CARDIOLOGIE TUNISIENNE

ARTICLE ORIGINAL

Surgical and endovascular management of subclavian artery steno-occlusive disease

Traitement endovasculaire et chirurgical de l'artère sous clavière

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Résumé

Objectif: Evaluer les résultats précoces et tardifs de la prise en charge chirurgicale et endovasculaire de la maladie athéroscléreuse de l'artère sous-clavière.
Méthodes: Données sur les patients consécutifs qui ont été soumis à une réparation chirurgicale ouverte (OSR) et une revascularisation endovasculaire (ES) de l'artère sous-clavière pour une maladie sténo-occlusive entre janvier 2001 et décembre 2018. Les données ont été collectées et analysées rétrospectivement. Les principaux critères de jugement comprenaient la survenue de décès, d'événements cardiaques et neurologiques, à 30 jours et à long terme, comparant les deux techniques et signalant séparément les résultats pour les lésions occlusives et pour les lésions sténosantes.
Résultats: 68 patients ont été traités en utilisant des techniques endovasculaires (49 patients) et une réparation chirurgicale ouverte (19 patients). Le taux de réussite technique était de 100% dans les deux groupes. À 1 mois, le taux de mortalité était de 0% et le taux de morbidité était de 2%. Le suivi moyen était de 36 mois. La mortalité tardive était de 2% et la morbidité tardive de 4%. La perméabilité primaire était de 96% à 6 ans. Dans le groupe de réparation ouverte, des symptômes vertébrobasilaires ont été notés dans 21%, une ischémie critique des membres supérieurs dans 57,8% et syndrome de vol coronaire dans 10%. Nous avons effectué 10% des revascularisations pour les patients asymptomatiques qui étaient candidats pour un pontage coronarien. À 1 mois, le taux de mortalité était de 0% et le taux de morbidité était de 5%. Le suivi moyen était de 48 mois. La mortalité tardive était de 5% et la morbidité tardive de 10%. La perméabilité primaire était de 90% à 8 ans.
Conclusion: ES et OSR se sont révélés sûrs, efficaces et durables dans le traitement de l'artère sous clavière. Les taux de perméabilité primaire à long terme pour l'ER et l'OSR ont montré de meilleurs résultats pour les lésions sténsantes.

Mots-clés

Artère sous clavière, Traitement endovasculaire, Traitement chirurgical, Maladie sténo-occlusive

Summary

Objective: The aim of the study was to report early and late outcomes of surgical and endovascular management of subclavian artery atherosclerotic disease (SAAD).
Methods: Data about consecutive patients who were submitted to open surgery repair (OSR) and endovascular revascularization (ER) of subclavian artery for steno-occlusive disease between January 2001 and December 2018 were retrospectively collected and analyzed. Primary outcomes included the occurrence of death, cardiac eventsand central nervous systemevents, both at 30-days and in the long term, comparing the two techniques and reporting separately the results for occlusive lesions and for stenotic lesions. Secondary outcomes included primary patency in the long term, reported separately for occlusive and stenotic lesions.Kaplan-Meier analysis was used to estimate long-term events. Chi-square and T-tests were used as appropriate to compare the outcomes of the two groups. A P value <0.05 was consideredstatistically significant.
Results: 68 patients were treated using endovascular techniques (49 patients) and open surgical repair (19 patients). Technical success rate was 100% in both groups. At 1 month, mortality rate was 0% and morbidity rate was 2%. Mean follow was 36 months. Late mortality was 2 % and late morbidity was 4%. Primary patency was 96 % at 6 years. In the open repair group, vertebrobasilar symptoms were noted in 21%, critical upper limb ischemia in 57.8% and coronary steal syndrome in 10%. We performed 10% of revascularizations for asymptomatic patients who were candidates for coronary bypass. At 1 month, mortality rate was 0% and morbidity rate was 5%. Mean follow was 48 months. Late mortality was 5% and late morbidity was 10%. Primary patency was 90 % at 8 years.
Conclusion: Both ER and OSR proved to be safe, effective and durable in the treatment of SAAD. In particular, the primary patency rates at long term for both ER and OSR showed better outcomes for stenotic lesions.

Keywords

Subclavian artery stenosis; steal syndrome; endovascular subclavian revascularization; subclavian bypass.

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INTRODUCTION

Subclavian artery atherosclerotic disease (SAAD) is often underdiagnosed in the general population, since most patients are asymptomatic [1]. When symptoms occur, patients may present dizziness and transient cerebral ischemic events for subclavian steal syndrome,upper extremity ischemia, orangina pectoris after coronary artery bypass grafting using an internal mammary artery. In these cases, patients require surgical or endovascular revascularization. Open surgical repair (OSR) is usually the first-line treatment in low-risk patients who have occlusiveSAAD. Endovascular techniques on the other side are the first choice for stenotic SAAD in patients of high surgical risk [2].

Both techniques are now well established, nevertheless in the literature there are few studies reporting long-term results of the two treatments. Moreover, the majority of these studies do not report separately the results for stenotic and occlusive lesions.

The aim of the study was to report early and late outcomes of surgical and endovascular management of stenotic and occlusive occlusions of the subclavian artery over a 18-years' period.

METHODS

Internal ethical approval was obtained for this research from the Institution. Data about consecutive patients who were submitted to surgical and endovascular revascularization of subclavian artery for steno-occlusive disease between 01/2001 and 12/2018were retrospectivelycollected. In particular, patients' records were reviewed for clinical data (age, sex), presence of cardiovascular comorbidities (diabetes mellitus, hypertension,dyslipidemia, smoking habits) and symptoms of SAAD, such as critical upper limb ischemia, vertebral-subclavian steal syndrome or coronary-subclavian steal syndrome.

Critical upper limb ischemia was defined by the presence of tissue loss or rest pain of the hand [3] Outcomes of upper extremity interventions for chroniccritical ischemia], while vertebral-subclavian steal syndrome was defined by the presence of vertebrobasilar insufficiency or arm claudication [4]. Finally, coronary-subclavian steal syndrome was defined as the presence of angina pectoris in patients who had undergone a previous coronary artery bypass grafting (CABG) using the left internal mammary artery.

Data about the type of lesion (either stenosis or occlusion) were recorded.

Preoperative evaluation included physical assessment with pulses examination and blood pressure measurements in both arms, to evaluatefor discrepancies in the upper limbs. A systolic pressure differenceof >10 mm Hg was consideredto be significant [5]. Duplex ultrasound with color flow imaging was then the noninvasive modality of choice, with the evaluation of reversal of ipsilateralvertebral artery flow.Computed tomographyangiography (CTA) was then performed to confirm the diagnosis and in order to plan the proper surgical management.

Indications for treatment included the presence of symptoms and occlusion of the subclavian artery or a stenosis that narrowed the vessel for more than 70% of the lumen diameter. Asymptomatic patients were treated only if they had occlusion or a stenosis >70% when candidates for coronary artery bypass grafting using internal mammary artery. In particular, endovascular technique were indicated as the first choice for stenosis shorter than 10 cm or short occlusions(< 2cm), while open repair was performed for long and calcified stenosis (>10 cm) or long occlusions (>2 cm). Technical success rate for endovascular procedure was defined as the restoration of a patent subclavian artery without a significant residual stenosis (<30%), whilefor surgical repair it was defined by a patent bypass at the end of the procedure.

Endovascular intervention was performed under local anesthesia, using either a radial/brachial or femoral approach. Systemic heparin was administered intraoperatively to achieve an activated clotting time of250 seconds.Primary stenting was performedin all cases. Completion angiography was then performedto assess the technical result.

Open repair was performed under general anesthesia, using either prosthetic grafts or autologous great saphenous vein (GSV) that was harvested at the leg.

All patients were discharged on oral antiaggregants(either acetyl-salicylic acid – ASA - 75-300 mg daily, Ticlopidine 250 mg bis in die or clopidogrel 75 mg daily). After endovascular procedures, patients were discharged on a dual antiplatelet therapy (ASA and clopidogrel/ticlopidine) for 3 months, then a single antiplatelet therapy was continued all life long.

After operation, patients were followed-up three times in the first year (at 1 month, 6 months, and 12 months) and annually thereafter unless there was another reason that required a closer follow-up over time (ie, the presence of a carotid stenosis between 50% and 70%, according to ECST measurement). Additional CTA was performed if noninvasivestudies suggested the presence of restenosis/occlusion and/or the patient had recurrent symptoms.

Follow-updata were obtained through medical records and telephoneinterview.

Primary outcomes included the occurrence of death, cardiac events and central nervous system

events, both at 30-days and in the long term, comparing the two techniques and reporting separately the results for occlusive lesions and for stenotic lesions. Secondary

outcomes included primary patency in the long term, reported separately for occlusive and stenotic lesions.
All collected data were inserted in a database andanalyzed as appropriate using the software STATA-IC®. Continuous variables arereported as median and interquartile range (IQR); categoricalvariables are presented as number (percentage).
Kaplan-Meier analysis was used to estimate long-term outcomes for bothgroups. Chi-square and T-tests were used as appropriate to compare the outcomes of the two groups. A P value <.05 was consideredstatistically significant.

RESULTS

A total of 68 patients were operated using endovascular (49 patients) or open surgical repair (19 patients). Characteristics of the patients in both groups are described in Table 1. As reported, most patients in both groups complained for symptoms of critical upper limb ischemia (32.7% in endovascular repair (ER) group and 57.8% in open surgical repair (OSR) group, P=0.07), while 20.4% of patients in ER group and 10.5% of patients in OSR group were asymptomatic and candidates for coronary artery bypass graft using internal mammary artery (P=0.7).

Table 1: Patients' characteristics of both groups. Significant P values are reported in bold.

	Endovascularrepair (49 patients)	Open repair (19 patients)	P value
Age (median, range)	60 (39-80 years)	71 (40-87 years)	0.5
Male Sex	40 (81.6%)	10 (52.6%)	0.03
DiabetesMellitus	20 (40.8%)	5 (26.3%)	0.5
Hypertension	15 (30.6%)	5 (26.3%)	0.8
Dyslipidemia	4 (8.1%)	0	0.7
Current/PastSmoking	10 (20.4%)	9 (47.3%)	0.2
Type of lesion			
- Stenosis	40 (81.6%)	15 (78.9%)	<0.0001
- Occlusion	9 (18.4%)	4 (21.1%)	
Localization of the lesion			
- Before VA origin	29 (59.1%)	13 (68.4%)	0.6
- After VA origin	20 (40.8%)	6 (31.5%)	
Symptoms			
- Vertebral subclavian steal syndrome	15 (30.6%)	4 (21%)	0.6
- Critical upper limb ischemia	16 (32.7%)	11 (57.8%)	0.07
- Coronary subclaviansteal syndrome	8 (16.3%)	2 (10.5%)	0.8
- Asymptomatic*	10 (20.4%)	2 (10.5%)	0.7

*Patients who were candidates for Coronary Artery Bypass Grafting using the Internal Mammary Artery. VA=Vertebral artery

mmHg (range 10-35 mmHg) of blood pressures between the left and right upper limbs. Duplex ultrasound examinations and then at CTA scans,40 stenosis and 9 occlusionsshorter than 2 cm were found in the ER group, while 15 long and calcified occlusions (>2 cm) and 4 long stenosis (>10 cm) were noted in the OSR group (P<0.0001). Lesions were localized in the right subclavian artery in 42 cases andin the left one in 26 cases. The lesions were localized in the proximal segment of the subclavian artery, before the vertebral ostium in 29 cases in the ER group and in 13 cases of the OSR group (P=0.6), while in the remaining cases they were localized after the onset of the vertebral artery, in the distal portion of the subclavian artery.
All endovascular procedures were performed under local anesthesia via radial puncture in 43 cases orbrachial puncture 3 cases, A percutaneous femoral access was used in 3 cases. Primary stenting was performed in all cases, using balloon expandable stents.
In the OSR group, a carotid-subclavianbypass was performed in 8 cases and a carotid-axillary bypass in 11 cases. The graft of choice was a 8 mm Dacron tube in 10 cases and autologous GSV in the remaining 9 cases.

Intraoperative and 30-days outcomes

Intraoperative/In-hospital details and 30-days outcomes for both groups are summarized in Table 2.

Table 2: In-hospital and 30-days outcomes of patients in both groups. Significant P values are reported in bold.

	Endovascular group	Open repair group	P value
Technicalsuccess rate	100%	100%	-
Length of stay (median, IQR)	2 days (1-3)	4 (3-5)	0.08
In-hospital complications	1/49 (2%)	2 (10%)	0.003
Pts treated for Stenosis	1/40 (2.5%)*	0/15 (0%)	-
Pts treated for Occlusion	0/9 (0%)	2/4 (50%)**	-
30-days Outcomes			
Mortality	0%	0%	-
Neurologicevents	0%	0%	-
Upperlimb salvage	100%	100%	-
Symptomsresolution	100%	100%	-

IQR= inter-quartile range
PTS=patients
*brachial hematoma after percutaneous access
**acute upper limb ischemia

Technical success was achieved in all cases. Length of stay was slightly lower for patients who underwent ER if compared to OSR (2 versus 4 days), even if the difference was not statistically significant.
In the ER group, postoperative course was uneventful in

all cases except for one patient who developed a brachial hematoma after a brachial access for stenting of subclavian artery stenosis. The patient was then treated surgically. In the OSR group, acute upper limb ischemia occurred for two patient who had undergone carotid-axillary by pass for subclavian artery occlusion, in postoperative day 2 and 4 respectively. Bothcases were managed surgically with a Fogarty embolectomy of the bypass and the upper limb arteries, with complete resolution. No complications occurred in patients with stenotic lesions of the subclavian artery treated in the group of OSR.
At 30 days, no deaths neither neurological/cardiac events were recorded in both ER and OSR groups. Symptoms resolution and upper limb salvage were 100% in both groups.

Long-term outcomes

Endovascular group

Two patients were lost to follow-up. One patient treated for stenosis died from a myocardial infarction. Two patients treated for subclavian occlusion presented with in stent restenosis, one of them was successfully treated with drug eluting balloon angioplasty. The remaining patient was first treated with drug eluting balloon angioplasty butthe stent re-thrombosed after 1 year. A carotid-subclavian bypass was then performedfor this patient. Primary patency was therefore 96% at 6 years in patients who had been treated for stenotic lesions and 90 % in patients who had been treated for occlusive lesions (Figure 1).
Overall, long-term primary patency in the ER group was 94 %.

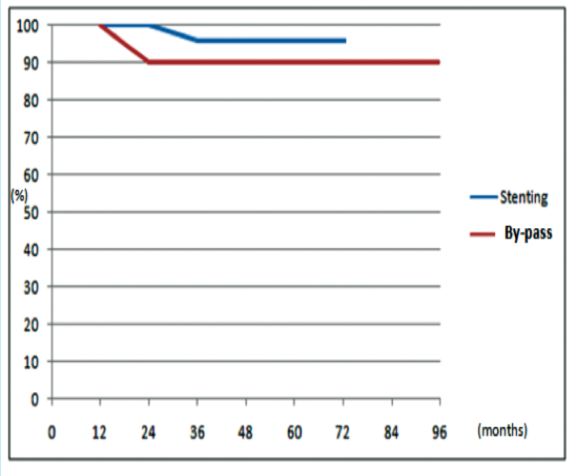

Figure 1: Primary Patency curve of endovascular and surgical procedures

Six patients were lost to follow-up (median … months, range … months). One patient treated for stenosis died from a myocardial infarction. Twofurther bypass thromboses occurred during follow-up in patients treated for occlusions, but revascularization was not required becauseboth patients were asymptomatic. Primary patency was then 90 % at 8 yearsin patients who had been treated for stenotic lesions and … in patients who had been treated for occlusive lesions (Figure 1).
Overall, long-term primary patency in the OSR group was 94%, being not significantly different from that reported after ER (P=0,3).

DISCUSSION

Our study showed satisfactory results at early and long terms after both endovascular and surgical repair of subclavian artery lesions, with no statistically significant differences.
These results seem to be consistent with those recently reported byGalyfos et al. [4] open vs endovascular treatment, who included in their meta-analysis 731 patients with SAAD undergoing 760 procedures. According to their pooled analysis, OSR and ER did not show any significant difference in terms of early and long-term outcomes, although OSR seemed to achieve better long-term primary patency rates.
The seven studies included in the analysis reported data about both OSR and ER procedures that were performed most in the late-1990s, up to 2012.
Until the mid-1990s, surgery was the preferred approach for subclavian artery occlusivedisease [8]. Treatment options,however, have changed during the last decades and less invasive percutaneous procedureshave gained general acceptance. Percutaneous balloon angioplasty and stenting has progressively emergedas a minimally invasive option, and has contributed to a shift in treatment patterns fromsurgery to endovascular approach. In comparison with open surgery, endovascular proceduresdemonstrated significantly lower percentage of intraoperative and postoperative complications,and, as a great advantage, they can be carried out under local anesthesia[9]. These results led some authors to indicate subclavianartery stenting as the procedure of choice for subclavian artery revascularization [9, 10].The guidelines of theEuropean Society of Cardiology that were published in 2011, in fact, recommended an endovascular-first strategy, whilesurgery was indicatedafter a failed endovascular treatment in lowsurgical risk patients[12].
However, some impressive studiescomparingthe results of ER to those of OSR, showed superior outcomes for OSR in the long term. AbuRahma et al. [14], for example, reported about 121 patients who underwent percutaneous transluminal stenting and carotid-

subclavian bypass grafts. They concluded that both procedures were safe and effective, but bypass was more durable in the long term. Therefore, in 2017, theguidelines changed in favor ofa "case-by-case" discussion according to the lesion's characteristics and patient's risk [13], and both open and endovascular revascularization options should now be considered.

As a matter of fact, however, the results reported so far about OSR and ER are not separated for stenotic and occlusive lesions.Chronic total occlusive lesions, particularly those located at the ostium of the subclavian artery, are more complicated and difficult to operate on if compared to stenotic lesions [17]. Therefore, the technical success and the patency ratesare excellent for stenosis, whereas they varies largely for occlusions [18].Motarjeme et al. [19] reported that ER of subclavian artery occlusionswas associated with a procedural success rate of 46% and a 50% of restenosis rate at 1 year, recommendingOSR as the treatment ofchoice, especially for long occlusions. In addition,Linni et al.[15]in their retrospective study reported aprimary failure in 30% of patients who underwent ER, all of them being subclavian artery occlusions.

On the other side, some authors comparing the results of OSR and ER in total occlusive lesions demonstrated equal effectiveness, but fewer complications with endovascular therapy [8].

In our clinical experience, in patients who had long and calcified occlusions of the subclavian artery, bypass was indicated as the first choice, as well as for patients who had multiple long stenosis (>10 cm) of the subclavian axis. Primary stentingwasindicated for short stenosis (<10 cm) or short occlusions (<2 cm), and our strategy revealed to be successful in 100% of patients.

The choice for a primary stenting *d'emblée* instead of a simple balloon angioplasty is supported by the results reported in the literature, according to whichthe routine use of stent implantation could improve long-term results[27], especially when treating occlusions [10].

However, the primarypatency rates at long term for both ER and OSR showed better outcomes for stenotic lesions, indicating that the complexity of the lesion may play a decisive role in affecting postoperative outcomes, irrespectively of the strategy of treatment.

That is the reason why OSR and ER should not be seen as antagonists of a match, but should be bothavailable as valid weapons for the treatment of SAAD, to be used appropriately for each lesion.

CONCLUSION

Both ER and OSR proved to be safe, effective and durable in the treatment of SAAD.In particular, the primary patency rates at long term for both ER and OSR showed better outcomes for stenotic lesions.

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