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Carotid Endarterectomy Using Patch Angioplasty without Routine Completion Duplex Scan

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부착포를 이용한 경동맥혈관내 절제술 시 완성 혈관조영술의 의미

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Purpose: Routine intraoperative duplex color-flow ultrasound carotid examination as a completion study has been welcomed by many vascular surgeons as the most recent, high proficiency tool to detect unsuspected remaining operative defects before the patient leaves the operating room, thereby improving operative outcome after Carotid Endarterectomy (CEA). However, after many years of experience gaining added knowledge about the clinical course and standardization of operative procedures of CEA for mainly occidental patients, the adherence to strict operative procedures using patch angioplasty and liberally added continuous-wave Doppler confirmation has been found to achieve well beyond acceptable operative results in our patients without routine intraoperative duplex scanning (IDS).
Methods: A retrospective review of 455 surgical patients who underwent patch angioplasty in a five year period, from January 1996, was performed to evaluated their operative outcome. Their perioperative morbidity, mortality, and follow up Duplex scan findings on restenosis for a mean of 20.8 months were observed for a comparison between our experience and recently reported results using routine IDS.
Results: We had a perioperative combined stroke-death rate of 2.0% (n=9), consisting of death in 0.9% (n=4) and stroke in 1.1% (n=5). Residual stenosis was confirmed by first follow up Duplex scanning in 13 patients a (4.2%), 6 of whom were resolved with time. Twenty-three (5.6%) recurrent stenoses, including 2 occlusions and 1 high grade stenotic internal carotid artery (ICA), and 1 occlusion with 2 severe stenoses in external carotid artery (ECA), appeared among 414 cases during follow up. Except for 2 patients who suffered perioperative stroke, one of whom died, all residual stenosis and recurrent stenosis patients stayed clinically symptom free. Among 5 immediate postoperative transient ischemic attacks (TIA) cases and 5 strokes, one residual stenosis accompanying stroke appeared during follow up. Of five cases that were re-explored in the operating room by continuous wave Doppler information with conversion of primary closure to patching (n=2) and revision of distal arteriotomy (n=2), all remained normal during follow up by duplex scan.
Conclusion: Routine patch angioplasty, meticulous surgical technique and continuous-wave Doppler information were enough to achieve an acceptable clinical outcome in our patients. IDS might be necessary selectively for concerned cases only. **(J Korean Surg Soc 2003;65:335-342)**

Key Words: Carotid endarterectomy, Carotid stenosis, Completion angiography
중심 단어: 경동맥혈관내 절제술, 경동맥협착증, 완성 혈관조영술

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INTRODUCTION

From the completion angiography dating back to 1967 by Blaisdell(*1*) recently to intraoperative color-flow duplex ultrasound, it has been widely and almost uninterruptedly advocated in the literatures(*2-5*) that they should be routinely incorporated at the end of the carotid endarterectomy to prevent unsuspected defects in the endarterectomized carotid artery for improvement of outcome. With many merits of color-flow duplex ultrasound compared to previous

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traditional Angiography owing to recently advanced technology and added experience of its use, many authors nowadays report improved results after CEA in postoperative neurologic complications and in restenosis rates.

Actually in many studies the recent outcome of CEA using routine IDS is remarkable from decreased periopeative stroke or decreased residual stenosis rates in short term to decreased recurrent stenosis rates in long term. Seelig et al(*3*) reports not one perioperative combined stroke-death rate in his study and Mays et al(*4*) shows only one case of residual stenosis of internal carotid artery among his one hundred operated patients. Mansour et al(*5*) also reports decreased recurrent stenosis of 1.4% by using routine IDS from previous 6.8% without IDS in his series.

Through more than four decades of CEAs since its introduction in 1954, we have seen steady improvement of postoperative outcomes and surgical techniques. And most vascular surgeons still do not employ intraoperative completion studies except continuous-wave Doppler examination for reasons of cost, or required skills to perform, or suspicion about the real value or practicability of IDS. Simply, if the benefit of IDS should be quite small to be insignificant, or if the outcome could be the same without helpless completion study which has been our constant belief with routine patch angioplasy and meticulous surgical procedures under direct vision of the whole lesion, it might be a clue that the improving outcome of recent ECA might not be due to routine IDS. It should be rather a fruit of steadily developing surgical techniques or added knowledge about the nature of the disease, which might release many patients undergoing CEA from being bothered with routine IDS, and the operation suppliers too.

So, in this study, we reviewed postoperative outcome on CEAs to see whether our experience could really bring us acceptable outcome compared to recent representative studies using routine IDS.

METHODS

1) Patient selection

Among 545 consecutive patients in our carotid arterial operation registry at Oregon Health and Science University (n=356) and Veterans Affairs Medical Center (n=189) during five years from January 1, 1996 to December 31, 2000, 455 consecutive cases of CEA patient with patch angioplasty were selected for review, including 18 cases of re-do operations referred from other hospital due to restenosis after initial CEA and 7 cases of CEAs for external carotid arteries also using patch.

The patients' basic features are shown in Table 1 as follows: 360 cases were male. The patients' mean age was 68.2 (range, 38～87) with underlying associated diseases not quite different from others in its pattern except the male and female ratio coming from male predominant patient distribution of Veterans Affairs Medical Center.

All the operated cases met the operative indication criteria proposed by North American Symptomatic Carotid Endarterectomy Trial (NASCET) and Asymptomatic Carotid Atherosclerosis Study (ACAS) Group of 70% and 60% diameter stenosis respectively, with its correlated Duplex scanning criteria of over ratio 4.0 of peak systolic velocity (PSV) of ICA/PSV of CCA and ICA PSV ≥290 and end diastolic velocity ≥80, previously published by us.(*6*,*7*) Criteria of diameter to grade carotid stenosis and its

Table 1. Profile of patients undergone CEA with patch angioplasty

Profile	Number, total=455 (%)
Mean age	68.2 years old
Male/Female	360/95 (20.9%)
Mean follow up period	21.8 months (range, 4～67)
Lost duplex follow up after 4 months	41 (8.8%)
Smoke history/CVA history	314 (69.0%)/75 (16.5%)
Associated diseases	
Hypertension	381 (83.7%)/64 (14.1%)
DM	127 (27.9%)
Coronary arterial disease	169 (37.1%)
Peripheral arterial disease	136 (29.9%)
Carotid atherosclerosis	
Amaurosis fugax/TIA/Stroke	102 (22.4%)/165 (36.3%) /36 (7.9%)
Asymptomatic/Symptomatic	189 (41.5%)/271 (58.5%)
Right/Left	223 (49.0%)/232

CVA = cerebral vascular accident; DM = diabetes mellitus; TIA = transient ischemic attack.

Table 2. Grading criteria of carotid stenosis for duplex scan data

Grade	Diameter reduction	Criteria
A	None	Normal finding
B	1~16%	Minimal spectral broadening
C	17~49%	Loss of spectral window
D	50~79%	PSV≥125 cm/sec
ACAS 60%	>=60%	ICA PSV≥290 and EDV≥80
NASCET 70%	>=70%	ICA PSV/PSV (prox) CCA≥4.0
D+		80~99%EDV≥140 cm/sec
E	Occluded	No flow

ACAS = asymptomatic carotid atherosclerosis study; NASCET = north american symptomatic carotid endarterectomy trial; PSV = peak systolic velocity; EDV = end diastolic velocity; ICA = internal carotid artery; CCA = common carotid artery.

guidelines referred for operative indications and follow up are briefly described in Table 2.

Cases with combined cervical vascular procedures such as carotid-to-subclavian bypass were excluded for fear of its inadvertent effect on CEA, and cases of follow-up of less than eight weeks were also excluded from study except complicated cases. Several cases of strokes attributed from contralateral hemispheric event were not included into follow up evaluation.

2) Surgical Procedure

All the operative maneuvers and postoperative patient care was applied to all patients identically by sugeons sharing same protocols for every procedures from evaluation to follow up. Thus for the operative procedures, surgeons followed the same procedures under the same principles, frequently in the same space of operating room while operating.

Except for five cases of cervical block anesthesia, all patients were operated under general anesthesia in reverse Trendelenburg's position. Arteriotomy was always tried to be made generous enough to expose the entire atherosclerotic carotid lesion after routine systemic heparinization, and also shunted routinely except six occasions of very small briskly back-bleeding ICAs imposing difficult anatomic condition to keep it in during plaque removal. Under ×3.5 magnified visual field, removal of the all small fronds and leaving smooth and wide internal carotic arterial lumen especially at the distal endarterectomy tip was always our greatest concern. For it, tacking down sutures were added liberally in 59% of operated patients having concerned end of internal carotid intimal tip or occasionally to proximal common carotid intimal edge also. Luminal surface after endarterectomy was repeatedly flushed by heparinized saline and inspected for fear of remnant fronds or flap elevation at the tip after arteriotomy closure. Synthetic materials, Dacron (n=436) or Polytetrafluoroethylene (PTFE) (n=10), were used for patching in most cases. In cases of high infective risk, such as six selective patients of re-do operations or anticipated operations near CEA site like resection of Zenker's diverticulum, autogenous saphenous vein was used as a patch in total 9 cases. For cases of external carotid endarterectomies which was indicated to help prevent neurologic events by previously occluded ipsilateral internal carotid arteries, procedures were basically the same as those for internal carotid arteries as described above using Dacron patches, but eversion endarterectomy was usual procedure for removal of coincidental ECA atherosclerotic plaque. Continuous-wave Doppler examination was routinely performed for shunt patency and for carotid arterial flow immediately after closure of arteriotomy.

Under direct vision, cautious handling of the artery to avoid embolism and smooth luminal surface and generous diameter of carotid artery by patch angioplasty was always the rule to be certain.

3) Patient Follow Up

Review was made of records such as surgeon's operation note and progress note, and findings of follow-up duplex scan performed by our vascular laboratory service usually at two weeks after discharge on the first or second postoperative day and three to six months after the first visit, and in one year intervals thereafter as long as otherwise no clinically unfavorable features were encountered. Patients were followed for mean period of 20.8 months (20.8±9.1, range 4~67) during which 41 patients (8.8%) were lost before third month after operation. Follow up period was discontinued at the time of the last Duplex scan in view of our interest

to relate the duplex finding to the clinical outcome., and the follow up period of complicated cases beyond the time of complication occurrence were included as long as the duplex scan continued. The patients' postoperative clinical outcome was evaluated up to the time the last duplex scan was taken.

RESULTS

From the total 455 cases of CEAs employing routine patch angioplasty, complications appeared as Table 3 shows: The perioperative combined stroke- death rate was 2.0% (n=9) representing four deaths and five strokes. One perioperative death was caused by a fatal occipital hemorrhagic stroke probably related to postoperative hyperperfusion. Other causes of deaths were two myocardial infaction and one hypovolemic shock from operation site hemorrhage. Among five perioperative strokes, two were aggravation of preexisting disability of aphasia or hemiparesis, and one was motor seizure which was recovered durng follow up, but the rest two strokes appeared immediately after operation with corresponding lateralized symptoms and in one case with mentality change. Transient ischemic attack (TIA) appeared immediate postoperatively in five patients mainly with symptoms of intermittent numbness less than several minutes of duration, one of which required five days for its complete resolution and patients naturally turned to normal and free from sequele.

Four patients of postoperative MI necessitated prolonged admission for medical treatment. Cranial nerve injury occurred in six patients, one of them had to undergo endoscopic gastrostomy from inability to swallow. Five cases of wound hematoma were discovered before discharge, two of them required bleeding control and hematoma evacuation, and four cases of wound infections were cured by conservative management without provoking serious problems by infectious spreading into carotid artery. One case of immediate postoperative Mallory-Weiss syndrome with signs of internal bleeding was treated conservatively.

Residual stenosis identified on the first duplex scan follow up after discharge, supposedly within two months after operation by which time all the patient had finished their first examination, occurred in 16 cases (3.5%) showing $\geq$50% diameter stenosis. Among them, six cases of ICA stenosis returned to normal after six months to one and a half year of follow up and 7 cases sustained their grade of stenosis through out the follow up period except one occlsion of ECA and one progression to high grade stenosis (D+) from severe residual stenosis (D) and one occlusion of ICA. ICA occluded patient had immediate postoperative stroke and two months later died from stroke. Recurrent stenosis was seen in 23 cases (5.6%) during the 20.8 months of mean follow up period among 414 cases they could be followed up. In total we observed 33 cases of

Table 3. Postoperative clinical outcome of CEAs

Complications	Number (%)	Comments
Combined stroke-death rate	9 (2.0)	
Death	4 (0.9)	1 hemorrhagic stroke, 2 MI, 1 hypovolemic shock
Stroke	5 (1.1)	1 motor seizure, 2 worsening of stroke, 2 major stroke
Postoperative TIA	5	2 numbness, 2 weakness, 1 blurred vision
Myocardial infarction	5	Cured without complication
Cranial nerve injury	5	1 gastrostomy
Wound complication		
Hematoma	5	2 reoperation
Infection	4	Cured conservatively
GI bleeding	1	Mallory-weiss syndrome
Residual stenosis	16/455 (3.5)	6 resolved, each 2 from ext. CEA and redo op.
Recurrent stenosis	23/414 (5.6)	3 occlusion, 1 D+, otherwise C, D
Oveall restenosis	33/414 (8.0)	10 from residual stenosis and 27 from recurrent stenosis

TIA = transient ischemic attack; GI = gastrointestinal; MI = myocardial infarction; CEA = carotid encarterectomy; op. = operation.

restenosis coming from 3 of CEA for ECA (n=7) and 4 of redo-operations (n=18), and the rest 26 from CEAs for ICA. Among them, as described above, 2 ICAs and 1 ECA were occluded and one ICA was highly graded stenotic ranging 80～99% stenosis while 31 of them were clinically uneventful postoperatively free from neurologic symptoms through the follow up period under antiplatelet medications except two complicated cases of immediate postoperative strokes of a motor seizure and a major stroke accompanied with mentality change. In case of five postoperative TIAs, all showed normal patency (grade A) (n=1) or minimal stenosis (n=4) (grade B) during the follow up period without evidence of changing degree of stenosis into significant grade.

We performed 5 cases of reexploration after arteriotomy closure from the information of abnormal continuous-wave Doppler which led to angiography and reexploration of defects of intimal flap (n=1) and thrombus (n=1) in the distal internal carotid artery and conversion of primary closure to patch angioplasty (n=2). One case of abnormally high frequency of Doppler signal showed no demonstrable cause of abnormal Doppler information such as contralateral carotid occlusion showing satisfacftory luminal patency. A distal ICA occlusion appeared from one of reexplored cases removing thrombus and this patient died from stroke in two months postoperatively. External carotid endarterectomy showed poor result in view of restenosis than that of ICAs, for one residual stenosis was occluded in four months after operation and 2 recurrent stenosis appeared by six months and twelve months after operation leading to total 3 restenoses from 7 cases. Eighteen re-do operation cases referred from other hospital showed 2 residual stenoses and 2 severe recurrent stenoses showing a restenosis rate of over 20%. We experienced 5 cases of proximal resection of ICA during CEA due to its redundancy and they were all widely patent during follow up.

Table 4. Recent outcomes in Literatures using IDS and against IDS (%)

Author (year) (operation period)	N	Defects/ Reexplored	Perioperative Stroke	Perioperative Death	Restenosis	F/U
Panneton (2001)[8] ('90～'94)	14 9	62/11	2/149 (1..3)			Short term
Mansour (2001)[5] ('93～'96)	21 2	47/6	3 (1.4)	0	15 (7.1)	2.0 years
Mays (2000)[4] ('95～'98)	10 0	33/22	1 (1.0)	0	1 occlusion, no residual stenosis	6 weeks
Roth (1999)[9] ('90～'97)	24 2	/12	1 (0.4)	0	6 (2.5)	27.4 months
Mansour (1999)[10] ('87～'97)	61 1	156/20	6/560 (1.1)		22/562 (3.9)	6 months
Seelig (1999)[3] ('91～'97)	11 5	29/14	0	0	12 (11.8)	21.3 months
Dykes (1997)[11] ('90～'95)	64		0		3 (4.7)	2.0 years
Baker (1994)[12] ('86～'92)	31 6	62/9	4 (1.3)	2 (0.6)	6 (1.9)	21.6 months
*Ricotta (1997)[13] ('88～'96)	22 9		7/229 (3.1): combined stroke-death rate		29/192 (15.1%): residual stenosis	Short term
*Krishna (1994)[14] ('85～'93)	41 7		9 (2.0)	4 (1.0)		Short term
*Ours ('96～'00)	45 5	455/5	5 (1.1)	4 (0.9)	33/414 (8.0)	20.8 months

*Literatures against routine IDS; N = number; F/U = Follow Up; / = numerator means number of events occurred.

DISCUSSION

The aim of CEA can be said to be an operation for prevention of neurologic disaster within the range that patients could at least have advantage by the operative management comparing with patients managed otherwise. Accordingly the acceptable range of complication widely acceptable among vascular surgeons issued. Up to the present, most surgeons agree to refer to a 3.0% limitation as a guideline for serious morbidity and mortality after CEA as suggested by ACAS group in 1995. But from spontaneous and continuous efforts to improve the outcome more satisfactorily, IDS has been widely tried since '80s(*2*) in many centers with insisted good or more favorable neurologic outcomes when IDS was routinely employed at the end of operation.

As we have described in the results, our perioperative combined stroke-death rate which surely seems to be one of the most important indices for the outcome of CEA and the recognized main merit for the justification of routine IDS proved to be 2.0% (n=9) out of four cases of postoperative deaths (0.9%) and five cases of postoperative strokes (1.1%) which should be comparable with the recent representative results obtained by routine IDS as shown in contrast with those against it in the Table 4,(*3-12*) where the stroke-death rates from 0% to 1.9% by routine IDS. Most of the stoke-death rates range from 1.0% to 1.9 percents without actual no postoperative deaths which only differs compared to the results against it, showing all the results staying in the same comparable range of guided limitation for acceptable complication rates. Although the rates goes down to zero in two studies of smallest study patients volume, I simply wonder their outcomes would continue up to these days with more cases without not one death because it seems inheritantly out of possibility.

In view of necessity of routine IDS and its probable benefits of preventing postoperative neurologic event by detecting remaining defect causing thromboembolism, we can consider the perioperative stroke rates separately. Most recent reviews on routine IDS made by Mays et al(*3*)(2000) and Mansour et al(*4*)(2001) shows postoperative stroke rates of 1.0% (1 from 100) and 1.4% (3 from 212) respectively, illustrating the same outcome with our 1.1% (5 from 455). Even when considering the one stroke which occurred among our perioperative death cases, our stroke rate showed no difference from the results using routine IDS except two perfect reports again with small patient volume in Seelig et al(*3*) and Dykes et al.(*11*) Even with the aid of IDS, stroke continues to happen and that in the same rate. It can be extended as a common finding for the last three were studies opposing routine IDS or completion study including our experience, to see the stroke rates commonly under 1.5% whether the routine IDS was used or not. From the outcome of combined stroke-death rates, and more of it in stroke rates, our result shows no significant difference in postoperative clinical outcome to recent ones accomplished by routine IDS and needlessly to remind, it meets the guided limitation of postoperative major complications.

Interestingly, our perioperative neurologically complicated cases of stroke (n=5) and TIA (n=5) patients kept patent carotid arterial flow on Duplex follow up except two cases of stroke accompanying 50～79% residual stenosis. And in our cases, 16 residual stenoses appeared in 3 of 7 external CEA and 2 of 18 redo-operation, and the remaining 11 from internal CEAs. All they stayed clinically stable postoperatively except two above perioperative strokes. Without residual stenotic duplex finding in our three cases postoperative stroke, the probability of detection of meaningfully large anatomical defect which might have been remaining at the end of meticulously performed CEA is not much presumable. The meaningful anatomic lesions liable to cause postoperative complications by embolization were usually categorized to be more than 3mm size by the users,(*10,12*) at the end of operation which are supposed to accompany significantly defective duplex finding during follow up, but which are not our cases because firstly postoperative neurologic events appeared more from patent carotid arteries and secondly most stenotic carotid arteries on duplex stay calm postoperatively.

From such facts, the merit from routine IDS should be too small for our patients to rely on to believe it will contribute significantly to reduce the incidence

of perioperative neurologic events. Because in our cases, the merit from routine IDS will be at best reduction of two perioperative strokes from 455 IDS. In fact even in above two patients, one motor seizure patient recovered during follow up and one stroke patient happened to undergo reexploration due to abnormal Doppler information, illiminating the possibility of benefit from IDS making it actually helpless.

We had 5 cases of re-explorations of arteriotomy at the end of operation, on follow up, 4 of them showed normal or minimal stenosis of ICA, but one distal ICA revised was occluded causing the patient die in two months postoperatively. All these reexplorations came from information of abnormal continuous-wave Doppler which we all agree it to be subjective in interpretation, but served well in our opinion because four severe defects of distal ICA could be identified in operation field by Doppler information of abnormally high pitched signals due to high velocity in four cases and loss of end diastolic signals in one case suggesting distal obstruction. In numbers, five cases exclude Doppler from its appropriate evaluability, but detection of four remnant lesions from five suspected means an 80% positive predictive value. We don't intend to expand, however, our well accepted agreement about the sound only continuous-wave Doppler information being rather simple and thus subjective, from our many cases of unexpected unsymptomatic restenoses we have faced after operations. Doppler should exactly be an auxiliary but useful tool we could use, as we have had for detection of suspicious flow disturbances.

Routine patch angioplasty can easily be expected to give a wider lumen after closure of arteriotomy wound, and when applied to the patients routinely beyond the scope of usual indication of 5 mm diameter or female patients,(*5*) it should undoubtedly give a more generous postoperative course concerning stenosis of the carotid artery, whether it may be a mere delay or a true eliminating effect of the restenosis which is yet to be cleared. From the view point of recent available restenosis rate of 4% to 22% in general, our restenosis rate 8.8% does belong to a better side by routine employment of patch. By now, there is no way to clearly tell the exact effect of patching but just telling the hopeful fact that clinical improvement both in short and long term(*17*) that opinion is widely shared among vascular surgeons making them prefer the patch angioplasty to adopt it around 70% of CEA cases nowadays.

Mansour et al(*5*) revealed 3 (1.4%) re-do operations due to $\geq$80% restenosis, showing the similar number of more than severe grade stenosis (D+, E) when compared to our 4 cases of redo operation indicated results of three occlusion and one high grade stenosis. But Mays et al(*4*) had only one occlusion without other cases of residual stenosis in their 6 week follow up which should be the best result among reports using IDS, and clearly much better when compared to our 16 (3.5%) residual stenoses. Through the results between studies in Table 4, restenosis is decreased approximately from near 10% to around 5% as long as the duplex finding is concerned which, however, does not seem to be comparable in a statistic means. Postoperative neurologic event seems to be caused by many factors from mainly thromboembolic episodes to hemodynamically inadequate circulation. As many studies similarly suggest,(*8,15*) intimal flap, intimal dissection, remnant plaque, fronds, stenotic repair of lumen, or thrombus adhering to dissected luminal surface after endarterectomy, any of above defect could cause neurologic events. But we never mean that residual stenosis or recurrent stenosis is harmless. Actually, we always do the best to minimize leaving unsuspected defect in the endarterectomized lumen to avoid disastrous neurologic event by any of above causes. But we should remind the fact in minds that many residual or recurrent stenosis are calm without postoperative neurologic events(*18*) or even shows spontaneous resolution as we have seen in our cases. In our study patients, six cases of residual stenosis returned to normal and all recurrent stenotic patients (n=23) are staying free from neurologically under antiplatelet medications and efforts to control the risk factors. It was the same for the patients showing highly stenotic (n=1) and two occluded cases from three of them in a sense that they were free from neurologic symptoms while they were not reoperated indicated by associated diseases and ages.

On balance, in our experience, from above results

we had, routine IDS seems unnecessary because of its small possible advantage to improve patient outcome comparing to the expenditure of resource. Strict adherence to the surgical principle of complete removal of the plaque and leaving smooth luminal surface especially at the distal internal encarterectomized area, adding diameter with patch angioplasty and easiest procedure for information by continuous-wave Doppler before wound closure warranted acceptable outcome for patients.

The problem of reducing restenosis should clearly be an important matter with more need for improvement, and we agree to the opinion that IDS was instrumental helping to improve surgical technique leading the surgeon to try more to avoid leaving large identifiable defect in endarterectomized carotid artery,(*12*) otherwise, we do not agree with the value of routine IDS.

Routine IDS does not seem to belong to the future for improved outcome of carotid endarterectomy.

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