

Our midterm restenosis results using patch angioplasty closure versus primary closure in patients undergoing carotid endarterectomy: A comparative study

Karotis endarterektomi yapılan hastalarda restenoz açısından yama anjiyoplasti ile primer kapamaya kıyasla yama anjiyoplasti ile kapama kullanılarak orta dönem restenoz sonuçlarımız: Karşılaştırmalı bir çalışma

Taner İyigün¹, Mugisha Kyaruzi¹, Barış Timur¹, Müzeyyen İyigün², Ünal Aydın¹

¹Department of Cardiovascular Surgery, University of Health Sciences, Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital, İstanbul, Turkey

²Department of Anesthesiology and Reanimation, Acibadem Mehmet Ali Aydınlar University, İstanbul, Turkey

ABSTRACT

Objectives: This study aims to compare midterm results of patch angioplasty with primary closure techniques in patients undergoing carotid endarterectomy (CEA) in terms of restenosis.

Patients and methods: This prospective, single-center, randomized study included a total of 137 patients (42 females, 95 males; mean age 64.4±8.8 years; range 36 to 86 years) who underwent CEA between January 2010 and October 2015. The patients were divided into two groups: the patch angioplasty group (n=70) and the primary closure group (n=67). The mean follow-up was 2-7 years. Carotid computed tomography angiography was performed to evaluate restenosis. Restenosis was defined as a lesion of >70% in diameter.

Results: During midterm follow-up, there was no statistically significant difference in the restenosis rate between the two surgical closure techniques (p=0.729).

Conclusion: Our study results show that the restenosis rate is similar using both closure techniques in patients undergoing CEA.

Keywords: Carotid endarterectomy; computed tomography angiography; patch angioplasty; primary closure; restenosis.

ÖZ

Amaç: Bu çalışmada karotis endarterektomi (KEA) yapılan hastalarda yama anjiyoplasti ile primer kapama tekniklerinin orta dönem sonuçları restenoz açısından karşılaştırıldı.

Hastalar ve Yöntemler: Bu prospektif, tek merkezli, randomize çalışmaya Ocak 2010 - Ekim 2015 tarihleri arasında KEA yapılan toplam 137 hasta (42 kadın, 95 erkek; ort. yaş 64.4±8.8 yıl; dağılım 36-86 yıl) alındı. Hastalar iki gruba ayrıldı: yama anjiyoplasti grubu (n=70) ve primer kapama grubu (n=67). Ortalama takip süresi 2-7 yıl idi. Restenozu değerlendirmek için karotis bilgisayarlı tomografi anjiyografi yapıldı. Restenoz >70 lezyon çapı olarak tanımlandı.

Bulgular: Orta dönem takip süresince restenoz oranı açısından iki cerrahi kapatma tekniği arasında istatistiksel olarak anlamlı bir fark bulunmadı (p=0.729).

Sonuç: Çalışma sonuçlarımız KEA yapılan hastalarda her iki kapama tekniğinin restenoz sonucunun birbirine benzer olduğunu gösterdi.

Anahar sözcükler: Karotis endarterektomi; bilgisayarlı tomografi anjiyografi; yama anjiyoplasti; primer kapama; restenoz.

Received: July 26, 2018 Accepted: August 27, 2018

Correspondence: Taner İyigün, MD. Mehmet Akif Ersoy Göğüs Kalp Damar Cerrahisi Eğitim ve Araştırma Hastanesi Kalp ve Damar Cerrahisi Kliniği, 34303 Küçükçekmece, İstanbul, Turkey. e-mail: taneriyi@gmail.com

Citation:

İyigün T, Kyaruzi M, Timur B, İyigün M, Aydın Ü. Our midterm restenosis results using patch angioplasty closure versus primary closure in patients undergoing carotid endarterectomy: A comparative study. Damar Cer Derg 2019;28(1):i-v.

Carotid endarterectomy (CEA) has been shown in large-scale, randomized-controlled trials to reduce the risk of stroke in selected patients with internal carotid artery stenosis.^[1] The surgical technique may affect restenosis and this topic is still unclear.

There are several studies which have reported restenosis rate following CEA.^[1-3] In these studies, about 6 to 36% of patients who undergo CEA have restenosis of greater than 50% as confirmed by Doppler ultrasound after a long follow-up period, often occurring within two years.^[2]

Patch angioplasty reveals to be superior in patients with marked intimal thickening of the distal internal carotid artery, reducing the turbulent flow in the transitional zone from the endarterectomized area to the residual distal artery. Although it is a useful technique, patching may be also associated with an increased perioperative stroke risk due to prolonged carotid artery clamping time. Two suture lines- or patch material-related complications include postoperative occlusion, arterial rupture, infection, or pseudoaneurysm formation.^[4,5] Patch angioplasty closure technique is technically demanding and may have longer cross-clamping time, compared to primary closure.

In the present study, we present our midterm results of two closure techniques in terms of the restenosis rate.

PATIENTS AND METHODS

This prospective, single-center, randomized study was conducted between January 2010 and January 2015. A written informed consent was obtained from each patient. The study protocol was approved by the Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital Ethics Committee (No. 2015-29). The study was conducted in accordance with the principles of the Declaration of Helsinki.

A total number of 342 patients underwent carotid endarterectomy. Our study population consisted of 137 patients who were uneventfully discharged. Patients who had renal failure or under dialysis and those who were lost to follow-up were excluded from the study. Patients living outside the province were called for control. Those who were unable to attend visit were also excluded. Some patients who underwent CEA also underwent cardiac surgery one week after CEA.

Those who lost their life due to cardiac surgery in the early period were also excluded.

Preoperatively, symptomatic patients with a carotid lesion greater than 70% on computed tomography angiography (CTA) or asymptomatic patients with a carotid lesion greater than 70% on CTA who were referred for open cardiac procedure were the candidates for CEA. Our patients were operated by different surgical teams of our hospital. The patients who underwent CEA using a patch were classified as patch angioplasty group (n=70) and those who underwent CEA through primary closure were classified as the primary group (n=67). Two groups were compared in terms of gender, level of cholesterol, diabetes, hypertension, smoking, type of lesion (intracranial vs extracranial), lesion side (left vs right), history of cerebrovascular events, combined cardiac procedures, surgical revision rate, use of drugs during postoperative period, length of hospital stay, postoperative cranial nerve injury, and restenosis. Postoperative carotid CTA was performed in all patients with a mean time of 2 to 7 years following CEA. Restenosis was defined as >70% diameter stenosis.

Surgical technique

We operated all patients who had neurological symptoms and a carotid lesion of greater than 70% as confirmed by CTA. Carotid endarterectomy was performed one week prior to cardiac surgery in patients who were referred for a cardiac operation. All patients were operated under general anesthesia. During the procedure, near infrared spectroscopy (NIRS) monitorization was routinely used. Following exploration of the common carotid artery and its branches, intravenous bolus heparin of 5,000 units was administered and cross-clamping was performed. Arteriotomy was done starting below the bifurcation of the common carotid artery and was extended toward the internal carotid artery. Atheroma plaque was gently removed. Depending on nature of the carotid artery and surgeon's daily experience, some patients underwent primary closure, while the others underwent patch angioplasty. All patients were given acetylsalicylic acid postoperatively. Some patients were also given clopidogrel or warfarin in combination with acetylsalicylic acid.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk,

NY, USA). Descriptive statistics were expressed in mean and standard deviation (SD), median (min-max), number, and frequency. The distribution of the variables was analyzed using the Kolmogorov-Smirnov test. Independent sample t-test and Mann-Whitney U test were used to analyze independent quantitative data. The chi-square test was used in the analysis of independent qualitative data. A *p* value of <0.05 was considered statistically significant.

RESULTS

There was no significant difference in the age and sex distribution of the patients between the primary

and patch angioplasty groups (*p*>0.05). There was no statistical significance difference between primary and patch angioplasty group in terms of length of hospital stay (*p*>0.05). The type of drug used in the primary and patch angioplasty groups did not differ significantly (*p*>0.05). Side distribution in the primary and patch angioplasty group did not differ significantly (*p*>0.05). The restenosis rate in the primary and patch angioplasty groups did not differ significantly (*p*>0.05). The rate of smoking, diabetes mellitus, hypertension, additional surgery rate and revision rate did not differ significantly in the primary and patch angioplasty groups (*p*>0.05). However, the rate of cranial nerve injury in the

Table 1. Demographic characteristics of patient groups

	Primary group				Patch angioplasty group				<i>p</i>
	n	%	Mean±SD	Median	n	%	Mean±SD	Median	
Age (year)			63.9±10.4	64.0			65.0±7.1	64.0	0.460*
Gender									0.865‡
Female	21	31.3			21	30.0			
Male	46	68.7			49	70.0			
Hospital stay			5.4±3.9	4.0			6.0±5.4	4.0	0.877†
Drug use									0.366‡
Ecopirin	41	61.2			48	68.6			
Ecopirin + plavix/coumadin	26	38.8			22	31.4			
Side									0.556‡
Right	34	50.7			32	45.7			
Left	33	49.3			38	54.3			
Stenosis degree									0.729‡
<70	56	83.6			60	85.7			
>70	11	16.4			10	14.3			
Smoking									0.231‡
(-)	39	58.2			47	67.1			
(+)	28	41.8			22	31.4			
Diabetes mellitus									0.366‡
(-)	47	70.1			44	62.9			
(+)	20	29.9			26	37.1			
Hypertension									0.688‡
(-)	31	46.3			30	42.9			
(+)	36	53.7			40	57.1			
Concomitant procedure									0.213‡
(-)	20	29.9			28	40.0			
(+)	47	70.1			42	60.0			
Cerebral vascular events									0.506‡
(-)	64	95.5			65	92.9			
(+)	3	4.5			5	7.1			
Revision									0.098‡
(-)	65	97.0			63	90.0			
(+)	2	3.0			7	10.0			
Peri-procedural cranial nerve injury									0.046‡
(-)	61	91.0			69	98.6			
(+)	6	9.0			1	1.4			

SD: Standard deviation; * T test; † Mann-Whitney U test; ‡ Chi-square test.

primary group was significantly higher ($p < 0.05$) than in the patch angioplasty group (Table 1). The patients who had restenosis and symptomatic were reoperated, while the patients who were asymptomatic were followed with medical therapy.

DISCUSSION

The most optimal technique for carotid arterial closure after CEA still remains debatable among many surgeons.^[6,7] However, some studies have suggested that the flow characteristics obtained by patch angioplasty may be superior to those obtained with arteries closed primarily.^[6-8] Patchplasty is preferable for most of the surgeons, particularly when this type of closure is either unavoidable or desirable in some cases (i.e., an artery with a narrow internal diameter or with an elongated plaque).^[9]

Previous studies showed that very few patients had to switch from primary closure to patching, as the artery was deemed too narrow for primary closure.^[10] The United Kingdom studies have also suggested that there is a divided opinion on how often patching is required: some surgeons use it all of the time, others rarely or never.^[2,11] As it has been suggested above by previous studies, closure techniques in our clinic depend on the surgeon's preference which mostly lies on clinical experience, although size and nature of the carotid arteries are also taken into account.

Our results in this study are consistent with previous data showing that the two procedures were not superior to one another in terms of restenosis during the mid-term follow-up period. Our results also suggest that patching is associated fewer peri-procedural cranial nerve injury events, compared to primary closure ($p = 0.043$).

Although Bernstein et al.^[12] reported that there were significant reductions in the risk of acute occlusion or long-term restenosis with patching, these data were limited by small sample size (particularly for acute occlusions) and lost to follow-up. In addition, treatment of restenosis is unclear in this patient population. However, some authors have recommended endovascular approach in risky patients. Our symptomatic patients with restenosis also underwent CEA. Similarly, Sarp Beyazpinar et al.^[13] suggested that risky patients could alternatively undergo endovascular repair.

To date, a series of factors have been outlined in the etiology of carotid restenosis. Local risk factors include a small (< 5 mm) internal carotid artery diameter, a redundant or kinked internal carotid artery, long arteriotomy, the use of tacking sutures, extensive proximal disease, an excessively deep plane of dissection, or failure to obtain precise arteriotomy closure. Systemic risk factors for recurrence include female sex, smoking, hyperlipidemia, diabetes mellitus, young age at the time of endarterectomy, and the presence of disseminated atherosclerosis.^[14,15]

Despite these findings, it still remains unclear whether local or systemic factors predominate in the pathogenesis of carotid restenosis.^[13] In our study, there was no significant difference in the demographic characteristics between the primary closure and patched groups.^[16-18] We also found out that pre- and postoperative factors did not show a significant difference in terms of restenosis between the two closure techniques.

On the other hand, the choice for closure technique during CEA is still unclear.^[10] Experience of the surgeon, and size and nature of carotid artery may be other factors which may guide the choice for closure during CEA, as there is no gold standard. Although our results showed no significant difference between the two procedures, our clinical experience was in favor of patch angioplasty. Uncu et al.^[19] also reported that patch angioplasty might be superior to primary closure.

Surgical experience is also an important factor. Many studies have indicated that inexperienced surgeons perform a lower number of surgeries. Therefore, postoperative complications would increase.^[20] Since we were unable to find a significant difference between two groups, we believe that surgeon's daily experience plays an important role in surgical preference.

The main limitations of this study include small sample size and its single-center design.

In conclusion, preference of the carotid artery closure technique can be both primary closure or patch angioplasty. Our study results show no significant difference in the restenosis rates between the groups, suggesting that both techniques can be used safely.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The authors received no financial support for the research and/or authorship of this article.

REFERENCES

1. Endarterectomy for asymptomatic carotid artery stenosis. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. *JAMA* 1995;273:1421-8.
2. AbuRahma AF. Processes of care for carotid endarterectomy: surgical and anesthesia considerations. *J Vasc Surg* 2009;50:921-33.
3. de Borst GJ, Zanen P, de Vries JP, van de Pavoordt ED, Ackerstaff RG, Moll FL. Durability of surgery for restenosis after carotid endarterectomy. *J Vasc Surg* 2008;47:363-71.
4. Bond R, Rerkasem K, AbuRahma AF, Naylor AR, Rothwell PM. Patch angioplasty versus primary closure for carotid endarterectomy. *Cochrane Database Syst Rev* 2004;2:CD000160.
5. Bond R, Rerkasem K, Naylor AR, Aburahma AF, Rothwell PM. Systematic review of randomized controlled trials of patch angioplasty versus primary closure and different types of patch materials during carotid endarterectomy. *J Vasc Surg* 2004;40:1126-35.
6. Cheng I, Vyas KS, Velaga S, Davenport DL, Saha SP. Outcomes of Carotid Endarterectomy with Primary Closure. *Int J Angiol* 2017;26:83-8.
7. Avgerinos ED, Chaer RA, Naddaf A, El-Shazly OM, Marone L, Makaroun MS. Primary closure after carotid endarterectomy is not inferior to other closure techniques. *J Vasc Surg* 2016;64:678-83.
8. Archie JP Jr. Prevention of early restenosis and thrombosis-occlusion after carotid endarterectomy by saphenous vein patch angioplasty. *Stroke* 1986;17:901-5.
9. Eikelboom BC, Ackerstaff RG, Hoeneveld H, Ludwig JW, Teeuwen C, Vermeulen FE, et al. Benefits of carotid patching: a randomized study. *J Vasc Surg* 1988;7:240-7.
10. Huizing E, Vos CG, Hulsebos RG, van den Akker PJ, Borst GJ, Ünlü Ç. Patch Angioplasty or Primary Closure Following Carotid Endarterectomy for Symptomatic Carotid Artery Stenosis. *Surg J (N Y)* 2018;4:e96-e101.
11. Murie JA, John TG, Morris PJ. Carotid endarterectomy in Great Britain and Ireland: practice between 1984 and 1992. *Br J Surg* 1994;81:827-31.
12. Bernstein EF, Torem S, Dilley RB. Does carotid restenosis predict an increased risk of late symptoms, stroke, or death? *Ann Surg* 1990;212:629-36.
13. Sarp Beyazpınar D, Harman A, Akovalı N, Ersoy Ö, Kayıpmaz Ç, Gültekin B, et al. Our treatment strategies of carotid artery restenoses. *Damar Cer Derg* 2018;27:71-7.
14. Clagett GP, Rich NM, McDonald PT, Salander JM, Youkey JR, Olson DW, et al. Etiologic factors for recurrent carotid artery stenosis. *Surgery* 1983;93:313-8.
15. Rossi PJ, Valentine RJ, Myers SI, Brilliant PT, Chervu A, Clagett GP. The durability of bilateral carotid endarterectomy. *Ann Vasc Surg* 1995;9:16-20.
16. AbuRahma AF, Khan JH, Robinson PA, Saiedy S, Short YS, Boland JP, et al. Prospective randomized trial of carotid endarterectomy with primary closure and patch angioplasty with saphenous vein, jugular vein, and polytetrafluoroethylene: perioperative (30-day) results. *J Vasc Surg* 1996;24:998-1006.
17. AbuRahma AF, Robinson PA, Saiedy S, Kahn JH, Boland JP. Prospective randomized trial of carotid endarterectomy with primary closure and patch angioplasty with saphenous vein, jugular vein, and polytetrafluoroethylene: long-term follow-up. *J Vasc Surg* 1998;27:222-34.
18. AbuRahma AF, Choueiri MA. Cranial and cervical nerve injuries after repeat carotid endarterectomy. *J Vasc Surg* 2000;32:649-54.
19. Uncu H, de Santis F, Fiorani P. Patch angioplasty in carotid endarterectomy. *Damar Cer Derg* 1994;3:13-8.
20. Yüksel V, Ozdemir AC, Huseyin S, Guclu O, Turan FN, Canbaz S. Impact of Surgeon Experience During Carotid Endarterectomy Operation and Effects on Perioperative Outcomes. *Braz J Cardiovasc Surg* 2016;31:444-8.