's T-test, ‡ Fisher's Exact Test, ¶ Mann Whitney U Test (HT: Hypertension, HL: Hyperlipidaemia, COPD: Chronic Obstructive Pulmonary Disease, DM: Diabetes Mellitus, CAD: Coronary Artery Disease, CRF: Chronic Renal Failure, PVD: Peripheral Vascular Disease)

Discussion

The primary goal in carotid artery revascularization is to prevent stroke in patients with carotid artery stenosis but there are two important questions which have not been answered yet. First one is CAS or CEA and the second one is which technique is most preferable while performing CEA.

On the basis of the extensive experience and several meta-analysis of randomized clinical trials comparing CAS with CEA disclosed no difference stroke or death rates in 30 days; in myocardial infarction (MI), stroke or death rates in 1 year.

[9,10] In some studies, CAS was associated with a lower rate of MI and procedural morbidity such as cranial nerve injury [9], but others found CAS to be inferior to CEA or associated with higher rates of periprocedural stroke.[11,12] In some reports, there is near equivalence between CAS and CEA.[13,14] However, CEA has maintained superiority in most clinical trials and remains the best treatment option for most patients who require revascularization for carotid artery disease.

There are many randomised controlled investigations about which technique is superior about CEA. Mannheim et al. compared polyurethane patch to primary closure and stated that the rate of residual stenosis (≥ 50%) at 0 or 3-month follow-up was significantly lower in the patch group (2 operations, 1,1%) compared with the primary closure group (17 operations, 8,9%) (p=0.001, OR, 0,114; 95% CI, 0.026 to 0.5). And they have stated that; ≥ 70% recurrent stenosis was seen in 18 postoperative arteries (5.2%) (14 (8,6%) after primary closure and 4 (2,2%) after patch angioplasty), ≥ 50% recurrent stenosis was found in 31 arteries (8,9%) (22 (13,6%) after primary closure versus 9 (4,9%) arteries with patch closure). They reported that only patch angioplasty was found to influence the restenosis rate.[15]

Karen J. Ho et al. reported intermediate term outcome of CEA with bovine pericardial patch closure compared with Dacron patch and primary closure. They found that 30-day stroke and death were significantly lower in primary closure group. When they compared groups about five year restenosis rates, they found out that patch closure (especially bovine patch closure) had better outcomes but they also stated that none of the variables proved significant predictors of restenosis.[16] Similarly, Efthymios et al. stated that there was no statistically significant difference among primary closure, patch closure and eversion closure about stroke and death rates.[17]

In EVEREST (Eversion Carotid Endarterectomy Versus Standard Trials) study, 1353 patients were included and divided into two groups (678 patients in the conventional group, 675 patients in the eversion group). They found no statistical difference in late outcome (stroke, death and restenosis) between standard (patch and primary closure) and eversion CEA. Subgroup analysis showed that restenosis were statistically comparable) 2,8% vs 1,5%) for eversion and patch, respectively, while both significantly lower restenosis rates than primary closure.[18]

In several studies, with respect to the technical component of the operation, there is consensus that patch closure is superior to primary closure.[18,19] On the other hand, there are many studies reported that primary closure technique is comparable and even superior to patch closure technique thanks to new medical treatment regimens and careful selection of patients. [20] Similarly, in our series, recurrent stenosis was seen in seven patients and only 3 of them serious (4 patients (3,3%) < 50% stenosis, 2 patients (1,7%) > 70% stenosis and 1 patient (0,8%) occlusion).

Study Limitations

This study is a retrospective, descriptive study and there is no control group of patients who underwent alternative techniques for comparison. Despite these, we believe that our study add useful information to the literature about safety and efficacy of primary closure technique for the CEA.

Conclusion

As a conclusion, primary closure technique for CEA can be used by experienced centres safely in selected patients with acceptable early and late complication rates, low mortality and low restenosis rate.

Declaration of conflict of interest

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