

Comparison of relative safety and efficacy of handmade S-shaped catheter and conventional catheters in concomitant carotid and coronary angiography

Koroner anjiyografi ile eş zamanlı yapılan karotis anjiyografide, elle S şekli verilen kateterin, konvansiyonel kateterle etkinlik ve güvenilirlik açısından karşılaştırılması

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ABSTRACT

Objective: This study was an evaluation of the feasibility, reliability, and imaging success of concomitant carotid angiography following coronary angiography using the same catheter in comparison with conventional catheters.

Methods: A total of 248 patients who were evaluated with both carotid and coronary angiography between 2010 and 2017 were enrolled in the study: 117 were evaluated with a right diagnostic catheter and 131 were evaluated with a handmade S-shaped (HMS) catheter.

Results: The basic parameters were similar in both groups. The total procedure time (7.34 ± 1.10 vs 9.56 ± 3.59 minutes; $p < 0.001$), fluoroscopy time (6.08 ± 1.72 vs 5.23 ± 1.00 minutes; $p < 0.001$), and contrast media volume (50.2 ± 15.6 mL vs 62.3 ± 17.9 mL; $p < 0.001$) were all lower in the HMS catheter group.

Conclusion: Concomitant imaging of the carotid arteries is advantageous for patients with severe coronary artery disease when performing coronary angiography, given the strong correlation between carotid and coronary artery disease. The catheter used for coronary imaging can be reshaped by hand for carotid imaging rather than using a special catheter. This method proved to be both efficient and safe.

The primary goal of this study was to demonstrate that concomitant carotid and coronary angiography can be performed safely and more efficiently using a single catheter that can be reshaped for the purpose.^[1-3]

Magnetic resonance imaging (MRI) and computed tomography (CT) can be used for an angiographic

ÖZET

Amaç: Bu çalışmada koroner anjiyografi yapılan hastanın ikinci bir işleme girmeksizin koroner anjiyografiyi takiben elle şekillendirilen kateterle karotis anjiyografi yapılabilirliğini ve konvansiyonel katetere göre pratiklik, güvenilirlik ve görüntüleme başarısını karşılaştırdık.

Yöntemler: 2010 ile 2017 yılları arasında koroner anjiyografi esnasında karotis anjiyografi yapılmış olan 248 hasta çalışmaya alındı. Bu hastalardan 117'sine sağ diyagnostik kateter, 131'inde de elle şekillendirilen yeni kateter ile karotis görüntüleme yapıldı.

Bulgular: Temel özellikler iki grupta da benzer bulundu. Toplam işlem süresi (7.34 ± 1.10 dk ve 9.56 ± 3.59 dk $p < 0.001$), floroskopi zamanı (6.08 ± 1.72 dk ve 5.23 ± 1.00 dk $p < 0.001$), kullanılan opak madde miktarı (50.2 ± 15.6 mL ve 62.3 ± 17.9 mL, $p < 0.001$) yeni kateter grubunda daha düşük bulundu.

Sonuç: Karotis arterlerin eş zamanlı görüntülenmesi, karotis ve koroner arter hastalığı arasındaki güçlü korelasyon göz önüne alındığında, koroner anjiyografi yapılırken ciddi koroner arter hastalığı olan hastalar için avantajlıdır. Koroner görüntüleme için özel bir kateter kullanmak yerine, karotis görüntüleme için kullanılan kateter elle yeniden şekillendirilebilir. Bu yöntemin hem etkili hem de güvenli olduğu kanıtlanmıştır.

evaluation of the carotid arteries and may be the first choice for imaging. However, for those who are to have the coronary arteries evaluated, concomitant conventional angiographic assess-

Abbreviations:

CT	Computed tomography
HMS	Handmade S-shaped
JR	Judkins right
MRI	Magnetic resonance imaging

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ment of the carotid arteries is much more suitable, as this provides much better imaging than CT or MRI. Invasive imaging is still the gold standard for neck malformations, carotid body tumors, neck injuries, or carotid artery stenosis, despite the great advances in biomedical devices and technologies.^[4-6] The results of this study also confirm that the quality and resolution of imaging with invasive carotid angiography are much better than with CT or MRI.

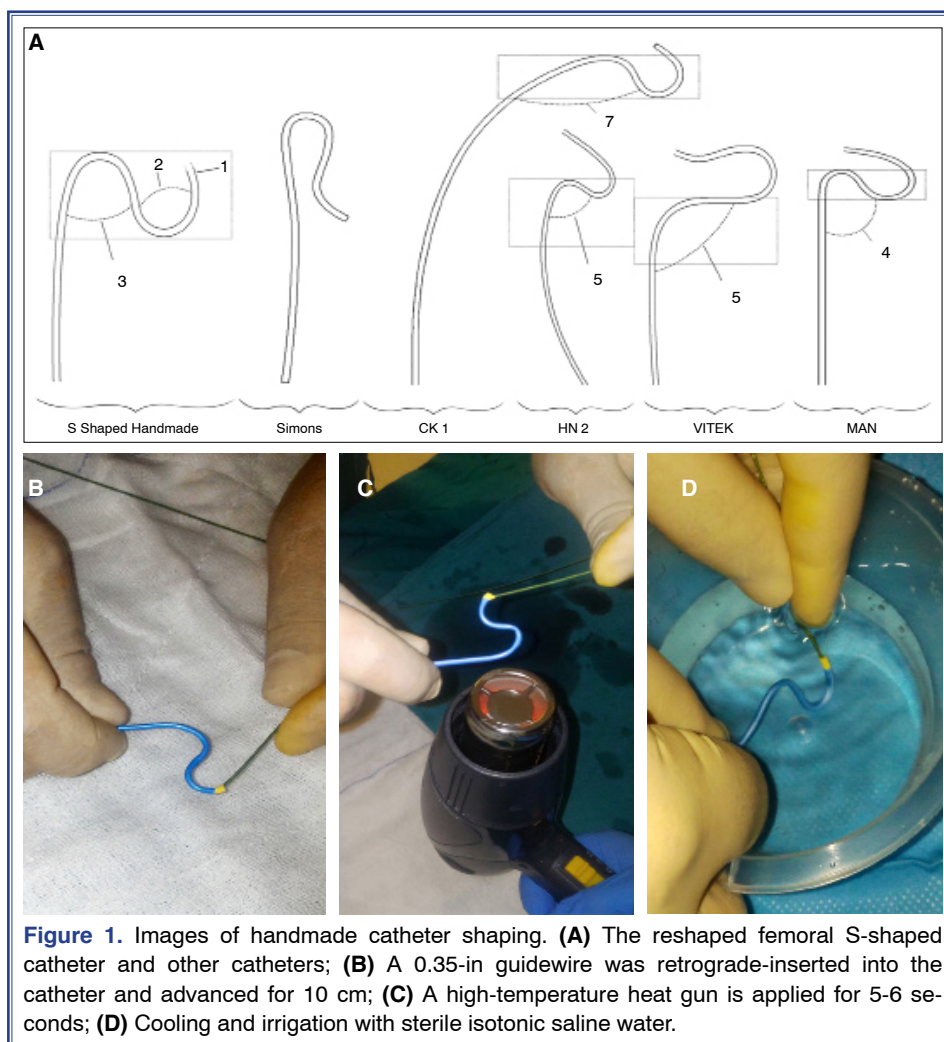
Most cardiologists use a right diagnostic catheter for carotid artery imaging when they perform coronary angiography. A Simmons, CK1 (Berenstein interventional neuroradiology catheter); HN2, HN4, HN5 (Newton catheters); Vitek (interventional neurology catheter); or MAN (Mani catheter) catheter may be preferred for interventional purposes during carotid angiography.^[7-11] However, these types of catheter are not used often and may only be supplied on demand and therefore not al-

ways available in most coronary angiography laboratories. Consequently, reshaping existing catheters may be useful for imaging anomalous vessels, or performing carotid or peripheral artery angiographies (Fig. 1).^[10-12]

METHODS

Patient selection

A total of 352 patients with a suspicion of carotid artery disease, history of stroke, carotid bruits, or carotid artery stenosis demonstrated with Doppler ultrasonography were evaluated with concomitant carotid and coronary artery angiography between 2010 and 2017. In all, 104 patients were excluded from this study because of high risk or unsuitability for carotid angiography. The exclusion criteria were aortic aneurysm (aortic diameter >4.9 cm), aortic dissection, evidence of severe plaque presence in the carotid artery ostia seen



on aortography, severe skeletal abnormalities, history of ascending aortic surgery or endovascular ascending or arcus aortic intervention.

Carotid angiography was performed via femoral access in 248 patients with an indication for carotid artery angiography. The first 124 patients were consecutively randomized to a conventional Judkins right catheter (JR) group and the next 124 consecutive patients were randomized to the handmade S-shaped (HMS) catheter group. Seven patients were reallocated to the improvised handmade catheter group when carotid angiography could not be performed with a JR catheter. In all, 117 patients were evaluated using a JR catheter and 131 patients were evaluated using an HMS catheter (Fig. 2).

All of the patients were informed about the coronary and carotid angiography before the procedure and informed consent was obtained from each patient, noting that the data could be used for future research at the center where this study was performed. Ethics committee approval was obtained from Sakarya University Faculty of Medicine on October 2, 2017, approval number 71522473/050.01.04-72. The study was conducted according to the Helsinki Declaration.

Angiography protocol

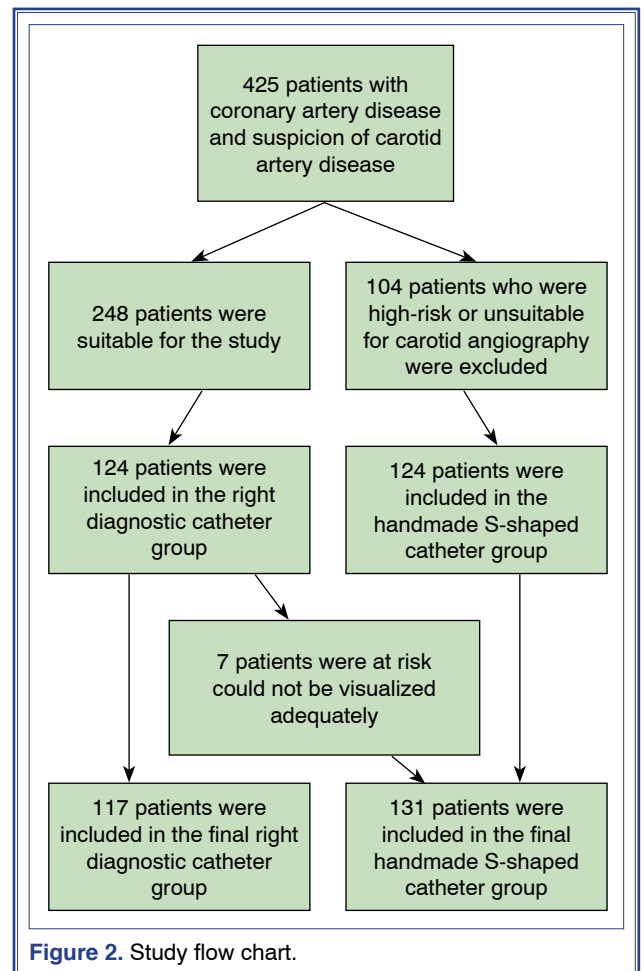
The patients were prepared and draped. Local anesthesia was administered with 10 mL of 5% prilocaine before sheath insertion into the femoral artery. A 6-F Glidesheath (Terumo Corp., Tokyo, Japan) was used to cannulate the femoral artery. Anticoagulation was provided with 5000 IU heparin through the sheath. Standard coronary angiography for the right and left coronary arterial systems was performed before proceeding with carotid artery angiography. After coronary angiography, aortography was performed to evaluate the aortic type, which is essential for the safety of the procedure.^[13]

New aortic classifications for carotid angiography^[14-16]

Type 1: (86%) Most common, right common carotid artery originates from the brachiocephalic trunk. Left carotid and left subclavian arteries originate directly from the aortic arch.

Type 2: (9%) Left and right common carotid arteries originate from the brachiocephalic trunk.

Type 3: (2%) Right and left common carotid arte-

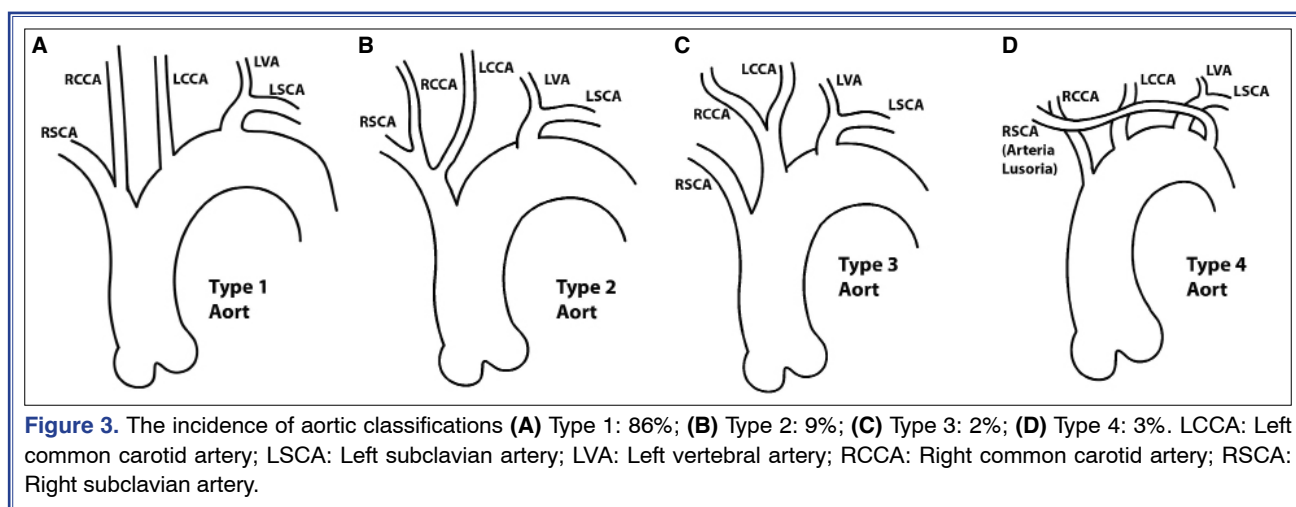


ries originate from a common trunk, not directly from the aorta.

Type 4: (3%) The more unusual kinds of branching of the great vessels, such as arteria lusoria, in which the right subclavian artery originates after the right common carotid artery. Many undefined variations are included in this group (Fig. 3).^[8,12-16]

When there were carotid arteries originating at unusual angles from the arcus aorta, or ostia that could not be visualized clearly, improvised catheters were preferred to JR catheters, and these patients were included in the improvised catheter group.

Catheter reshaping and HMS catheter carotid artery angiography procedure The right coronary diagnostic catheter was taken out of the sheath and rinsed thoroughly. The stiff end of the 0.038-in guidewire of the femoral sheath was introduced about 10 cm into the catheter from the distal tip. The distal end of the catheter and guidewire was manipulated



by hand to give it an “S” shape. It was then heated with a heat gun that produces 500°C of hot air for 5–6 seconds from a distance of 7–8 cm while moving the catheter back and forth. The catheter was cooled and dipped into sterile isotonic saline water, which is routinely used in the angiography laboratory. Water was injected through the proximal end of catheter for 1 minute.^[8,12] The guidewire was removed while the water injection was in progress. After removal of the guidewire, cooling with sterile isotonic water injection was continued for about 30 seconds. Once the desired tip shape was achieved, the catheter was introduced into the aorta over a 0.038-in guidewire for right and left carotid artery imaging.^[12]

Primary end points

1. Success of selective imaging: Cases in which the carotids could not be evaluated clearly with either type of catheter and required other imaging methods for visualization were excluded. Selective imaging was declared successful when contrast media delivery into the carotid arteries was achieved without leaking. Cases in which imaging with remote contrast media administration that successfully demonstrated the lesions but the catheters could not be engaged properly into the carotid arteries were classified as non-selective imaging.

2. Imaging time: The duration of carotid imaging. Percutaneous intervention time was not included.

3. Fluoroscopy time: The duration of fluoroscopy used for imaging. Percutaneous intervention time was not included.

4. Contrast media volume: The total volume of

contrast media used for coronary and carotid angiography. Volume used during percutaneous intervention was not included.

5. Complications:

a. Local hematoma: Hematoma formation at the femoral sheath insertion site.

b. Major hematoma and bleeding: Cases requiring a blood transfusion, i.e., blood loss that decreased blood pressure more than 20% and/or hemoglobin level by 2 g/dL, and cases where life is threatened.

c. Procedure related cerebrovascular event: Cerebrovascular events during or within an hour after the procedure.

d. Contrast induced nephropathy (CIN): The most widely used CIN definition is from the Contrast Media Safety Committee of the European Society of Urogenital Radiology: An increase in serum creatinine of at least 25% or 44 $\mu\text{mol/L}$ within 3 days after contrast media administration in absence of an alternative etiology.^[17]

Statistical analysis

The continuous variables are presented as mean \pm SD and nominal variables as numbers and percentages. Comparisons between the 2 catheter approaches were performed using Student’s t-test for continuous variables and a chi-square or Fisher’s exact test for nominal variables. A 2-sided p value <0.05 was considered significant.

RESULTS

Both groups were similar with respect to the number of female patients; body mass index; average age; in-

cidence of hypertension, diabetes mellitus, or hyperlipidemia; history of coronary artery bypass surgery or percutaneous intervention; and renal insufficiency (Table 1).

The total procedure time (7.34 ± 1.10 minutes vs. 9.56 ± 3.59 minutes; $p<0.001$), total fluoroscopy time (5.23 ± 1.00 minutes vs. 6.08 ± 1.72 minutes; $p<0.001$) and total contrast media volume (50.2 ± 15.6 mL vs. 62.3 ± 17.9 mL; $p<0.001$) were better in the HMS catheter group.

Severe hematoma formation and/or bleeding was observed in 1 HMS catheter group patient who required 3 units of erythrocyte suspension. Compression was applied to the sheath insertion site. Two weeks later, there was no problem other than local ecchymosis at the site. There were no cerebrovascular events or mortality in either group. One patient in the JR catheter group and 2 in the HMS catheter group had pseudoaneurysm formation. All 3 patients were treated surgically by the cardiovascular surgery team with no permanent sequelae.

Both groups were similar with respect to allergic reactions (3 [2.3%] vs. 5 [4.3%]; $p=0.378$), hypotension (12 [9.2%] vs. 6 [5.1%]; $p=0.222$), development of contrast media nephropathy (1 [0.8%] vs. 0 [0%];

$p=0.289$), and local hematoma formation (1 [5.3%] vs. 10 [8.5%]; $p=0.319$). The overall complication rates were also similar in both groups (15 [11.5%] vs. 14 [10.7%]; $p=0.602$).

Both groups were similar with respect to the presence of carotid and coronary artery disease. The presence of more than 50% stenosis of the carotid artery in patients with more than 50% stenosis in at least 1 coronary artery was similar in both groups (72 [61.5%] vs. 84 [64.1%]; $p=0.674$). In other words, the frequency of significant carotid artery stenosis is more than 60% in patients with significant coronary artery disease (Table 2).

The success rate of selective imaging was significantly greater in the HMS catheter group (96.9% vs. 50.4%; $p<0.001$).

DISCUSSION

There is a strong correlation between carotid and coronary artery disease. In our study, we found that in patients with $\geq 50\%$ stenosis of a coronary artery, the probability of significant carotid artery stenosis exceeded 60%. This is a high predictive value.^[18] If patients with significant coronary artery stenosis are evaluated with concomitant carotid angiography, the

Table 1. Baseline patient characteristics

	Conventional catheter (n=117)			Femoral S catheter (n=131)			p
	n	%	Mean \pm SD	n	%	Mean \pm SD	
Female gender	42	35.9		44	33.6		0.703
Age (years)			68.20 \pm 8.76			67.60 \pm 8.9	0.542*
Weight (kg)			84.18 \pm 15.88			82.15 \pm 14.55	0.293*
Height (m)			1.68 \pm 0.10			1.68 \pm 0.10	0.777*
Body mass index			29.55 \pm 5.14			29.01 \pm 4.60	0.378*
Hypertension	112	95.7		122	93.1		0.376*
Diabetes mellitus	50	42.7		54	41.2		0.809**
Smoker	35	29.9		34	26.2		0.511**
Prior stroke or transient ischemic attack	41	35.0		56	42.7		0.214**
Prior percutaneous coronary intervention	33	28.2		37	28.2		0.995**
Prior coronary artery bypass graft	25	21.4		33	25.2		0.478**
Hyperlipidemia	97	82.9		100	76.3		0.201**
Renal failure	2	1.7		3	2.3		0.745**

*Independent sample t-test (95% confidence interval). **Chi-square correlation test.

Table 2. Results

	Conventional catheter (n=117)			Femoral S catheter (n=131)			<i>p</i>
	n	%	Mean±SD	n	%	Mean±SD	
Total procedure time (min)			9.56±3.59			7.34±1.10	<0.001*
Fluoroscopy time (min)			6.08±1.72			5.23± 1.00	<0.001*
Contrast media volume (mL)			62.3±17.9			50.2±15.6	<0.001*
Selective imaging	59	50.4		127	96.9		<0.001
CAD with carotid artery disease [#]	72	61.5		84	64.1		=0.674**
All complications	15	12.8		14	10.7		=0.602**
Pseudoaneurysm	1	0.9		2	1,5		=0.629**
Local hematoma	10	8.5		7	5.3		=0.319**
Allergic reaction	5	4.3		3	2.3		=0.378**
Hypotension	6	5.1		12	9.2		=0.222**
Opaque nephropathy	1	0.9		0	0.0		=0.289**
Major hematoma bleeding	0	0.0		1	0.8		=0.344**
Procedure-related CVA	0	0.0		0	0.0		–

CAD: Coronary artery disease; CVA: Cerebrovascular accident.

*Independent sample t-test (95% confidence interval). [#]The presence of significant plaque in the carotid arteries of patients with stenosis of 50% or more in the coronary arteries. **Chi-square correlation test.

probability of finding significant carotid artery disease is more than 60%. Therefore, there is a clear benefit to performing a concomitant carotid artery angiography in patients undergoing coronary artery angiography and vice versa.^[1,2]

Due to this likelihood of coexistence, a single combined invasive angiography procedure may be preferable to MRI or CT carotid angiography. When focused only on the carotid arteries, coronary artery disease may be neglected and the risk of a myocardial infarction may threaten the patient. Non-invasive imaging techniques do not have the image quality of invasive imaging. Invasive imaging reveals the characteristics of the plaque, its fragility, and its contents. These are important clues for the treatment strategy.^[2,8]

Medline and Google Scholar research revealed a few studies of invasive carotid angiography, but we did not find any study about the efficacy of catheters used in carotid angiography immediately following coronary angiography via femoral access.

Cardiologists performing carotid angiography often use a right diagnostic catheter for carotid imaging

after coronary angiography.^[1,2] If a comparative study were performed, we believe that Simmons, HN4 and HN5, MAN, and CK1 catheters would be found to be superior to a right diagnostic catheter in carotid imaging. However, we could not find any studies in the literature about the comparative advantages, safety, and efficacy of any of these catheters for use in carotid angiography.^[10-12]

The results of this study confirm that physicians performing coronary angiography can easily also perform carotid angiography safely and effectively by reshaping the right diagnostic catheter without the need for another type of catheter.

A catheter that does not have much contact with the aortic endothelium will cause much less plaque disruption and fewer embolic events. The right common carotid artery usually originates from the right subclavian artery with an acute angle, so HMS catheters are not needed for visualization. However, if there is significant plaque formation between the origins of the right subclavian and left common carotid arteries, searching for the ostia of those arteries with a right diagnostic catheter that is not supported by a 0.035-in guidewire may cause complications. The tip of the

HMS catheter described in this study does not extend into the aorta, so the search may be safer with an HMS catheter. The distal angulation of the HMS catheter comes into contact with the aortic endothelium rather than the tip, thus allowing for a successful and safer carotid artery angiography procedure.

In other words, thanks to the S-shape, the tip of HMS catheter does not directly touch the inner aorta; the catheter rotation can be performed safely without 0.038-in guidewires at the end of catheter. Selective engagement of the carotids with an HMS catheter is easier than with other catheters (Figs. 4, 5).

We suppose that catheter reshaping is performed in many angiography laboratories, but there are few studies on the subject.^[7-9] Similar studies will enhance our knowledge and experience of angiography and contribute to the development of the procedure. All invasive procedure experiences open new areas for percutaneous interventions. Fifteen years ago, retrograde recanalization of chronic total occlusions was impossible with the instruments and techniques at that time.^[19] Transcatheter aortic valve replacement was a dream 20 years ago.^[20] All of these achievements were

made possible with the scientific publication of new techniques.

It has been demonstrated that the coincidence of carotid artery stenosis and significant coronary artery disease exceeds 60%. At the time of coronary angiography, without the extra cost of a special catheter, a right diagnostic catheter can be reshaped to image the carotid arteries quickly, safely, and effectively. If carotid angiography is indicated, it can be performed concomitantly with coronary angiography.

Study limitations

A version of the HMS catheter could be professionally manufactured and a comparative study could be designed to examine the usability, efficacy, and safety with CK, HN, MAN, and Simmons catheters. A larger comparative series would be even better. In this study, we have tried to be as neutral as possible. Different physicians were involved in the performance and evaluation of the procedures. Nonetheless, if there had been more physicians performing the angiography procedures in this study the results would be more valuable. Intravascular ultrasonographic or CT

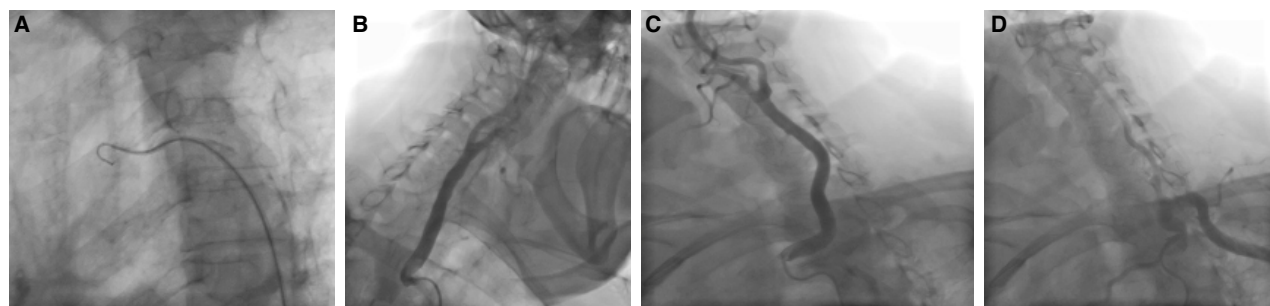


Figure 4. (A) Femoral S-shaped catheter in position with guidewire in the arcus aorta; (B) Right carotid angiography, right lateral view; (C) Left carotid angiography, left lateral view; (D) Left subclavian artery angiography, left lateral view.

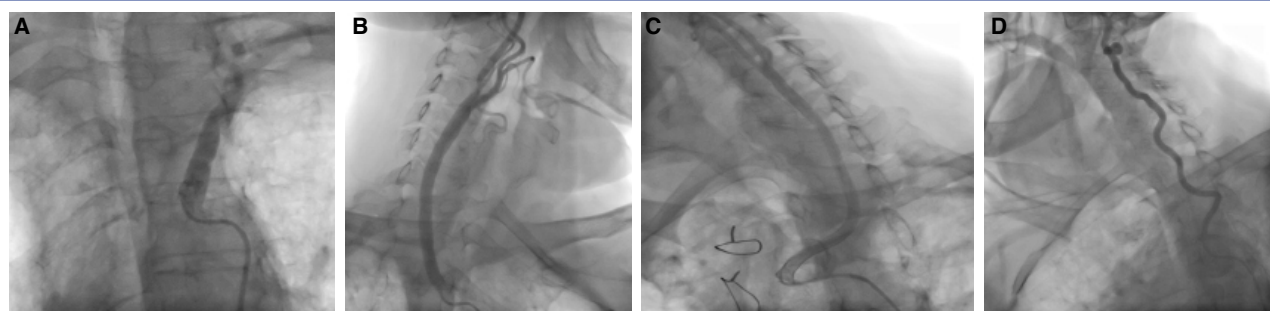


Figure 5. Other examples of the use of the femoral S-shaped catheter. (A) Left subclavian artery angiogram, left lateral view; (B) Right carotid angiogram, right lateral view; (C) Left carotid angiogram, left lateral view; (D) Left vertebral artery angiogram, left lateral view, illustrating the artery arising separately from the aortic arch.

evaluation of the ostia of the carotid arteries or internal surface of the aorta could have revealed data that may have been supportive of our claims.

Disclosures

The author confirms that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

Ethics Committee Approval: This study was approved by the Local Ethics Committee (October 2, 2017, approval number 71522473/050.01.04-72).

Peer-review: Externally peer-reviewed.

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Keywords: Carotid angiography; catheter shaping; multipurpose catheter; stroke.

Anahtar sözcükler: Karotis anjiyografi; kateter şekillendirme; çok amaçlı kateter; inme.