MEDICAL SCIENCE MONITOR

CLINICAL RESEARCH

e-ISSN 1643-3750
© Med Sci Monit, 2018; 24: 9026-9031
DOI: 10.12659/MSM.912142

Received: 2018.07.17
Accepted: 2018.11.30
Published: 2018.12.13

Evaluation of TurboHawk Plaque Rotation System in Treatment of Superficial Femoral Atherosclerosis

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCEG 1 Sheng Guan*
BCF 2 Juan Sun*
BC 1 Tang Jiareke
CDEF 1 Xiaohu Ge

1 Department of Vascular Surgery, People's Hospital of Xinjiang Uygur Autonomous Region, Urumqi, Xinjiang, P.R. China
2 Department of Cardiology, The First Affiliated Hospital of Xinjiang Medical University, Urumqi, Xinjiang, P.R. China

* Sheng Guan and Juan Sun equal contributors

Corresponding Author: Xiaohu Ge, e-mail: 15022979570@189.cn
Source of support: This work was supported by grant No. 2014211C060 from the Xinjiang Urumqi Science and Technology Bureau

Background: To investigate the curative effect and utility of the TurboHawk plaque circumcision system in the treatment of patients with superficial femoral atherosclerosis (SFA).

Material/Methods: We retrospectively analyzed 60 cases of superficial femoral atherosclerotic stenosis and occlusion treated with the TurboHawk plaque circumcision system for endovascular ablation of the superficial femoral artery in the People's Hospital of Xinjiang Uygur Autonomous Region between January 2016 and December 2017.

Results: The sample comprised of 50 male and 10 female patients with an average age of 65±4.5 years (range 47 to 70 years). This group of patients had varying degrees of limb ischemia, with disease duration ranging from 1 week to 3 years. The main symptoms included markedly cooler lower-extremity skin temperature, pale and cyanotic, intermittent claudication (10 cases), resting pain (31 cases), distal limb mild ischemic ulcer (14 cases), and tissue ischemic necrosis and gangrene (5 cases). All cases were in stages 3–6 of the Rutherford classification. Almost half (28 patients, 47%) had a significant improvement in their affected limbs and more than half (32 cases, 53%) had a moderate improvement in clinical symptoms after the intervention. After surgery, lumen stenosis decreased and ankle brachial index (ABI) increased significantly ($P<0.05$).

Conclusions: The TurboHawk plaque circumcision system is a feasible and effective method for the treatment of SFA with the advantages of less trauma and better safety, and shows a significant curative effect in a short period.

MeSH Keywords: Intermittent Claudication • Lower Extremity • Peripheral Arterial Disease • Plaque, Atherosclerotic

Full-text PDF: https://www.medscimonit.com/abstract/index/idArt/912142

Indexed in: [Current Contents/Clinical Medicine] [SCI Expanded] [ISI Alerting System] [ISI Journals Master List] [Index Medicus/MEDLINE] [EMBASE/Excerpta Medica] [Chemical Abstracts/CAS]

Background

Superficial femoral atherosclerosis (SFA) is a common disease observed by vascular surgery specialists, with an incidence rate of 10% in the general population. The incidence rate shows an upward trend with increasing age and reaches a proportion of almost 20% among people 70 years or older. Due to the serious complications of SFA, the mortality rate is high [1]. With the development and advances in interventional technology, minimally invasive endovascular therapy is being used widely in clinical treatments, predominantly due to less trauma and faster recovery. However, SFA is often subjected to various types of pressure such as twisting, compression, and stretching, causing easy fracture of the implanted stents. In addition, mechanically squeezing the arterial patch sites and making it adherent to the balloon expansion may cause embolism by peeling off plaque in distal arterioles. If the pressure is too high, the blood vessel walls can be damaged, leading to blood vessel intimal hyperplasia and postoperative blood vessel narrowing. This has long been a major problem in vascular surgery. In 2007, the TransAtlantic InterSociety Consensus (TASC) revised the guidelines for the diagnosis and treatment of femoropopliteal arterial lesions, recommending vascular bypass surgery as the first choice in the treatments of TASC-II C and D femoropopliteal artery disease [2]. However, due to the development of endovascular techniques and interventional devices, vascular surgeons in China and other parts of the world tried to treat TASCII-C and D lesions with endovascular intervention technology, with successful outcomes. Considering the clinically intractable problems such as the low patency of long-term vascular grafts, in-stent restenosis, and occurrence of rupture after percutaneous balloon angioplasty and stenting, plaque atherectomy treatment can effectively remove the arterial wall plaque as well as improve the resection of the vascular stenosis by reshaping the lumen and also alleviates the ischemia of the limb. Some reports about the patency rate of the proximal to long-term vessels have also indicated favorable clinical efficacy of plaque resection. This study retrospectively analyzed 60 SFA patients treated by endovascular rotation of the superficial femoral artery in Xinjiang Uygur Autonomous Region People's Hospital from January 2016 to December 2017, and evaluated the efficacy and utility.

Material and Methods

Research subjects

In this study, we reviewed the medical records of PAD patients admitted from January 2016 to December 2017 in the Department of Vascular Surgery of the People's Hospital of Xinjiang Uygur Autonomous Region, China. Among these, there were 50 male and 10 female patients. All cases had persistent and intractable resting limb pain before surgery, which could not be relieved by anticoagulation, vasodilation, and other conservative treatments. For inclusion criteria, the selection of study cases was guided by the guidelines for the treatment of lower-extremity arteriosclerosis obliterans (Vascular Surgery Group, Chinese Medical Association Surgical Branch, 2008 edition), which were diagnosed by femoral artery blood vessel ultrasonography or lower limb CT angiography (CTA) or digital subtraction angiography (DSA) examination. The diagnosis for inclusion was TASC-II grade C/D type of the long segment obstruction of the superficial artery with obvious symptoms such as low skin temperature of the lower extremities, pale or cyanotic skin, as well as serious resting limb pain. Ulcers and gangrene of varying degrees were observed in ssome patients. Exclusion criteria were: cases with TASC-II grade A/B; stenosis and occlusion in all 3 branches below the knee examined by CTA and (or) vascular Doppler color ultrasound; cases without feasible distal outlets; and cases having severe heart, lung, kidney dysfunction, limb necrosis, and uncontrollable infection. All the selected patients received long-term oral administration of aspirin (100 mg/time, 1 time/day) and clopidogrel (75 mg/time, 1 time/day. Patients also received anticoagulation, lipid regulation, antihypertensive, and expansive vascular drug treatment, depending on their conditions. The ankle brachial index (ABI) was reviewed 3 days after surgery. Design and implementation of the experiments were audited and approved by the Ethics Committee of the First Affiliated Hospital of Xinjiang Medical University (approval number: IACUC-20130217777).

ABI measurement method: The ratio of the highest segmental systolic blood pressure to the highest systolic blood pressure of the brachial artery.

Puncture access and methods

Retrograde puncture through the contralateral femoral artery was performed on 56 patients with multiple stenosis of the superficial femoral artery and the remaining 4 cases with stenosis and obstruction in mid- and distal segments of the superficial femoral artery, especially in the popliteal artery, were punctured through the ipsilateral femoral artery. Subsequently, the TurboHawk plaque circumcision system (Model: FG 02550, EV3) procedure was performed. Patients were given heparin and the 4F single-contrast radiograph catheter combined with the supersliding guidewire passed through the lesion, and an arterial protection umbrella was placed at the distal end of the popliteal artery. The catheter was delivered to the site of arterial disease and the lesions were removed in different directions. The stripped atheroma or calcified plaque was taken out. After removing the resection system, angiography was performed. The removed plaque or hyperplastic inner membrane was removed from the protective umbrella at the tip of the

Indexed in: [Current Contents/Clinical Medicine] [SCI Expanded] [ISI Alerting System] [ISI Journals Master List] [Index Medicus/MEDLINE] [EMBASE/Excerpta Medica] [Chemical Abstracts/CAS]

Table 1. Rutherford clinical efficacy evaluation criteria after surgery.

Grade	Clinical manifestations
Significant improvement	Clinical symptoms disappeared or were improved significantly and postoperative ABI value is greater than 0.9
Moderate improvement	Clinical symptoms presented at least one grade of improvement and ABI values was increased by at least 0.1
Slight improvement	No clinical grade change was observed and postoperative ABI value is increased by 0.1 or more; the increase in Postoperative ABI value is less than 0.1 with clinical grade improvement
No improvement	No clinical grade change, and the increase in postoperative ABI value is less than 0.1
Slight deterioration	No clinical grade change, the decrease of postoperative ABI value is more than 0.1; the clinical grade declined, and the ABI value is less than 0.1
Moderate deterioration	Clinical grading is deteriorated more than 1 grade or have unexpected minor amputees
Severe deterioration	Clinical grading is deteriorated more than 1 grade or have unexpected large amputees

catheter. The vascular lumen morphology and blood flow velocity of the treated segment were observed by contrast and stopped when the residual stenosis was <30%. After peeling, percutaneous balloon dilatation was performed if the residual stenosis rate in lesions was >30%. If the remaining stenosis rate was over 50% after percutaneous balloon dilatation, the case required stent implantation. Criteria to stop further plaque resection were residual stenosis below 30%, residual stenosis over 30% after multiple resections, or developing serious complications such as arterial wall penetration. The recessed catheter was withdrawn after reaching the stopping criteria, and the puncture point was closed by a vascular closure system.

Efficacy evaluation

In the criteria for a successful operation, adequate blood flow was confirmed by angiography after surgery and residual vascular stenosis was less than 30% without arterial dissection. The index for efficacy evaluation was: (1) ABI value comparing the ABI value before and after surgery; (2) Postoperative clinical efficacy assessment, with the main criteria for judging the postoperative clinical efficacy being improvements in resting limb pain, intermittent claudication, skin temperature, arterial pulse, and ulcer defect, and the Rutherford clinical efficacy evaluation was performed according to the Technical Committee of Interventional Radiological Evaluation graded as significant improvement, moderate improvement, slight improvement, no improvement, slight deterioration, moderate deterioration, and severe deterioration [3]. Details are listed in Table 1. (3) The levels of arterial stenosis of the affected limb before and after surgery were evaluated and classified based on international diagnostic criteria: Grade 1, no or slight stenosis (≤25%); Grade 2, mild stenosis (26% to 50%); Grade 3, moderate stenosis (51% to 75%); and Grade 4, severe stenosis or occlusion (>75%).

Table 2. General clinical information of patients.

Information	Case number (n=60)	
Male	50	(83.33%)
Female	10	(16.67%)
Long-term smoking history (10/day)	22	(36.67%)
Hypertension	36	(60.00%)
Diabetes	30	(50.00%)
Hyperlipidemia	27	(45.00%)
Coronary heart disease	23	(38.33%)

Statistical analysis

SPSS 11.5 statistical software was used to perform the paired *t* test to compare the degree of DSA stenosis and ABI values before and after surgery. P values of <0.05 were considered statistically significant for group differences.

Results

General information of patients

In the total sample of 60 patients, there were 50 males and 10 females, with an average age of 65(±4.5) years (range, 47 to 70 years). General information of patients selected for the study is shown in Table 2.

Clinical symptoms of the patients

Selected patients showed different degrees of limb ischemia, with a duration of 1 week to 3 years. The main symptoms were cold extremities, numbness, skin hair loss, pale or

Indexed in: [Current Contents/Clinical Medicine] [SCI Expanded] [ISI Alerting System] [ISI Journals Master List] [Index Medicus/MEDLINE] [EMBASE/Excerpta Medica] [Chemical Abstracts/CAS]

Table 3. Clinical symptoms of the patients.

Grade	Rutherford Classification	Case numbers () N (%)
Asymptomatic, no significant hemodynamic changes	0	0
Slightly limp	1	0
Moderately limp	2	0
Severely limp	3	10 (16.67%)
Rest pain	4	31 (51.67%)
Mild tissue loss (mild ulcers)	5	14 (23.3%)
Severe tissue loss (ulcer or gangrene)	6	5 (8.33%)

dark skin, intermittent claudication (10 cases), resting pain (31 cases), distal limb mild ischemic ulcer (14 cases), and tissue ischemic necrosis and gangrene (5 cases). All cases met the Rutherford classification 3-6. The clinical symptoms of patients are shown in Table 3.

Postoperative improvement on clinical symptoms

On the third day after surgery, the clinical symptoms of 60 patients (60 limbs) were evaluated according to the degrees of improvements in postoperative resting pain, intermittent claudication, skin temperature, skin color, arterial pulse, and ulcer defect. Almost half (46.67%, 28/60) of the cases showed significant improvement, while most of the cases (53.33%, 32/60) had moderate improvement.

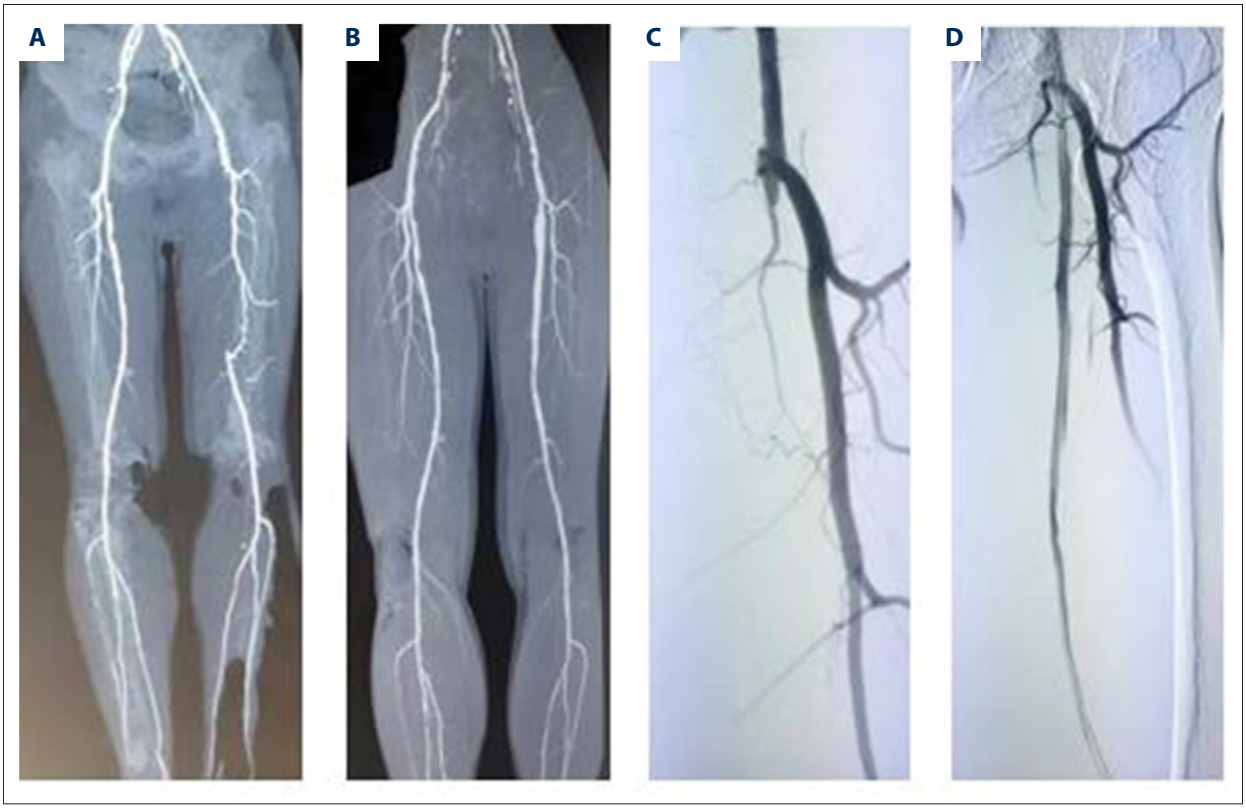

Figure 1. CTA and angiographic results of patients with superficial femoral artery stenosis before and after surgery. Lower-extremity arterial CTA before (**A**) and after surgery (**B**); Lower-extremity arteriography before (**C**) and after surgery (**D**).

Table 4. Comparison of DSA lumen stenosis and ABI before and after excision.

	Clinical efficacy		t	p
	Before	After		
DSA lumen stenosis	0.9±0.08	0.26±0.05*	20	0.015
ABI	0.25±0.13	0.85±0.11*	18	0.023

Indexed in: [Current Contents/Clinical Medicine] [SCI Expanded] [ISI Alerting System] [ISI Journals Master List] [Index Medicus/MEDLINE] [EMBASE/Excerpta Medica] [Chemical Abstracts/CAS]

Comparison of the degree of DSA lumen stenosis and ABI values in patients before and after surgery

The *t* test was used to compare the DSA lumen stenosis and ABI values in patients before and after the procedure. After surgery, the degree of stenosis significantly decreased (0.9±0.08 *vs.* 0.26±0.05) (P<0.05) and ABI values were significantly increased (0.25±0.13 *vs.* 0.85±0.11) (P>0.05) (Figure 1, Table 4).

Discussion

In this study, more than one-third of the cases had chronic smoking history, hypertension, diabetes, hyperlipidemia, and coronary heart disease. Studies have shown that the occurrence of arteriosclerosis is related to age; the older the patient, the greater the severity of arteriosclerosis [4–7]. Smoking is an independent risk factor for arteriosclerosis. It has been confirmed that tobacco contains thousands of chemicals that can cause blood hypercoagulability and accelerate the development of arteriosclerosis obliterans. Increases in levels of cholesterol, low-density lipoproteins, and triglycerides in the blood can also accelerate the development of arteriosclerosis. Diabetes can induce extensive and severe atherosclerosis and increase the amputation rate of arteriosclerosis by 4 to 7 times. Most (50% to 70%) of the patients with arteriosclerosis had hypertension, which can damage the arterial wall, leading to arterial stenosis and hardening. All patients selected in this study were in Rutherford classification grades 3–6, most of whom had a long history of smoking, hypertension, diabetes, coronary heart disease, or hyperlipidemia. We found that 46.67% of patients had significantly improved symptoms after the atherectomy treatment and 53.33% of patients were moderately improved, indicating the effectiveness of atherectomy treatment. All the cases that underwent endovascular intervention in this group were visually examined before surgery and were consistent with TASC-II C/D type superficial femoral artery disease. The ABI values before surgery were 0.25±0.13 since most patients had insufficient knowledge of arteriosclerosis obliterans in the lower extremities and patients with intermittent claudication never sought medical treatment until they experienced severe intermittent claudication, resting pain, or limb ulcers. This increased therapy difficulty and risk. ABI examination can assist in examining the severity of ischemic limbs in patients with SFA and it can act as an index to evaluate the improvement of pre- and postoperative ischemia. The ABI values were significantly improved after successful surgery in treated cases in this study and the improvement level was consistent with the degree of vascular stenosis.

According to the clinical case study of SFA in our hospital, 60 patients had recanalization of the diseased blood vessels after plaque removal. The ABI values were significantly improved. Our results show that the TurboHawk plaque removal technology is a practical feasible, and effective method to treat SFA, with the advantages of less trauma, high safety, and good curative effect. However, the indications for use of the TurboHawk technique are narrow and mainly apply to lesions of the iliac artery, superficial femoral artery, and popliteal artery.

The pathological basis of SFA is atherosclerosis, which is characterized by abnormal deposition of fibrous stroma, lipids, and tissue fragments on the wall of blood vessels, resulting in abnormal proliferation of the intima and/or media of the artery, thickening and unevenness of the blood vessel wall, stenosis, and other diseases. SFA often occurs in large and medium-sized arteries such as the abdominal aorta, carotid artery, iliac artery, femoral artery, and popliteal artery. Arteriosclerotic occlusive lesions may occur in multiple sites and multiple segments. About 30% of SFA occurs in the main iliac artery and 70% occurs in the femoropopliteal and lower knee arteries. Recent clinical data show that the lower-extremity arterial stenosis, occlusion lesions, and other related clinical symptoms of SFA patients are irreversible without clinical intervention [8,9], and about 25% of the patients with intermittent claudication develop severe limb ischemia resulting in resting pain, limb ulcers, and gangrene. According to the results from published research, approximately 7% to 9% of patients diagnosed with intermittent claudication will experience aggravated symptoms within 1 year, and 1% to 3.3% of SFA patients with intermittent claudication need amputation within 5 years [10]. The amputation rate of SFA patients with diabetes is relatively higher. Prognostic ABI suggests that SFA patients with ABI <0.5 have higher risk of amputation.

As a new endovascular technology, the TurboHawk plaque circumcision system is employed to perform intraluminal interventional therapy on the affected part of the patient by removing the plaque without implanting foreign matter. This technology is especially useful to treat blood vessels of the proximal femoral arteries, such as the femoropopliteal artery, which is a restricted area of stent placement. Given that this site is flexible due to frequent activities and the implanted stent is likely to bend or break, plaque atherectomy can directly achieve revascularization without leaving foreign matter in the vessel so as to avoid stent thrombosis, treat complex lesions, and remedy the technical defects of percutaneous balloon and stent implantation. In this study, 2 cases were diagnosed with severe stenosis or occlusion of the femoropopliteal transarticular joint. The plaque atherectomy technology can be applied for cross-joint rotary cutting to significantly improve the symptoms of the affected limb. For multiple lesions or long lesions, the atherectomy system can be used for several lesions with multiple vascular stenosis at the same time and with multiple treatment cycles avoiding the need for multiple stents and balloons. From the patients' perspective, the

Indexed in: [Current Contents/Clinical Medicine] [SCI Expanded] [ISI Alerting System] [ISI Journals Master List] [Index Medicus/MEDLINE] [EMBASE/Excerpta Medica] [Chemical Abstracts/CAS]

technology can not only avoid implanting foreign matter and improve treatment efficiency, it also can decrease the overall cost compared with traditional treatments. In the treatment of arterial stenosis and occlusive lesions of the lower extremity, use of the TurboHawk system needs further evaluation. Its success rate is high in the treatment of various complex arterial diseases of the lower extremities and also in the removal of various types of plaques. After removing plaques, there is a reduced need for stents and the plaque removal can be repeated with high reliability. Thus, the TurboHawk system can achieve a patency rate similar to that of stent implantation and has the potential to be a substitute for conventional stent and balloon dilation technologies.

The limitation of this study is that there was no long-term follow-up study on vascular ultrasound or CTA examination of SFA. Therefore, the long-term efficacy of TurboHawk plaque circumcision technology needs to be evaluated by following up a large number of postoperative clinical cases for a longer period.

Conclusions

The TurboHawk plaque circumcision system is a feasible and effective method for the treatment of SFA, with the advantages of less trauma and better safety, and it shows a quick and satisfactory curative effect.

Conflict of interest

None.

References:

1. Liu C: [Lower extremity arteriosclerosis obstructive disease treatment guidelines.] Chinese Journal of Practical Surgery, 2008; 28: 923–24 [in Chinese]
2. Norgren L, Hiatt WR, Dormandy JA et al: Inter-society consensus for the management of peripheral arterial disease (TASC II). J Vasc Surg, 2007; 45(Suppl. S): S5–67
3. Rutherford RB, Baker DJ, Ernst C et al: Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surg, 2001; 33(4): 802–5
4. Olin JW, Sealove BA: Peripheral disease: Current insight into the disease and its diagnosis and treatment. Mayo Clinic Proc, 2010; 85(7): 678–92
5. Jaff MR, White CJ, Hiatt WR et al: An update on methods for revascularization and expansion of the TASC lesion classification to include below-the-knee arteries: A supplement to the inter-society consensus for the management of peripheral arterial disease(TASC II): The TASC Steering Comittee. Ann Vasc Dis, 2015; 8(4): 343–57
6. Alzamora MT, Forés R, Baenadíez JM et al: The peripheral arterial disease study (PERART/ARTPER): Prevalence and risk factors in the general population. BMC Public Health, 2010; 10: 38
7. Di Minno G, Spadarella G, Cafaro G et al: Systematic reviews and meta-analyses for more profitable strategies in peripheral artery disease. Ann Med, 2014; 46(7): 475–89
8. Norgren L, Hiatt WR, Dormandy JA et al: TASC II Working Group. Inter-society consensus for the management of peripheral arterial disease (TASCII). J Vasc Surg, 2007; 45(1): SSA-S67A
9. Cacoub PP, Bhatt DL, Steg PG et al: Patients with peripheral disease in the CHARISMA trial. Eur Heart J, 2009; 30(2): 192–201
10. Hirsch AT, Haskal ZJ, Hertzer NR et al: ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic). Circulation, 2006; 113(11): e463–654

Indexed in: [Current Contents/Clinical Medicine] [SCI Expanded] [ISI Alerting System] [ISI Journals Master List] [Index Medicus/MEDLINE] [EMBASE/Excerpta Medica] [Chemical Abstracts/CAS]