



FACULTEIT GENEESKUNDE EN
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Complication rate after carotid endarterectomy comparing patch angioplasty and primary closure

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Masterproef voorgedragen in de master in de specialistische geneeskunde
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Voorwoord

Dit is mijn masterproef ‘Complication rate after carotid endarterectomy comparing patch angioplasty and primary closure’. Deze masterproef is geschreven in kader van mijn afstuderen aan de opleiding Master in de Specialistische Geneeskunde afstudeerrichting Heelkunde aan Universiteit Gent.

Samen met mijn promotor Dr Cedric Coucke en zijn collega Dr Yves Blomme, beiden vaatchirurg in het AZ Sint Lucas te Gent, heb ik een database opgesteld om de complicaties na carotisendarterectomie na te gaan bij manier van kwaliteitscontrole. Hierbij kwamen we dan op het idee om een vergelijking te maken tussen de chirurgische techniek met en zonder patchplastie. Dit werd de onderzoeksvraag van mijn masterproef.

Na het uitvoeren van deze retrospectieve studie werd onze abstract aanvaard en door mij gepresenteerd op het VEITH symposium (*Veith Symposium, New York, USA, November 21th 2014*). Ons manuscript werd gepubliceerd in de *Annals of Vascular Surgery* (*Maertens V, Maertens H, Kint M, Coucke C, Blomme Y. Complication rate after carotid endarterectomy comparing patch angioplasty and primary closure. Ann Vasc Surg. 2016 Jan;30:248-52. (IF 1.2; Q3 Surgery)*). Ondertussen zitten we niet stil en wordt onze vervolgstudie afgerond, waarbij we de complicaties op lange termijn (5-jaar follow-up) evalueren.

Hierbij wil ik graag mijn promotor bedanken voor de begeleiding en Heidi Maertens voor de samenwerking. Ook wil ik mijn man, familie en vrienden bedanken voor morele steun en advies.

Ik wens u veel leesplezier toe.

Vicky Maertens, Gent, mei 2018.

Abstract

Objective

Carotid endarterectomy (CEA) reduces the risk for stroke in patients with internal carotid artery stenosis. The optimal surgical technique remains subject of debate. Literature suggests patch angioplasty reduces complication risk. However, primary closure shortens cross-clamp times and eliminates graft-specific complications. This study aimed to assess complication rate after CEA with selective patching.

Methods

Two-hundred-thirteen consecutive CEAs over a 3-year period from January 5th 2011 to December 19th 2013 were retrospectively analysed. Postoperative complications were evaluated within 1 month after surgery.

Results

Primary closure was used in 110 operations, and patch angioplasty in 103 procedures. Primary closure was performed when the carotid artery had a diameter above 5 mm, when there was a high carotid bifurcation and when the contralateral carotid artery was occluded. After primary closure we found 4(3.6%) complications: 2(1.8%) bleeding and 2(1.8%) cranial nerve damage. Following patch angioplasty 5(4.9%) complications occurred: 1(1.0%) bleeding, 2(1.9%) cranial nerve damage, 1(1.0%) cerebrovascular event and 1(1.0%) cerebral hyperperfusion resulting in mortality. There was no higher complication risk after primary closure ($P = 0.68$). Clamp time was significantly longer when using patch angioplasty ($P < 0.001$).

Conclusions

Primary closure appears to be an equivalent closure technique compared to patch angioplasty when used in selected patients.

Introduction

Carotid endarterectomy (CEA) reduces the risk of cerebrovascular and long-term ischemic events in patients with symptomatic or high grade (> 80%) asymptomatic internal carotid artery stenosis.¹⁻³ The risk for adverse events caused by this intervention depends upon achieving a smooth endarterectomised surface with gradually tapered distal endpoint and precise closure of the artery. An accurate closure technique contributes to optimal haemodynamics of the vessel; however, the ideal surgical closure technique during carotid endarterectomy remains a subject of debate.

The use of patch angioplasty has been suggested to improve haemodynamic flow in the artery by increasing the carotid artery diameter.⁴⁻⁶ However, this positive influence of patch closure on the haemodynamic profile has been questioned. Harrison et al. found no favorable flow dynamics after patching, since incorporation of a patch increases areas of low wall shear stress and high oscillatory shear index at the bifurcation.⁷ The clinical impact of these haemodynamic changes on patient's outcome has been studied. Some studies indicate that carotid patch angioplasty reduces the risk of immediate postoperative complications, and significantly lowers vessel restenosis and occlusion rates.⁸ However, patch angioplasty has also been associated with rare patch specific complications, such as patch rupture, false aneurysm formation, and thrombo-embolism stemming from the dilated, aneurismal carotid bifurcation.^{9, 10} Especially saphenous vein patch angioplasty has been shown to be prone to aneurismal dilatation.¹¹⁻¹³

Primary closure has the advantage of eliminating graft-specific complications and reducing cross-clamp times in comparison with patch angioplasty.^{9, 10, 14} In addition, large published

series of carotid endarterectomy showed excellent results when primary closure was used.^{15, 16} These considerations have led many surgeons to recommend selective use of patch closure.

This study aimed to examine 30-day morbidity and mortality rates after carotid endarterectomy and to compare these results according to closure technique: primary closure versus patch angioplasty. Additional follow up using yearly duplex ultrasound during a 5-year period is ongoing, in order to allow assessment of late complications and long-term patency of the CEA.

Material and methods

1. Study population

Two-hundred thirteen consecutive CEA procedures (115 left, 98 right) carried out at Sint-Lucas Hospital, Ghent, Belgium, were analysed in this retrospective study. Data were collected over a period of 3 years from January 2011 to December 2013. No subjects were excluded. One-hundred and forty-one males and 72 females were included in this study with a mean age of 73 years (SD 8.57, range 53-95).

Individual patient characteristics were registered, including preoperative ipsilateral and contralateral stenosis on carotid color duplex ultrasound scans and angiographic studies¹⁷, baseline blood cholesterol and triglyceride levels. Preoperative risk factors were listed, including hypertension, diabetes mellitus, coronary artery disease, smoking status and preoperative use of aspirin and/or anticoagulants.¹⁸ Indications for surgery were asymptomatic high grade carotid stenosis (> 80%) and symptomatic carotid artery stenosis, categorised into transient ischemic attack, cerebrovascular attack and amaurosis fugax. Thirty-day morbidity and mortality data were registered.

2. Procedure and materials

All CEA procedures were performed under general anesthesia with administration of systemic heparin. There was no shunting technique used.¹⁹ The decision to perform patch angioplasty or primary closure was made by the primary operator during surgery, based upon patient characteristics and experience of the surgeon. Primary closure was performed when the carotid artery had a diameter above 5 mm (measured during surgery), when there was a high carotid bifurcation and when the contralateral carotid artery was occluded.

Primary closure was performed using 6-0 polypropylene suture material (Prolene; Ethicon, Inc, Somerville, NJ). For patch closure, a collagen-coated knitted polyester patch 6x75mm (Hemacarotid Knitted Ultrathin Patch; Maquet Getinge Group, Rastatt, Germany) was tapered to the appropriate size to reconstruct the shape of the carotid artery. The patch was sewn into place with the same 6-0 Prolene suture material.

To obtain haemostasis, an absorbable hemostat and digital pressure were applied before skin closure (Surgicel® Fibrillar™ Absorbable Hemostat; Ethicon, Inc, US). Protamine was given at the end of each procedure. Postoperative care included application of closed suction drainage and aspirin therapy. If patients were not under aspirin therapy, aspirin was started at least 24 hours before surgery (Aspirin 80mg daily). The patients were admitted to the intensive care unit or recovery postoperatively to monitor heart rate and blood pressure for at least 24 hours. All procedures were carried out by two vascular surgeons, both using the same techniques and decision making criteria to perform primary or patch closure.

3. Statistical analysis

Patients were grouped retrospectively according to primary closure or patch closure during the CEA procedure. Cross-clamp time was peroperatively recorded. Postoperative bleeding,

infection, cranial nerve injuries, cerebrovascular events, cerebral hyperperfusion and mortality were evaluated within 1 month after surgery.

For statistical analysis SPSS 22.0 (Statistical Package for the Social Sciences, IBM Company, US) was used. The values for the different groups deviated significantly from the Gaussian distribution ($P < 0.05$), therefore non-parametric tests were used for all statistical analyses. Mann-Whitney U test was used to compare both groups (primary closure versus patch angioplasty).

Results

A total of 213 patients underwent CEA. Primary closure was performed in 110 operations and patch angioplasty in 103 procedures. Primary closure was more frequently used in male patients (81 vs. 29; $P = 0.02$). Except for gender, there were no statistical differences between the demographic and clinical data in both groups: age ($P = 0.82$), nicotine abuse ($P = 0.58$), hypertension ($P = 0.88$), hypercholesterolemia ($P = 0.64$), diabetes ($P = 0.30$), preoperative anti-platelet medication ($P = 0.31$), preoperative anticoagulant medication ($P = 0.80$), operation side ($P = 0.68$), preoperative percentage of stenosis (duplex ultrasound $P = 0.36$; MRA $P = 0.67$; CTA $P = 0.45$) and preoperative percentage of stenosis on the contralateral side ($P = 0.07$). The duration of hospitalisation was similar whether or not patch angioplasty was performed ($P = 0.49$).

The perioperative morbidity and mortality rates are illustrated in Table I. Following CEA using primary closure we found 4(3.6%) complications, including 2(1.8%) bleeding and 2(1.8%) cranial nerve damage. No cerebrovascular events were seen. When patch plasty was used 5(4.9%) complications occurred: 1(1.0%) bleeding, 2(1.9%) cranial nerve damage,

1(1.0%) cerebrovascular event and 1(1.0%) cerebral hyperperfusion resulting in mortality. Both after primary closure and patch angioplasty no infections occurred.

When comparing complication rates between patch angioplasty and primary closure, the results indicate no significant differences between both groups for bleeding ($P = 0.24$), stroke ($P = 1.00$), cranial nerve damage ($P = 1.00$), death ($P = 1.00$) and cerebral hyperperfusion ($P = 1.00$). The results show no overall higher complication risk when using primary closure compared to patch closure ($P = 0.68$).

Clamp time was significantly longer when performing patch angioplasty ($P < 0.001$) (Figure1). When using primary closure a mean clamp time of 13.71 min (SD 3.67) was registered. Using patch closure, mean clamp time increased to 17.05 min (SD 3.14).

Discussion

Current literature shows conflicting results concerning closure technique during carotid endarterectomy. Literature suggests some benefit performing carotid patch angioplasty to reduce the combined perioperative and long-term risk of stroke and the risk of restenosis compared to primary closure; however more data are needed.^{5, 20-22} There is no general consensus among surgeons regarding the benefits and roles of patching during surgery. Closure technique mainly depends on the individual surgeon's experience and preference. According to a recent survey in the UK 35% of vascular surgeons patch selectively. The decision seems to depend on vessel size and mode of anaesthesia.²³

In this study primary closure was performed when the carotid artery measured a diameter above 5 mm. This is an arbitrary limit, based on thresholds used in literature.^{23, 24} Primary closure was used when the contralateral carotid artery was occluded to reduce clamp time and

possible ischemic time. Also, when there was a high carotid bifurcation primary closure was preferred because of the technically challenging and time consuming patch placement in these cases. We found no higher complication risk after primary closure in comparison with patch angioplasty. This is consistent with the results of Ahmed et al.²⁵ and Aburahma et al.²⁶, who found no statistically significant difference between both groups. Aburahma et al. showed a complication rate of 14.8% after primary closure and 9.5% following patch angioplasty.²⁶ Our results are also consistent with Katz et al. who demonstrated no significant difference in the perioperative morbidity or mortality and Al-Rawi PG et al. who found no statistically significant difference between the two groups in terms of vessel occlusion, morbidity or mortality.^{27, 28} According to the results of Mannheim et al. perioperative mortality and neurologic events were similar in both groups.²⁹ In contrast, Lord et al. found neurologic complications were more frequent after primary closure, however the differences between the groups were not significant. They found postoperative aneurysmal dilatation of the common or internal carotid artery was present in 9.23% of the polytetrafluoroethylene patch closures but was absent in non-patched arteries. Although these aneurysms are usually asymptomatic, they can be complicated by thromboembolism or carotid occlusion and stroke.

In literature it is still under discussion which closure technique shows less recurrent carotid disease. According to recent studies, patching is an extremely safe treatment for carotid stenosis with very low perioperative complications and low rates of recurrent stenosis.²⁰ Mannheim et al. found reduced restenosis rates after patching compared to primary closure.²⁹ Similarly, Malas et al. found a significant reduction in the 2-year risk of restenosis when using patch angioplasty.²¹ However, it has been suggested that although there might be a significantly higher restenosis in men and women after primary closure in short term, only women show a higher risk of restenosis after 5-year follow-up.^{30, 31}

In contrast, Clagett et al. found that the incidence of recurrent carotid disease was unexpectedly higher in the group with patch closure (12.9%), than in patients with primary closure (1.7%). However, it should be taking into account that venous patch material was used in this study. It seems that patch procedures using saphenous vein have not shown superior long-term results (5 years) compared with the use of primary closure.²⁴

Our study has a number of limitations. It was a single centre study and the results may not be generalisable. The low number of complications may not be sensitive enough to find significant differences in complication rate among both groups. Furthermore, occurrence of restenosis after 30 days was not examined.

The present study aims to achieve a 5-year follow-up. In this period an annual duplex ultrasound will be carried out to observe the incidence of restenotic lesions and aneurysms after carotid endarterectomy with and without patching.³²⁻³⁴ Additional CTA will be performed when restenosis or aneurysms are seen on ultrasound imaging. In the meantime, we conclude that the current evidence suggests primary closure can be of value in a select group of patients. Vascular surgeons agree that carotid artery patching is positively desirable in patients with very narrow internal carotid arteries or long plaques needing extended arteriotomy.³⁵ However, in literature it is not examined how narrow the diameter of the carotid artery should be before a patch angioplasty procedure is indicated. Clagett et al. used an arbitrary limit of < 5mm diameter to determine closure technique.²⁴ In the UK, half of the surgeons performing CEA procedures with selective patching apply the same median artery threshold of 5mm diameter.²³ This is also the threshold we used in our study; however, literature does not provide evidence to support this choice of threshold. Further studies are

needed to determine the internal carotid artery diameter threshold and other criteria in which primary closure can be used.

Our results show a significant 5 minutes shorter clamping time after primary closure. These findings are consistent with current literature.^{9, 10, 29, 36} Although this added time does not seem to affect peri-operative morbidity and mortality³⁷, it might be an important factor in patients with high comorbidity and contralateral carotid artery occlusion. Additionally, costs of patch materials and operating time should be considered.

Conclusion

Short term results indicate primary closure appears to be an equivalent closure technique compared to patch angioplasty when used in selected patients with broad internal carotid artery (diameter above 5 mm), a high carotid bifurcation or occlusion of the contralateral carotid artery. Further studies are needed to confirm these specific criteria and patient characteristics in which primary closure can be indicated. A prospective study is ongoing to address the long term outcomes.

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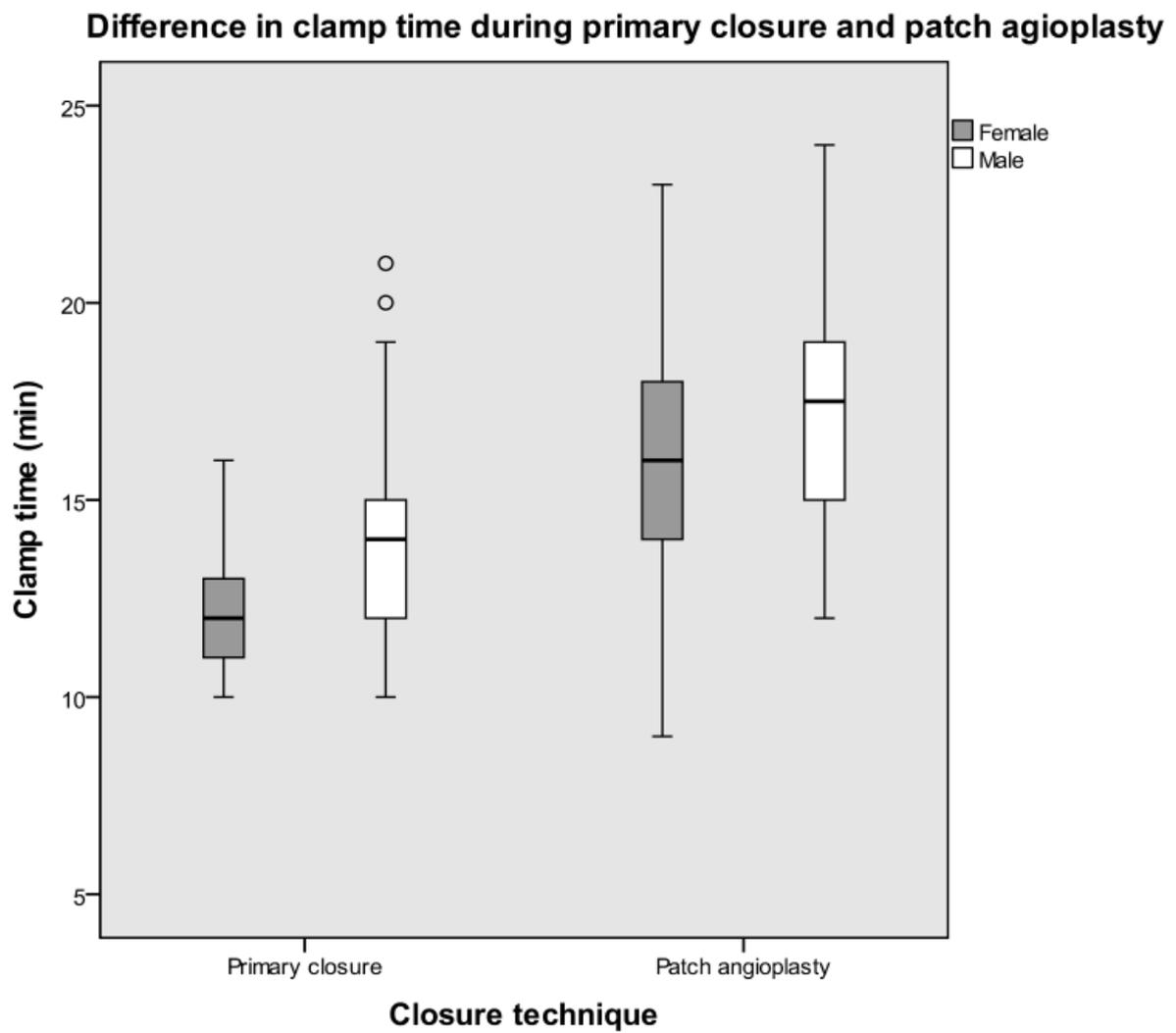
Tables

Table I: complication rate comparing primary closure and patch angioplasty closure technique

	Closure technique		P-value
	Primary closure	Patch angioplasty	
No complications	106	98	
Total complications	4 (3.6%)	5 (4.9%)	0.68
Bleeding	2 (1.8%)	1 (1.0%)	0.24
Cerebrovascular event	0	1 (1.0%)	1.00
Infection	0	0	-
Acute myocardial infarction	0	0	-
Nerve damage	2 (1.8%)	2 (1.9%)	1.00
Hyperperfusion and mortality	0	1 (1.0%)	1.00

Figures

Figure 1: Boxplot illustrating a significant difference in clamp time (min) during patch angioplasty and primary closure ($P < 0.001$).



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Complication Rate after Carotid Endarterectomy Comparing Patch Angioplasty and Primary Closure.

Maertens V¹, Maertens H², Kint M³, Coucke C³, Blomme Y³.

Samenvatting

Carotisendarterectomie vermindert het risico op stroke in patiënten met hooggradige stenose van de arteria carotis interna. Over de optimale chirurgische techniek is men het in de literatuur nog niet eens. Volgens bepaalde gerandomiseerde studies gaat de voorkeur naar sluiten met patch om het complicatie risico te verminderen. Doch er zijn ook een aantal studies waarbij gesuggereerd wordt dat het niet altijd nodig is om met patch te sluiten en op die manier de klemtijd te beperken en patchgerelateerde complicaties te vermijden. Vaak verkiest de chirurg de techniek waarmee hij het meeste ervaring heeft.

Het doel van dit retrospectief onderzoek is om een vergelijking te maken in peri- en postoperatieve complicaties tussen patiënten na carotisendarterectomie met selectieve patching. Over een periode van 3 jaar (2011-2013) werden 213 carotisendarterectomies geanalyseerd. Postoperatieve complicaties werden geëvalueerd binnen 1 maand na de ingreep.

Tijdens 110 ingrepen werd primair gesloten en bij 103 procedures werd gebruik gemaakt van patch angioplastie. Er werd primair gesloten bij een brede arteria carotis interna met diameter boven de 5mm, bij een hoge carotis bifurcatie en bij occlusie van de contralaterale arteria carotis interna. De resultaten tonen 4 (3.6%) complicaties na primair sluiten, namelijk 2(1.8%) bloedingen en 2(1.8%) gevallen van craniale zenuw schade (hypoglossus). Na patch angioplastie werden 5(4.9%) complicaties gezien, waaronder 1(1.0%) bloeding, 2(1.9%) gevallen van cranial zenuw schade (hypoglossus), 1(1.0%) CVA en 1(1.0%) patiënt met cerebrale hyperperfusie met overlijden als gevolg. Er werd geen hoger risico op complicaties gezien na primair sluiten ($P = 0.68$). De klemtijd was significant langer na patch angioplastie ($P < 0.001$).

We kunnen besluiten dat primair sluiten bij carotisendarterectomie op korte termijn een

gelijkwaardige sluitingstechniek lijkt te zijn in vergelijking met patch angioplastie, wanneer het toegepast wordt bij geselecteerde patiënten.