The Cost Effectiveness of Digital Subtraction Angiography in the Diagnosis of Cerebrovascular Disease

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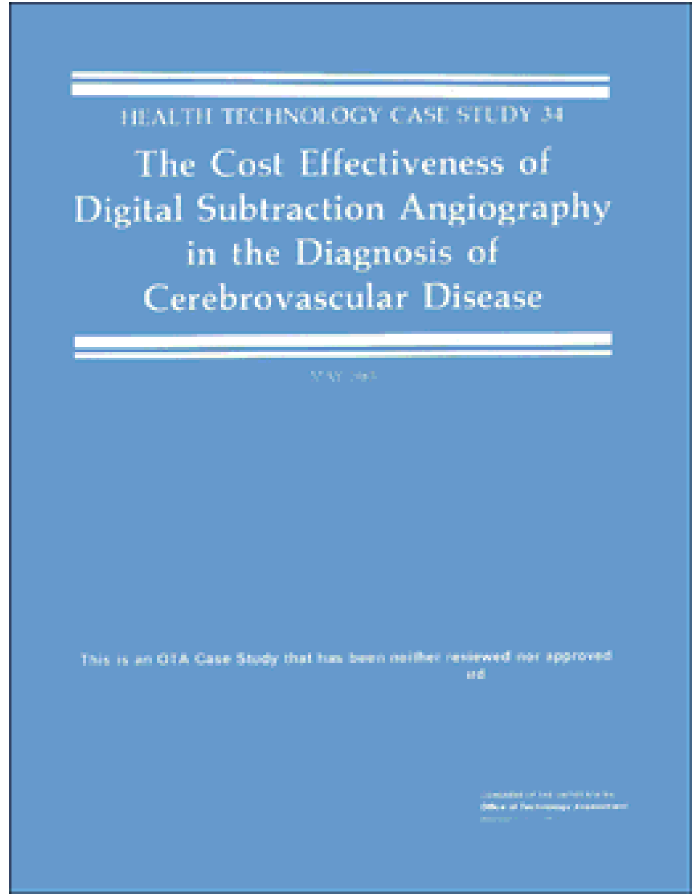

HEALTH TECHNOLOGY CASE STUDY 34

The Cost Effectiveness of Digital Subtraction Angiography in the Diagnosis of Cerebrovascular Disease

MAY 1985

This case study was performed as part of OTA's Assessment of

Medical Technology and Costs of the Medicare Program

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Preface

The Cost Effectiveness of Digital Subtraction Angiography in the Diagnosis of Cerebrovascular Disease is Case Study 34 in OTA's Health Technology Case Study *Series.* This case study has been prepared in connection with OTA's project on *Medical Technology and Costs of the Medicare Program*, which was requested by the House Committee on Energy and Commerce and its Subcommittee on Health and the Environment and the Senate Committee on Finance, Subcommittee on Health. A listing of other case studies in the series is included at the end of this preface.

OTA case studies are designed to fulfill two functions. The primary purpose is to provide OTA with specific information that can be used in forming general conclusions regarding broader policy issues, The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall project on *The Implications of Cost-Effectiveness Analysis of Medical Technology.* By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. The design and the funding levels of most of the case studies are such that they should be read primarily in the context of the associated overall OTA projects. Nevertheless, in many instances, the case studies do represent extensive reviews of the literature on the efficacy, safety, and costs of the specific technologies and as such can stand on their own as a useful contribution to the field.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panel to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e. g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies are either prepared by OTA staff, commissioned by OTA and performed under contract by experts (generally in academia), or written by OTA staff on the basis of contractors' papers.

OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated project. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are sent by OTA to numerous experts for review and comment. Each case is seen by at least 30 reviewers, and sometimes by 80 or more outside reviewers. These individuals may be from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists, sociologists, decision analysts, biologists, and so forth, as appropriate, also review the cases.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA's concern with each case study's scientific quality and objectivity. During the various stages of the review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize divergent points of view.

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[b] Original publication numbers appear in parentheses.

[c] The first 17 cases in the series were 17 separately issued cases in *Background Paper #2: Case Studies of Medical Technologies,* prepared in conjunction with OTA's August 1980 report *The implications of Cost-Effectiveness Analysis of Medical Technology.*

[d] Background paper #3 t. The *Implications of Cost-Effectiveness Analysis of Medical Technology,*

[e] Background Paper #5 to *The Implications of Cost-Effectiveness Analysis of Medical Technology.*

[f] Background paper #1 to OTA's May 1982 report *Technology and Handicapped People.*

[g] Background Paper #2 to *Technology and Handicapped People.*

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1.

Introduction and Summary

Introduction and Summary

BACKGROUND

Digital subtraction angiography (DSA) is a new, and rapidly developing, technology in the field of diagnostic radiology. DSA is one of several computer-assisted radiologic tools for diagnosing conditions associated with the internal structure of blood vessels. The technique usually involves injecting contrast medium into the veins and measuring over time the changing concentration of contrast medium passing through the vascular structures of interest.[1] Through the use of a computer, the images before the contrast injection are "subtracted" from those after injection to give a numerical representation of the arterial structure under study. This relatively noninvasive[2] technique can be performed on an outpatient basis with very low risk of morbidity compared to conventional and (invasive) techniques such as arteriography.[3]

DSA has been shown to have important clinical uses in diagnostic studies of the carotid, renal, intracranial, and peripheral arteries, the aorta and in pulmonary studies. There are reasonable expectations that this procedure will develop to the point where it will have wide applicability in the diagnosis of coronary artery disease in the next several years.

Since 1980, when prototype commercial systems were introduced in the United States, improvements in the design and capacity of available DSA equipment have established the clinical efficacy and effectiveness of this procedure for certain purposes. These improvements have also raised the possibility of applications in dozens of additional areas of diagnostic radiology.

The rapidity with which this technology has been developed and diffused throughout the medical care system in the United States raises important public policy questions about the cost implications of the procedure, especially its relative cost effectiveness when compared to other diagnostic radiology technologies it may replace. It is likely that the fact that this technique is relatively noninvasive will increase its importance and frequency of use as a preliminary examination procedure for the diagnosis of certain types of diseases. For these reasons, it is important to know under what conditions it may be expected to yield cost savings over currently available technologies.

In this case study, a single category of clinical problems where DSA is in use on a broad scale—cerebrovascular disease—is selected as the context within which the cost effectiveness of DSA is explored.[4] This case study does not present new primary data from a prospective study of DSA use in the diagnosis and management of cerebrovascular disease. Rather, the data derived from the very few studies that already exist are used to test certain assumptions about the cost effectiveness of this new technology compared to conventional arteriography. Furthermore, because the data available to explore these questions are not precisely what would be required to conduct the appropriate test, the calculations presented in this case study will not be completely satisfactory to those with expertise in cost-effectiveness analysis.

The intention of this study, however, is to present a careful description of the current and potential application of DSA within the area of diag-

'With respect to cerebrovascular diagnostic studies, both intravenous and intra-arterial DSA have been employed. However, in this case study the notation "DSA" is used to signify intravenous applications only. The focus is limited to intravenous DSA, because it is the method employed in the evaluation of the extracranial circulation, especially the carotid arteries, in most cases as of October 1983, when this case study was submitted to OTA for final editing.

2A relatively noninvasive technique is a technique that involves puncturing or catheterizing a vein, which carries considerably lower morbidity than techniques that involve puncturing or catheterizing an artery, such as conventional arteriography.

'See the glossary of terms for definitions of selected medical terms (app. B).

4A majority of the DSA procedures performed are examinations of the carotid arteries. The diagnosis of carotid artery disease (a common manifestation of cerebrovascular disease) is important since it is a major cause of stroke.

nostic radiology concerned with cerebrovascular disease and to suggest the implications of the technology for patterns of clinical practice and patient care costs under different assumptions. The diagnosis and treatment of stroke, as well as the problems of identifying patients at high risk for stroke, represent clinical activities with broad implications for American health care resource allocation. Because of the importance of stroke as a leading cause of death, and because of the high cost of acute medical care, rehabilitation, and long-term care requirements for stroke victims, the investigation of new techniques for clinical management of this set of problems merits serious attention by health care providers and policymakers alike.

SUMMARY AND CONCLUSIONS

DSA is clearly a major technological advance in the field of diagnostic imaging radiography. Further refinements of the basic technology in the next several years are expected to enhance its present utility in the diagnosis of cerebrovascular disease, a major cause of death in the United States.

There are several technologies of varying degrees of invasiveness already in widespread use in the diagnosis and treatment of cerebrovascular disease. DSA presents a new alternative to conventional arteriography for establishing the presence or absence of carotid artery stenosis (narrowing). Although the technique is more sensitive and specific than some noninvasive tests (i. e., ultrasonography) for the diagnosis of arterial stenosis, and more effective than real-time ultrasound for the diagnosis of ulcers, DSA remains somewhat less accurate than conventional arteriography, especially for the evaluation of ulcerative lesions. However, as technological improvements take place, the speed and spatial resolution of DSA images of the cerebral vascular system are expected to eventually approach the accuracy of arteriography. Physician acceptance of DSA as a substitute for arteriography is expected to occur rapidly and to reach a level beyond 80 percent replacement (64), except perhaps in some teaching medical centers. In these centers, diagnostic evaluations are often duplicative.

For those patients who are now being examined by arteriography, it is relatively simple to formulate a reasonable estimate of the number who may subsequently receive only a DSA examination. It is more difficult to estimate the number of patients at risk of cerebrovascular disease in the general population who might be screened through the use of DSA, but who would not be considered candidates for arteriography or surgery.

This case study outlines a number of assumptions about the way in which DSA might be integrated with current patterns of practice in primary care and neurological specialties. In the United States, *87* percent of the patients served by neurologists are referred by other (usually primary care) physicians. The management of patients with a clinical diagnosis of transient ischemic attack (TIA), one of the most common clinical indicators of cerebrovascular disease and possibly a forthcoming stroke, is determined by the physician who has first contact with the patient following such an event. Because a physician will almost never witness a TIA, most TIAs are diagnosed on the basis of the history and physical examination of the patient some time after the TIA has occurred. Since TIAs are presumed signs of a possible forthcoming stroke, they usually precipitate the patient's contact with the medical care provider.

There is considerable ambiguity and confusion among physicians (in neurology and in primary care specialties) over the most appropriate management strategies for patients with a history of TIAs (105). Moreover, there is a significant risk that some patients will be misdiagnosed as having had a TIA. It is important to recognize that TIA is a clinical diagnosis; it is not a diagnosis formulated on the basis of a radiographic test or procedure. When arterial stenosis is discovered with a DSA exam, the physician may conclude that a patient's dizzy spell, temporary numbness in a hand or foot, or an unusual ocular problem was a TIA. The problem with this pattern of decisionmaking and medical practice is that asymptomatic atherosclerosis is prevalent in the general population. A temporary neurological problem and arterial stenosis often coexist, and yet may be totally unrelated to one another. Causality is established through clinical judgment alone.

At present, conventional arteriography is the most accurate technology for testing the hypothesis of carotid artery stenosis. Because of the risk of morbidity and the special circumstances under which this procedure is done (usually requiring hospitalization of the patient), there are many factors operating to constrain the overuse of conventional arteriography. The introduction of DSA makes available a less costly, relatively low risk, highly accurate, and useful source of the same diagnostic information now available through arteriography.

The introduction of any new medical technology is usually followed by a period of experimentation during which individual physicians explore the utility and accuracy of the new technology, while continuing to use those techniques with which they are familiar, Such a pattern may be expected with DSA. In the near future, DSA may be expected to duplicate or supplement the diagnostic information provided by other noninvasive tests, and arteriography, the test currently used in the diagnosis of arterial stenosis. Later, the other noninvasive tests may be expected to be used less frequently. As the accuracy of DSA becomes accepted as a sufficient basis for surgical decisionmaking, the utilization of conventional arteriography for the diagnosis of carotid artery stenosis may be expected to significantly decline as well.

An important variable in determining the costs of DSA is the level of use of each DSA facility (whether in a hospital or non-hospital setting)– that is, its operational efficiency. Moreover, it is necessary to measure the subsequent use of conventional arteriography and other imaging facilities. For example, if the use of arteriography declines substantially, but the equipment, facilities, and personnel are maintained, then the costs of DSA will only add to the total costs of diagnostic imaging services taken as a whole. Similarly, if DSA equipment diffuses widely, and is not utilized efficiently, then the high fixed costs of the technology will exceed any expected benefits.

As with all types of technology, there is an efficient level of use that includes regionalization and the sharing of facilities. However, there are important features of many diagnostic technologies, like DSA and arteriography, that present special problems with respect to their cost impact. Unlike therapeutic technologies, which are directed toward known manifestations of disease, diagnostic technologies have been developed to aid in the search for clinical evidence to define and explain conditions of presently unknown origin. Some of these technologies have been developed for the diagnosis of particular diseases, but later have been found to have wider applications (5). It is the general pattern of clinical use of these technologies (which can entail rather open-ended exploratory uses of a wide variety of technologies), combined with their technical sophistication and accessibility, that determines their eventual cost effectiveness.

The estimation of the cost effectiveness of DSA must be undertaken in a broad context. In this cost-effectiveness analysis, concern is with the measurement of the incremental cost of a unit of benefit under average conditions of use. In the field of medical practice, it is "average conditions of use" that make the estimation of cost effectiveness so problematic.

This case study suggests **that DSA** is likely **to be cost** effective if its pattern of use is a substitute for, rather than a *supplement* **to, conventional arteriography in the diagnosis of carotid artery disease.** Preliminary accuracy and sensitivity data for DSA suggest the prospects for this pattern of acceptance and use are rather high.

However, under average conditions of use, **the availability of DSA is likely to result in a much larger number of patients evaluated for possible carotid artery disease.** In fact, seven times the number of patients now receiving conventional arteriography would, it is estimated, receive DSA examinations in connection with the diagnosis of carotid artery disease, and it is likely that many of these patients will also receive more than a single DSA exam during the same episode of care.

Because DSA offers an alternative to conventional arteriography that has a lower risk of morbidity and can be done on an outpatient basis, it can be expected that many patients (once they know about its availability) will **want the procedure performed.** These patients and their families are likely to value the procedure highly for its ability to reduce the worry and uncertainty associated with certain diagnostic conditions.

Given the demonstrated high quality, sensitivity and specificity of DSA images for the study of carotid artery disease, the relatively low risk of morbidity and the lack of need for hospitalization, it is likely that an increasing number of patients will have DSA studies ordered by their primary care physicians prior to consultation with a necrologic specialist. Whereas conventional arteriography was almost never performed without benefit of a necrologic opinion, DSA will frequently become part of the primary physician's initial evaluation protocol. Since DSA results are of such high quality and presumably easier to interpret, it is likely that necrologic consultants will be bypassed more frequently by primary physicians in their decisions to refer patients for surgical therapy when carotid artery disease is diagnosed. **The use of DSA by primary care physicians in diagnosing carotid artery disease is likely to increase the volume of unnecessary surgical therapy for patients undergoing DSA examinations,** These trends warrant careful attention over the next several years.

ORGANIZATION OF THE CASE STUDY

Chapter 2 presents an overview of cerebrovascular disease generally, and stroke specifically, as clinical problems. After discussing the direct and indirect costs of stroke, the theory of preventive therapy is introduced, using TIAs as an example. Numbness of a foot or a hand, blindness in one eye or double vision, are all "early warning" signals of stroke and should lead to further neurological examination. Chapter 2 concludes that new medical techniques are needed to help in the early diagnosis of stroke.

Chapter 3 provides an indepth look at the technology, DSA. It describes the development, growth and operation of DSA and compares DSA to arteriography. Efficacy and safety are highlighted as two explicit advantages of DSA. The evaluation of aortic arch abnormalities, aortic coarctation, and vascular bypass grafts are some of the clinical applications of DSA discussed in chapter 3.

Chapter 4 looks at the costs of DSA. There are many costs involved in acquiring a new technology. Chapter 4 initially analyzes two main types of costs: capital costs (computers, X-ray equipment and facilities) and operating costs (personnel and supplies). Next, direct implicit and intangible costs, costs related to diffusion, and social costs are all discussed.

The purpose of chapter 5 is to study the cost effectiveness of DSA. "Cost per procedure" and "cost per lesion" are compared with the same data found for arteriography. Conclusions are then made concerning the increase in future use of DSA in the diagnosis of cerebrovascular disease.

2.
Stroke as a Clinical Problem

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Stroke as a Clinical Problem

THE EXTENT OF THE PROBLEM

Stroke (completed cerebral infarction) is the third most common cause of death in the United States. In addition to its importance as a cause of mortality, stroke and associated disorders affecting the central nervous system account for a significant burden of illness treated by the medical care system. A major cause of stroke is carotid artery disease (a common manifestation of cerebrovascular disease), which is often diagnosed through digital subtraction angiography (DSA) examination.

Several studies have reported that the incidence of stroke has declined over the last several years in the United States *(40,41,79,95)*. Future projections of the need for diagnostic or therapeutic technologies for treating stroke need to take these trends into account. However, the age-specific death rates from these conditions, taken as a whole, have continued to be significantly higher for persons beyond the age of 55 than for younger persons (see table 2-1). Likewise, the volume of diagnostic procedures used in the care of persons suspected of having cerebrovascular disease is higher among those older age groups.

Table 2-1.—Death Rates for Cerebrovascular Diseases by Age Groups, United States, 1980 (number of deaths per 100,000 resident population)

Total, all ages, adjusted	41.5
Total, all ages, crude	76.6
Under 1 year	3.8
1-14 years	0.3
15-24 years	1.2
25-34 years	2.7
35-44 years	8.6
45-54 years	26,1
55-64 years	67.8
65-74 years	222.4
75-84 years	834.7
85 years and older	2,094.0

SOURCE: U.S Department of Health and Human Services, National Center for Health Statistics, *Health, United States, 1982*, table 19, p 67

Cerebrovascular disease in general has been estimated to have an annual incidence of 195 per 100,000 population per year (62). The Office of Graduate Medical Education of the U.S. Department of Health and Human Services (DHHS) convened a special panel of experts to consider the number of neurological care physicians needed to care for this volume of illness on an annual basis *(42)*. This panel concluded that *967* hours of neurological specialty care would be required annually per 100,000 population. This level of medical specialty care would also be provided by types of health personnel other than neurologists—physiatrists (specialists in rehabilitation medicine), physical therapists, speech pathologists, occupational therapists, and others *(42)*.

Cerebrovascular disease occupies a significant portion of the practice of primary care physicians as well. Although stroke is not among the top *25* outpatient diagnostic encounters recorded by family physicians, cerebrovascular disease (ICD-9 Code 336: "Acute, but ill-defined, cerebrovascular disease") is the second most common diagnosis for hospital patients of office-based general practice and family physicians in the United States (43). It has been estimated that 13 percent of all hospital patients have a primary and/or secondary necrologic diagnosis (113), and that at least 50 percent of these diagnoses are for cerebrovascular disorders *(46)*. This situation reflects the frequency with which stroke patients require long-term institutional care.

The costs of stroke are enormous. In 1975, the direct and indirect costs of stroke were estimated to be approximately $9.5 billion annually *(103)*. Because many patients with a stroke have losses of intellect and locomotion that require long-term institutionalization, prevention of stroke is a major health care objective at this time.

TREATMENT OF STROKE

Once a completed stroke has occurred, no known treatment can repair damaged tissue to restore function. Thus, preventive care is essential in the management of patients with cerebrovascular disorders. Since completely effective preventive therapy—the elimination of hypertension and atherosclerosis—is not available at this time, "half-way" preventive therapies are currently employed. These include general medical measures, such as control of hypertension and cardiac arrhythmias, if present, as well as surgical measures, such as endarterectomy (the surgical removal of cholesterol plaque from the inner surfaces of arteries) or cerebral bypass surgery.

The dominant theory underlying preventive therapies for stroke is the identification of stroke-prone individuals who have had transient ischemic attacks (TIAs). A TIA is a reversible episode of cerebrovascular insufficiency that usually lasts less than one hour, and always lasts (by definition) less than *24* hours. These "warning spells" have an incidence of **30 per 100,000 total population per year** *(62)*. The interval between episodic attacks varies from several hours to several months or longer. While the episodes often follow a stereotyped pattern in a given patient, their modes of occurrence vary. It is most commonly thought that they arise from the passage of microemboli of fibrin-platelets or cholesterol into the cerebral circulation.

Although TIAs area form of physiologic disturbance, they are generally grouped on an anatomic basis by clinicians according to the visible symptoms. TIAs include those of carotid artery origin, those of vertebral and basilar artery origin, and those of indeterminate origins. It should be noted that a physician rarely witnesses a TIA and is dependent for clinical diagnosis upon the patient's recall and medical history. The hallmark of a TIA is the localized disturbance of brain function that is associated with specific physiologic symptoms. A hand or foot may become numb, or one side of the body may show such symptoms. One eye may become blind, or partly blind, or double vision (diplopia) may occur. Vertigo and dizziness, disturbances of speech and language, and episodes of leg weakness, are other symptoms that may reflect the occurrence of a TIA.

When a TIA is suspected, a clinician performs a complete physical neurological examination and searches for evidence of heart disease or disease of the carotid / vertebrobasilar systems. A murmur (bruit), audible with a stethoscope, over a major artery in the neck is often **a** sign of turbulent blood flow resulting from atherosclerosis of the underlying vessel. This sign is a good bedside indicator of arterial narrowing (stenosis), but both the presence or absence of a bruit may be misleading. For example, it is known that as a vessel becomes progressively narrowed, the loudness of a bruit may actually diminish, so that when disease is severe and advanced, no bruit maybe audible. Other bedside signs include a difference of greater than 15 percent between the blood pressures recorded in both arms, absence of a palpable branch of the external carotid artery, or the visualization of embolic material in the retinal circulation with an ophthalmoscope.

To supplement bedside testing, a number of "noninvasive" tests (requiring neither arterial nor venous punctures) are currently employed to assess the extracranial circulation. Ophthalmodynamometry enables physicians to record the blood pressure in the ophthalmic artery, the first major intracranial branch of the carotid artery itself. A computed tomography (CT) scan may demonstrate a stroke in the brain. Such a test suggests that the clinical impression of TIA was in error, and that a completed cerebral infarction, or stroke, has actually occurred. Strokes may be ischemic (reduced CT density), hemorrhagic (increased CT density), or both. Thermography may show a diminished temperature over the medial forehead, which may indicate carotid artery disease. Real-time ultrasound (also known as a B-scan, a test which measures the anatomical structure of vessels), and a Doppler device (an imaging device for measuring the flow velocity of blood through the arteries), may provide evidence of the extent of arterial lumen compromise and disturbance of blood flow.

If the physician decides that the patient is at significant risk for a stroke, and that surgery may be indicated to relieve arterial obstruction, an arteriogram (also called an angiogram) has always heretofore been indicated. This is an "invasive" test requiring direct arterial puncture. The overall complication rate of this test is 1.7 to 3.7 percent. The radiation exposure is approximately *20* REM per arteriogram *(24)*. Apart from risk of associated morbidity, the conventional arteriogram is uncomfortable for the patient and usually requires a period of inpatient hospitalization to observe the patient for possible complications arising from the procedure. Most practicing physicians recommend consultation with a neurologist and/or surgeon for the majority of patients who are possible candidates for arteriography to determine: a) that symptoms are due to TIA; b) that a significant risk of stroke remains if no therapy is provided; and c) that surgery is feasible if arteriography demonstrates a significant lesion. Because of careful screening, carotid lesions are usually demonstrated in 75 to *80* percent of all patients having arteriograms following carotid TIAs *(24)*.

For patients who are not surgical candidates (before or after arteriography), anticoagulant drug therapy is usually considered. Another possible therapy includes medications that inhibit platelet aggregation (e.g., aspirin or dipyridamole). Available data suggest that TIAs maybe prevented with long-term medical prophylaxis, especially in men, but the effectiveness of this therapy to prevent strokes due to extracranial vascular disease remains uncertain **(103,104).**

3.

Introduction to Digital Subtraction Angiography

3. Introduction to Digital Subtraction Angiography

Digital subtraction angiography (DSA) is a new radiographic technology used in diagnosing vascular disease. DSA is employed to obtain images of arteries in various parts of the body and is highly effective in contrasting arterial structures with their surrounding bone and soft tissue (3). DSA has proven especially useful in the identification of vascular abnormalities, including occlusions, stenoses, ulcerated plaques, and aneurysms (21,58,107).

The potential importance of DSA in the diagnosis of cerebrovascular disease is suggested by Reuter's (87) observation that as much as one-quarter of the combined volume of neuroradiology and angiography services in some medical centers is now directed toward evaluating carotid and cerebral atherosclerosis, including stroke. The Cooperative Study of Transient Ischemic Attacks (TIAs) (102) reported an average of 5.4 definite TIAs per 100 acute beds per year in the participating medical centers. Estimates of the use of arteriography procedures for these hospitalized patients range between *87* and *97* percent *(23)*. DSA will either supplement or replace a large portion of the arteriographic procedures.

TECHNOLOGICAL DEVELOPMENT

The development of DSA was a result of the research of medical physics groups at the University of Wisconsin, the University of Arizona, and the Kinderklinik in Kiel, West Germany during the early *1970s (21,58,74)*. Fundamental advances in intravenous arteriography, which had been intermittently used since the 1930s, were made possible by the introduction of cesium iodine image intensifiers and advances in digital electronic methods of storing and manipulating information (21). By 1978, the feasibility of DSA for human subjects was demonstrated, and prototype commercial DSA systems were introduced in 1980 at the Universities of Arizona and Wisconsin, the Cleveland Clinic, and South Bay Hospital in Redondo Beach, California *(57,58,74)*. There are now nearly *20* manufacturers of DSA systems and many more in the process of developing new systems **(18).**

The size of the market for DSA equipment is somewhat difficult to estimate because of the uncertain future of demonstrated uses of DSA in coronary angiography. A spokesperson for one of the major manufacturers of DSA equipment shared two projections of investment banking firms for all types of DSA units for the period from 1982 through 1986. One firm projected total sales of 5,160 units, while the other firm projected sales of 9,800 units for the same period. There were estimated to be about 600 DSA units of all types in operational status as of January 1983.

CONTEMPORARY METHODS AND CLINICAL APPLICATIONS

With respect to cerebrovascular diagnostic studies, both intravenous and intra-arterial DSA have been employed. However, in this case study the notation "DSA" is used to signify intravenous applications only. The focus is limited to intravenous DSA, because it is the method employed in the evaluation of the extracranial circulation, especially the carotid arteries, in most cases.[1]

[1] As of October 1983, when this case study was submitted to OTA for final editing.

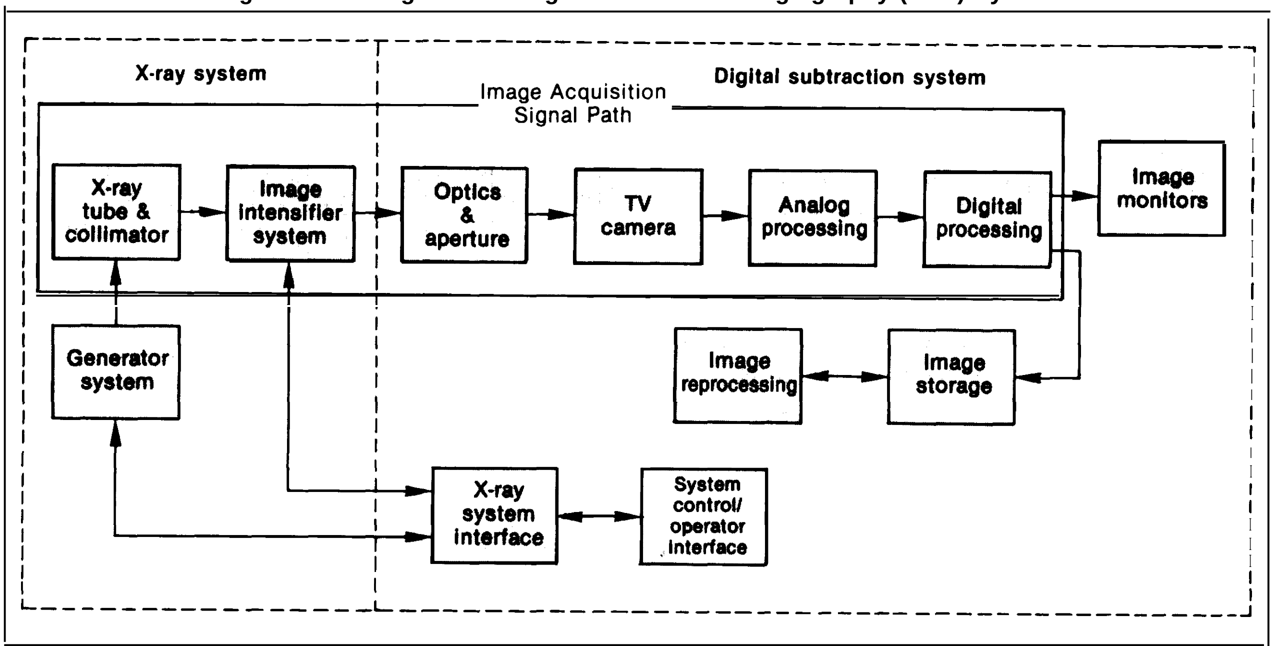
DSA systems work in the manner depicted in figure 3-1 as follows: a contrast medium is injected intravenously; X-ray detection of the contrast medium produces 1 to 30 exposures per second (before and after the injection of contrast medium); and arterial images are converted from analog to digital form and transmitted to a computer-storage complex (55). The digitalized image information makes it possible to "subtract" the precontrast images from those obtained after contrast injection so as to visualize arterial structures without direct arterial puncture and injection. The data can be recalled for viewing on a video screen, and successive images created through subtraction techniques which allow the contrast of the arterial structures to be visualized for the detection of abnormalities.

The purpose of the subtraction process used in DSA is to eliminate (or factor out) the bone and soft tissue images that would otherwise be superimposed on the artery under study **(12,58).** The serial images show changes in the contrast appearance over time (temporal subtraction) and at varying X-ray intensities (energy subtraction) **(12,57).**

Most DSA examinations require *25* to 45 minutes to perform **(63,99,112),** if there are no technical complications (e.g., difficulties with catheterization), and can be performed on an outpatient basis. This is a considerable advantage in safety and cost over most standard arteriographic examinations, which require at least overnight observation of the patient in the hospital to detect post-procedure arterial obstruction or hemorrhage **(24,33).** However, a small number of the latter have been safely performed on an ambulatory basis in recent years (45).

DSA has a wide range of clinical applications in addition to its use in carotid artery studies. Mistretta and his colleagues (74) at the University of Wisconsin have substituted DSA for standard arteriography in the evaluation of aortic arch anomalies, aortic coarctation, and vascular bypass grafts. Digital subtraction techniques have also been used for imaging of the abdominal, cardiac, pulmonary, carotid, intracerebral, and peripheral vessels. Table 3-1 provides an overview of the range of attempted applications of DSA imaging technology reported in the literature. Be-

Figure 3-1 .—Diagram of a Digital Subtraction Angiography (DSA) System



SOURCE: Office of Technology Assessment. Adapted with permission of the General Electric Co, from G. S. Keyes, N. J. Pelc, S. J. Riederer, et al., *Digital Fluorography: A Technology Update* (Milwaukee, WI: General Electric Co., 1981),

Table 3-1 .—Attempted Applications of DSA Reported in the Literature[a]

Principal author of study	Carotid	Thoracic	Cardiac	Abdominal	Intracranial	Pulmonary	Peripheral	Aorta	Renal	Other
	Anatomical regions studied									
Weinstein, et al. (1981)[b]	X		X	X	X	X	X		X	X
Crummy, et al. (1980)	X		X				X		X	
Levy, et al. (1982)	X		X	X	X	X	X		X	
Brody, et al. (1982)	X									
Turnipseed (1982)	X		x			x	X			x
Buonocore, et al. (1981)								X	X	
Mistretta, et al. (1981)	X		X						X	X
Hillman, et al. (1981)									X	
Johnson (1982)				X			X	X	X	
Kruger, et al. (1981)	X		X							
Meaney, et al. (1980)	X	X	X	X		X	X			
Pond, et al. (1982)	X					X	X		X	
Chilcote. et al. (1981)	X									

[a]Does not necessarily imply routine clinical use at this time
[b]Full citations found in References Section

SOURCE Off Ice of Technology Assessment

cause of problems with spatial and contrast resolution, virtually all examinations of the coronary arteries, which cannot be adequately visualized with intravenous DSA at the present time, require arteriography.

Because DSA functions as both a screening procedure for at-risk or asymptomatic patients and as an evaluative procedure for reconstructive surgery (74,108), estimates of the probable volume of use based only on the latter type of use are bound to be conservative. DSA makes a unique contribution to the field of diagnostic radiology (3), serving as a bridging technique between totally noninvasive tests and conventional arteriography, at times replacing the latter. Turnipseed and his colleagues *(107)* clarified the respective uses of the techniques available to the radiologist and clinician for diagnostic imaging:

> Arteriography has played an important role in the surgical management of peripheral vascular disease because of its ability to precisely define the location and severity of arterial lesions. However, its clinical use has been limited by the risks of arterial catheterization, hospitalization cost, and poor patient acceptance. Arteriography is now commonly used to confirm a diagnosis of vascular disease and to plan appropriate surgical management in patients with symptoms and physical findings of arterial insufficiency.
>
> Because arteriography has not been practical for routine diagnostic screening, a variety of noninvasive screening tests have been developed as diagnostic aids. These noninvasive methods allow more objective evaluation of larger patient populations and are attractive because of safety, cost efficiency, patient acceptance, and the accuracy in detecting hemodynamically significant occlusive lesions. These techniques have been used primarily for diagnostic screening and postoperative assessment.
>
> Although noninvasive methods are useful, they have limited capabilities and some serious shortcomings. Many noninvasive tests are indirect and restricted by technical limitations to evaluation of isolated arterial segments. Most cannot define or distinguish minor stenosis and ulceration from normal vessels and have difficulty in assessing remote areas of the circulation (intracranial, cardiac, and visceral systems). Noninvasive equipment is expensive, often very specialized, and requires personnel with specific technical and interpretive skills **(107).**

DSA, therefore, has the potential of significantly improving the radiologist's and clinician's capabilities in diagnostic screening and postoperative assessment.

Furthermore, DSA is likely to limit the use of older noninvasive tests (e. g., periorbital ultrasonography and thermography), because of greater sensitivity and specificity for diagnostic purposes. However, the evaluation of DSA as a diagnostic technology for the study of carotid artery disease must note the increasing development and diffusion of ultrasound-based methods for diagnosing extracranial occlusive vascular dis-

ease. These technologies have developed very rapidly and newer methods are likely in the future. Because of the safety of these tests, their popularity in clinical practice is not likely to be displaced by DSA in complex or poorly understood clinical situations. However, it may be expected that, where the diagnosis of a carotid TIA seems highly likely on clinical grounds alone, the physician may select DSA as the initial diagnostic test.

Of the large and growing number of noninvasive tests, ultrasound imaging has proved to be the most versatile and reliable in clinical practice. A combination of B-mode real-time imaging, with a Doppler scanning device (often called "duplex scanning"), has become increasingly prevalent. Using this method, an image of the carotid vessel is obtained with the B-scan, and then the blood flow pattern at a given anatomic location is determined with the Doppler signal. This method is advantageous in noninvasive diagnosis in skilled hands, but it takes considerable experience for an operator to become sufficiently expert in the use of this tool to produce reliable and reproducible information of clinical value. However, in part because these techniques have proved popular with practicing clinicians, and in part because they are affordable in office-based practice, industry is likely to respond to the demand for this technology with more accurate and more easily performed duplex scanning in the near future.

By way of comparison, the indirect noninvasive tests (e.g., periorbital ultrasonography), which monitor the cerebral and orbital circulations beyond (downstream from) a carotid lesion, have been shown in most practice settings to have a lower sensitivity and specificity than DSA and/or arteriography and are employed much less frequently at this time than was the case only a few years ago. This trend is likely to be accentuated in the coming years.

As described above, DSA is also likely to limit the use of, or substitute for, arteriography under many clinical circumstances. In addition, it will be employed in situations where arteriography is inapplicable, thus increasing the total volume of arterial examinations. For example, some patients for whom arteriography is risky—such as elderly patients, who are at greater risk for stroke from cerebral arteriography--can have their carotid arteries examined easily and with reduced risk of complication using DSA. Also, DSA may be performed repeatedly on the same individual in order to monitor postoperative or therapeutic progress, without significant morbidity and with good patient compliance. The comparative advantages of DSA and standard arteriography have been summarized in table 3-2.

It is clear that DSA examinations are not **a** simple substitute for arteriograms. Instead, for those conditions for which DSA and arteriography are both applicable, the lower radiation and complication rates of DSA, the outpatient site of testing, the reduced time required for the procedure, and patient acceptance **(83,112)** may result in a use rate of DSA many times greater than that of arteriography. In addition, DSA may be used as a substitute for or a supplement to other noninvasive tests. Two studies of DSA cost effectiveness estimate that for patients with suspected TIAs, clinicians order DSA examinations (where this technology is available) at approximately twice the current rate of arteriographic studies (24,33). However, at present there are no empirical bases for future estimates of DSA utilization.

Table 3.2.—Comparative Advantages of DSA and Conventional Arteriography

Advantages of DSA	Advantages of standard arteriography
Decreased morbidity	Increased spatial resolution[a]
Decreased patient discomfort	Feasibility of selective injections
Decreased hospitalization time	Less degradation of patient motion
Decreased procedure time	Visualization of smaller blood vessels
Decreased film cost	
Increased contrast resolution[b]	
Usefulness in patients with limited arterial access	
Lower cost per examination	

[a]*Spatial resolution:* extent to which radiographic image makes it possible to detect and distinguish anatomically contiguous structures.
[b]*Contrast resolution:* extent to which computer can detect subtle differences in amount of contrast medium present

SOURCE: M. F. Steighorst, C. M. Strother, C. A. Mistretta, et al., "Digital Subtraction Angiography: A Clinical Overview," *Applied Radiology* 10(6):45-49, 1931.

CLINICAL EFFICACY AND EFFECTIVENESS OF DSA

The claimed advantages and disadvantages of DSA derive, in large part, from the efficacy and safety of the technology. A substantial volume of evidence regarding the efficacy and safety of DSA is now available through clinical testing of DSA in several medical centers.

Banta and Behney (8) define technological *efficacy* as "the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under *ideal* conditions of use" (emphasis added). *Effectiveness* is the probability of benefit under *average* conditions of use. The literature to date on DSA generally addresses clinical efficacy and safety, not effectiveness. Most studies have been conducted in institutions engaged in clinical research under carefully monitored conditions (21). An exception is the experience documented at Scottsdale Memorial Hospital in Arizona (63). It is not clear whether experimental and early clinical data from academic medical centers, such as the Universities of Wisconsin and Arizona—each with several years of pioneering experience in DSA use—can be employed reliably to predict the effectiveness and safety of DSA by radiologists and clinicians in community hospitals, clinics, and group practices and the resulting patterns of DSA use.

Measurement of the efficacy of DSA is multidimensional, as depicted in table 3-3 (adapted from Fryback [38]), because benefits can be discerned at the levels of: 1) physical image; 2) the detection, accuracy, and sensitivity of tests; 3) diagnostic decisionmaking; 4) therapeutic decisionmaking (or "management efficacy"); 5) patient outcome; and 6) social utility (38). Implicit in this scheme is the belief that increasing diagnostic accuracy is not an end in itself, but rather an instrumental value. The overall efficacy of DSA, then, lies in its contributions to better patient outcomes and ultimately to improved social welfare (31,38),

Most of the clinical evaluations of DSA have taken place at levels 1 and 2 of the Fryback model, namely, with a focus on image quality or on diagnostic sensitivity, specificity, and accuracy. "Sensitivity" may be defined as the proportion of positive tests in all patients with disease; "specificity" is the proportion of all negative tests in patients without disease; and "accuracy" is the ratio of correct diagnoses to all diagnoses.

Investigations of the efficacy of DSA have not yet concentrated on the effects of DSA throughout the medical care system. The literature generally does not address differences in physician diagnosis, selection of treatment alternatives, patient outcomes, or social welfare attributable to DSA. The majority of studies consider the accuracy of DSA for diagnosis in comparison to other diagnostic techniques, usually conventional

Table 3-3.—Levels At Which Diagnostic Technologies May Be Assessed

Level of the measurement	Typical output measures
Level 1: Image efficacy	quality of image resolution
Level 2: Image and observer efficacy	percentage yield of abnormal cases; percentage correct diagnoses; sensitivity; specificity
Level 3: Diagnostic efficacy	change in order of clinician's diagnostic considerations
Level 4: Management efficacy (therapeutic decisionmaking)	percentage change in therapeutic protocol; percentage change to appropriate therapy
Level 5: Patient outcome efficacy	survival rates; percentage cures; morbidity measures; reduced worry of patient and family
Level 6: Societal efficacy (or utility)	dollars added to GNP; age-adjusted survival rates

SOURCE: Off Ice of Technology Assessment, Adapted from D G. Fry back, "A Conceptual Model for Output Measures in Cost. Effectiveness Evaluation of Diagnostic Imaging, " paper presented at the Symposium International de Evaluation Cout-Efficacite en Neuroradiologie, Bordeaux, France, May 14-15, 1982.

arteriography. For images of good diagnostic quality (approximately *85* percent), the sensitivity (95 percent), specificity (99 percent), and accuracy (97 percent) of DSA appear to be very good (19,112).

in general, the principal reason for inadequate visual resolution is movement of the patient during the scan procedure. The quality of images can be affected by swallowing, breathing, peristalsis (movement of esophagus), or other physical motions, depending on the vessels to be visualized (112). Other causes of failure are inadequate venous access, leakage of dye, and faulty injection.

THE SAFETY (ASSOCIATED PATIENT RISKS) OF DSA

OTA defines the "safety" of a medical technology to be:

> . . . the judgment of the acceptability of relative risk in a specified situation;

while "risk" is defined as:

> . . . the probability of an adverse or untoward outcome occurring and the severity of the resultant harm to health of individuals in a defined population associated with use of a medical technology applied for a given medical problem under specified conditions for use **(8).**

Using these definitions, the safety of DSA may be measured and compared to the present methods of diagnostic imaging for vascular diseases. As noted by Patterson (81), the efficacy and safety of neurosurgical and related technologies are only estimated informally, because of measurement difficulties, different conditions of use, and the experimental nature of some technologies. This appears to be the case for DSA. There are no rigorous epidemiological or randomized clinical studies that document either the direct or indirect safety effects. This seems to be due to the fact that most clinicians are impressed with the apparent low risk of DSA relative to benefit, as compared with alternatives.

The amount of radiation from DSA is so small that clinical decisionmaking generally does not take radiation into consideration. Radiation doses for DSA reported in carotid studies are given in table 3-4. Radiation exposure varies depending on the subtraction method selected for the exam and the number of views required for diagnosis (21, 24,56).

Complications from DSA are minimal compared to standard arteriography. Both peripheral and central intravenous injections are likely to be less risky than arterial punctures required for arteriography. In particular, arteriographic procedures may cause stroke due to dislodging embolic material (19), dissecting the arterial walls, or rupturing aneurysms (54), whereas this does not occur with DSA.

A survey of radiologists at 514 hospitals showed that about 2 to 3 percent of all patients undergo-

Table 3-4.—DSA Radiation Exposure Estimates for Cerebrovascular Studies

Principal author of study	Area of study	Estimated radiation exposure per image[a]
Crummy, et al. (1980)[b]	Extracranial arteries	100-150 mR[c]
Chilcote, et al. (1981)	Carotid arteries	230 mR
Brody, et al. (1982)	Carotid arteries	130 mR
Detmer, et al. (1982)	Extracranial arteries	3.6 R[d]

[a]Number of images per study may vary considerably depending on anatomical site, operators, or Patient characteristics.
[b]Full citations found in References Section.
[c]mR . milliroentgen (1 Roentgen (R) = the unit of radiation exposure equivalent to 2.08 x 10° ion pairs in one cc. of air. The measure of radiation exposure in human tissue conventionally used is the "Rad " the absorbed dose of 100 ergs/gin of tissue. One Rad is equivalent to 1.02 Roentgen, the difference between two units of measure being considered negligible,)
[d]R . Rad. (Detmer, et al. (24), the source for data on a complete DSA study (including multiple images), note that a conventional arteriographic study would expose the patient to approximately 20 Rads of radiation.)

SOURCE: Office of Technology Assessment, ing a total of 118,591 arteriographic exams—transfemoral, transaxillary, translumbar—suffered complications which required additional therapy or prolonged the patient's hospital stay (54). These complications included 30 deaths (0.03 percent of all exams). Another study indicated that of 1,328 patients who were suspected of having TIAs and had arteriograms, 13 percent had temporary complications and 0.65 percent suffered permanent neurological complications (102). Johnson (56) concludes that:

> "(t)he complexity, expense, and a certain morbidity and mortality associated with this radiographic procedure [arteriography] compel a set of indications virtually as strict as that for surgery."

Certain complications can arise in DSA exams due to leakage of contrast medium outside the vein, venous reflux (contrast medium going into vein the wrong direction), or patient reaction to the contrast medium (21,57,108,112). Various clinical studies have documented only a small number of such problems—all were transient—of several thousand patients examined (19,21, 57,112).

The safety as well as the clinical efficacy of DSA will depend to a considerable extent on the quality of the particular equipment being used (a factor which also affects diagnostic accuracy and specificity); the compatibility of new DSA equipment with existing facilities; the techniques used; and the experience of the physicians and allied health personnel performing and interpreting these diagnostic images. Several investigators have noted some variability in imaging capabilities of DSA under different technical conditions and have evaluated the physical requirements of the imaging systems with regard to assuring high quality standards (6,67).

4.
The Costs of Digital Subtraction Angiography

4. The Costs of Digital Subtraction Angiography

The costs of acquiring digital subtraction angiography (DSA), building or modifying an existing physical facility to house the equipment, and initiating the service in an operational mode are of many forms. This chapter attempts to summarize existing experience with respect to the costs of DSA in the United States.

PURCHASE AND UTILIZATION COSTS

A technology such as DSA requires both capital and operating expenditures. Capital outlays are necessary in most instances for the equipment itself and for the physical space within which to operate the equipment. Unfortunately, it is difficult to estimate the rate of amortization of DSA equipment at this stage in the development and implementation of the technology.

Freedman (33) estimated that the investment in a DSA computer, X-ray equipment, and room will range from $400,000 to $800,000. The costs a hospital or clinic may incur depend on whether the radiographic/fluoroscopic equipment is already present. If so, most hospitals can add a digital computer to their radiography rooms for an average cost of $250,000. The price range for these "add-on" systems in January 1982 was $135,000 to $350,000 (61). In the future, considerable savings are expected from combining the data processing and storage requirements of the various kinds of computer-assisted radiographic techniques, such as the use of a single computer to retrieve and store information from more than one DSA machine (1,29).

Operating costs include fixed personnel costs and variable supply costs. Personnel costs, although fixed for a given facility, vary considerably among facilities depending both on the facility's caseload and the configuration of DSA in relation to other radiologic technologies. For example, a physician is required to be physically present in or around a DSA unit to supervise the injection of the contrast agent, but this physician can also service a second adjacent room where another DSA or computed tomography (CT) scan unit is operating. There are circumstances where a physician could supervise a third room as well, possibly a room equipped with a real-time ultrasound unit.[1] Thus, a rotating physician can effectively supervise several radiological procedures in different, but adjacent, rooms simultaneously, therefore reducing the fixed personnel costs of all of these procedures.

With a caseload of six to eight cases per day (1,500 to 2,000 annually), it is commonly estimated that two full-time technicians (requiring a total of $50,000 in salary and fringe benefits annually) will be required to operate a DSA efficiently (33). A secretary is required to make appointments, complete insurance forms, and to perform other activities. Because this secretary *is* likely to participate in other activities, such as scheduling patients for other radiologic examinations, this fixed personnel cost is factored into a miscellaneous category (of about $50,000 annually) which includes insurance, administrative costs, utilities, etc.

Supply costs were estimated in 1982 to average approximately $100 per DSA examination, allowing for 20 percent waste and repeating the study (33). Since that time, special DSA *procedure* kits have been developed which cost approximately $60 each. Allowing for a 10 percent waste factor, current supply costs should range between

[1]See ch. 2 for a description of real-time ultrasound.

$65 to *$75* per case. Some variation in costs is associated with the way in which the contrast medium is injected. A peripheral injection usually requires a supply cost of approximately *$80* per case; when the catheter is placed in the superior or inferior vena cava, these costs are approximately $100. Among the more expensive items that contribute to variable costs are the catheter ($18), floppy disk for the computer ($10), and the contrast agent (150 cc. at $15) (33).

It is useful to summarize these cost data by way of a breakeven analysis. If it is assumed that *variable* (supply) costs are $80 per case (with peripheral injection of contrast agent), and there is a caseload of eight patients per day, 250 days per year, the total variable costs would be **$160,000** per year. If this figure is added to an annual *fixed* cost of $400,000, **a** figure within the range of actual experience in late **1982 (33),** the total annual costs of operating a DSA unit on a per case basis can then be calculated. Using these figures, one can estimate a total annual cost of $560,000 assuming a total of 250 working days per year. With an annual caseload of 2,000 patients (250 days X *8* patients per day), this yields a breakeven cost of $280 per case.

PATIENT COSTS AND CHARGES

The total expenditures associated with performing a procedure such as DSA also include institutional and professional charges billed to the patient or the insurance carrier. Reports of billed charges in the literature **(24,33,61)** average between $175 and $300 for institutional providers. These figures incorporate fixed overhead costs, variable supply costs, and the volume of DSA procedures performed. As the volume increases, the cost per procedure may decrease, although the actual charges to the patient may not.

On a national level, third-party insurer responses to DSA are difficult to summarize. As an example, however, in **1983** physicians and hospitals in New Jersey were paid at the rate of $500 per DSA examination. The basis on which this figure was determined is not clear, but informal conversations with individuals directly involved with setting the charge suggest that the figure was derived by examining the costs of inpatient arteriography, a more expensive procedure that produces similar information. Detmer and colleagues (24) assumed a charge of $1,120 for inpatient arteriography in their study, including the cost of hospitalization and professional fees. In New Jersey, however, the arteriography charge appears to be substantially higher, perhaps in the neighborhood of $2,300 per arteriogram.

Despite the seemingly arbitrary current rates of DSA reimbursement, it is clear that third-party payers view DSA as a potential cost-saving tool. Not only does DSA eliminate the necessity for hospitalization of the patient, but there is the possibility that with time and experience, as well as further technological advances, this procedure will substantially replace a large portion of the current demand for inpatient cerebrovascular arteriography. A reduction in inpatient arteriography will lead to overall lower costs for each patient examined.

IMPLICIT AND INTANGIBLE COSTS

The costs as delineated above are likely to change. Thus, a long-range evaluation of the cost effectiveness of DSA as compared to alternative imaging technologies is very difficult. This is an inherent problem of evaluating the costs and benefits of an evolving technology.

Another significant problem with this type of evaluation is that the future level of use of conventional arteriography is uncertain. Currently, arteriography is available in most U.S. hospitals. If DSA substantially reduces the need for arteriography, as is contemplated, the costs of maintaining the fixed arteriography facilities will rapidly increase on a per-arteriogram basis. These unit cost increases may be partially offset by the integration of DSA and arteriography units, or by the closure and consolidation of arteriographic facilities among inpatient care institutions. The adoption of Medicare's diagnosis-related group (DRG) and other prospective payment systems is likely to further stimulate this consolidation process.

On the other hand, arteriography use may remain high despite the widespread introduction of DSA. The digital subtraction processes used in intravenous DSA are now being applied to conventional arterial studies; the improvements in computer data processing and image quality may allow the study of previously inaccessible vascular structures. Thus, a prospective cost analysis cannot treat arteriography as a "steady-state" technology, nor its current level of utilization as a stable pattern. The cost-effectiveness analysis of DSA in chapter 5 incorporates flexible levels of arteriography use to reflect this uncertainty.

The costs of DSA equipment may change dramatically as well. Presumably, the high costs of research and development (R&D) are incorporated into the early models. These R&D costs should decrease over time, and with economies of scale in production, *lower* the cost, and hence the price, of the equipment. One possible offsetting factor, though, is that manufacturers maybe able to make continual qualitative improvements in the technology and thereby maintain a high price. If present equipment becomes obsolete, this will stimulate either the purchase of new equipment before the existing units are fully depreciated or the upgrading of existing equipment through the purchase of additional components. It is likely that DSA is not yet a mature technology—either in technical development or in its medical applications—and will experience significant changes similar to the CT scan in years ahead.

DIFFUSION AND SOCIAL COSTS

Diffusion of a technology may lower per procedure expenditures, depending on economies of scale in production and further innovations of the technology. Similarly, the per procedure costs of DSA may decrease in association with its increase in availability. This could further result in reduction of the economic and social impact of stroke (3,103).

However, technology diffusion also has the potential for enormous aggregate costs as well as *savings.* Any assessment of DSA must consider not only how the costs of DSA compare with arteriography, but the extent to which DSA leads to increases in the total volume of diagnostic studies performed. Thus, the evaluation of the economic impact of DSA should include the change in expenditures per examination as well as the increase (or decrease) in total examinations performed.

It seems certain that the demand for DSA technology by many clinical specialists will be very high. Neurosurgeons, cardiologists, vascular surgeons, neurologists, and other physicians will make frequent use of DSA. Also, general practitioners and family physicians learn of diagnostic imaging breakthroughs in primary care journals *(29)* and may refer their patients for those imaging studies.

If diffusion of DSA is unconstrained, utilization of DSA will undergo rapid growth. This will occur because: 1) the lower complexity and risks of DSA will make it useful for large numbers of patients who would not ordinarily undergo arteriography; *2)* the applications of DSA are increasing; 3) the numbers of specialists who would use DSA (and are being trained in its use) are growing, and they are more widely dispersed geographically; and 4) the ambulatory nature of DSA makes it available to a greater number and variety of health care institutions, including group practices, multispecialty clinics, and hospitals.

Restraints on the diffusion of DSA can come from at least two sources, health planning agencies and third-party payers for medical care. A 1980 OTA study found that health planners were primarily oriented toward health "needs," usually consider only capital costs, and never explicitly weigh costs and benefits in certificate-of-need recommendations (as reported in 8). The economic (or political) reason for this behavior is that there is no mechanism for effecting a direct budget constraint in the health planning process (8). It is therefore disadvantageous for a local agency to deny specified medical needs and benefits when the costs of adopting the new technology are spread throughout the insurance system.

Similarly, the enthusiasm of technology manufacturers, providers, and insured patients for the expanded use of DSA is not likely to be offset by the reimbursement procedures of third-party payers. Medicare and Blue Cross/Blue Shield, as examples, make coverage decisions based on: 1) efficacy, 2) safety, 3) state of development, and 4) acceptance by the medical community (8,44,51). Billed charges are not a criterion for deciding *whether* to cover a new procedure. Charges become relevant only with respect to decisions regarding the level of payment.

Since fee schedules generally reward the use of technology-intensive services *(68),* "it may be more advantageous to a physician to order and read diagnostic tests than to expend the time he spends with a patient performing a physical examination" (23). It has been demonstrated that a physician can triple his/her income merely by ordering a higher volume of tests for the same number of patients (93).

Greenberg and Derzon (44) note these and other difficulties with medical payment policies, and offer four general options: 1) restrict coverage of "unproven" procedures, presumably those whose efficacy has not been demonstrated in controlled, randomized clinical trials; 2) introduce cost effectiveness criteria; 3) educate physicians in appropriate uses of technology; and 4) educate consumers. The introduction of these criteria for insurance coverage, particularly cost effectiveness, is not likely to have a substantial impact by itself (8). For reasons already stated, there are strong forces operating against the control of technology development and diffusion in the case of DSA.

5.

The Cost Effectiveness of Digital Subtraction Angiography

5.
The Cost Effectiveness of Digital Subtraction Angiography

The final objective of a thorough cost and quality assessment of any new medical technology is to ascertain the degree of relationship between the incremental costs of the new procedure and the extent to which the prevention and/or treatment (cure) of the relevant diseases has occurred or is likely to occur. In this case study of digital subtraction angiography (DSA), the focus of inquiry is somewhat more limited. Although it would be ideal to be able to compare all technologies of all types relevant to cerebrovascular disease on the basis of their contribution to improvements in patient morbidity, mortality, disability, longevity, and productivity, the information needed for such an analysis simply does not exist. Thus, the conventional approach to cost effectiveness analysis for a diagnostic imaging technology is to compare the "cost per procedure" and the "cost per lesion found" between the new technology and one or more existing technologies (24,33).

In the case of carotid artery disease, a "significant lesion" is usually defined as arterial stenosis of 50 percent or greater. This is the approach taken in this analysis of the cost effectiveness of DSA. In other words, this analysis seeks to measure the "cost per unit of effectiveness" of DSA in comparison with conventional arteriography, a competing alternative technology with common objectives (8). It also reviews the existing cost effectiveness analyses.

REVIEW OF EXISTING STUDIES OF THE COST EFFECTIVENESS OF DSA

Two cost effectiveness studies of DSA have been performed (24,33). Each compared conventional arteriography with DSA in the evaluation of patients with transient ischemic attacks (TIAs). Freedman (33) limited his analysis to the cost of studies of the carotid arteries. The primary unit of analysis in both studies was the "cost per identified lesion"; Detmer and colleagues *(24)* also included a measure of "radiation dose per lesion found." The key assumption, monetary values, and findings from each study are listed in table *5-1*.

In these studies, the population to be studied with DSA is assumed to be approximately twice as large as the population currently examined with arteriography. These estimates are derived from a cooperative study of TIAs conducted in five academic medical centers *(102)*. Freedman (33) notes that the incidence of TIAs reported in the cooperative study appears to be low. He argues that incidence can range up to four or five times that level in a community with a large elderly population. It would appear, then, that the population at risk has tremendous implications for the overall costs of DSA imaging as a technological alternative to conventional arteriography.

Yield rates (the numbers of lesions found per population screened) are also widely variable, even for arteriography. Eisenberg and Nicklin (28) observed that abnormalities found in arteriographic studies ranged from 22-42 percent to 100 percent for TIA patients. This variability is due to the inclusion or exclusion of ulcerative lesions, differences in the populations screened, local differences in patterns of practice in certain medical specialties, and whether the findings were reported in the clinical or radiological literature. Detmer and colleagues *(24)* base their estimated yield of 75 percent for arteriography on the actual yield of that technology at the University of Wiscon-

Table 5-1 .—Data Used for Cost-Effectiveness Analysis of DSA

Assumptions	Detmer, et al. (1982)[a]		Freedman (1982)[a]	
I. Patient population examined:				
A. Definite TIAs	8.4 TIAs/100 beds		5.4 TIAs/100 beds	
B. Possible TIAs.	17.4 TIAs/100 beds		16.8 TIAs/100 beds	
II. Yield rates:				
A. DSA	High = 75 percent Low = 25 percent		High = 80 percent Low = 40 percent	
B. Arteriography	High = 75 percent Low = 25 percent		High = 80 percent Low = 40 percent	
III. Cost/procedure:				
A. DSA	$ 225		$ 500	
B. Arteriography	$1,120		$1,200	
IV. Cost effectiveness (cost/lesion found)				
	Population examined			
Screening protocols	Low	High	Low	High
A. Arteriography only	$1,492		$1,500	
B. DSA followed by arteriography if DSA is positive.	$1,438	$1,590	$1,825	$2,033
C. DSA, followed by arteriography in only 50 percent of positive DSA exams as a confirmatory measure	$ 936	$1,065	$1,225	$1,433
D. (1) DSA, followed by arteriography in only 10 percent of positive DSA exams (Freedman)	–		$ 775	$ 950
(2) DSA, followed by arteriography in only 5 percent positive DSA exams (Detmer. et al.)	$ 376	$ 512	—	

[a]Full citations found in References Section.

SOURCE Office of Technology Assessment

sin Hospital; they assume that DSA accuracy is equal to that figure (adjusted for a 5-percent rate of technical failure of DSA). Detmer and his colleagues (24) noted, however, that DSA does not currently approach that level of accuracy for ulcerative lesions. The generalizability of this rate is quite limited, and the estimated yield rates for DSA means that the Detmer and the Freedman studies must be carefully interpreted. The same conditions will limit the accuracy of this cost effectiveness analysis of DSA in the diagnosis of cerebrovascular disease.

The validity of the estimated costs of DSA and arteriography are also subject to scrutiny. Detmer and colleagues (24) present no cost findings at all, but simply list the billed *charges* for these procedures at the University of Wisconsin Hospital. Further, costs in their analysis do not include professional fees (approximately *$150) (33).* Freedman (33) does not provide detailed estimates of the fixed and variable costs of DSA imaging, but only gives "point estimates, " rather than ranges, of cost effectiveness.

Interpretation of these studies is further complicated by the fact that the estimates are derived from operational costs in two large and innovative radiology practices, one of which is part of an academic medical center. These practices may reflect a very different cost experience from community hospitals and ambulatory sites, particularly with respect to the allocation of overhead costs.

NEW TECHNOLOGY AND PATTERNS OF MEDICAL PRACTICE: CRITICAL ASSUMPTIONS UNDERLYING AN ANALYSIS OF COST EFFECTIVENESS

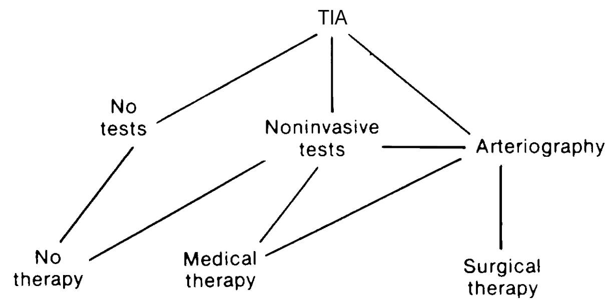
In order to investigate the cost effectiveness of a new diagnostic tool such as DSA, it is important to attempt to understand its potential role in the care of patients with TIAs or patients who may have had a completed stroke. It is essential that predicted changes in the process of health care delivery and its outcome be identified. Thus, a cost effectiveness analysis of DSA should proceed from a conceptual model of how this technology will "fit" with existing technologies and patterns of practice relevant to the disease(s) of focal interest.

The hypothesis made in this case study of the impact of DSA on existing patterns of medical practice and technology use in the diagnosis and treatment of cerebrovascular disease is illustrated in figures 5-1 and *5-2*. Prior to the introduction of DSA, as figure 5-1 depicts, the physician who encountered a patient with a TIA or a stroke had several diagnostic procedural options to consider. For a number of reasons, the physician may have decided that no tests were indicated, perhaps because of coexistent medical problems that made invasive testing and surgical therapy unwarranted. In other circumstances, the physician may have moved to noninvasive testing followed by arteriography, or arteriography could have been employed as the initial test. The interplay of technologies illustrated in figure 5-1 is based on three important assumptions:

1. No surgical therapy is currently performed without arteriography.
2. Arteriography maybe the initial diagnostic test.
3. Arteriography may be the only diagnostic test.

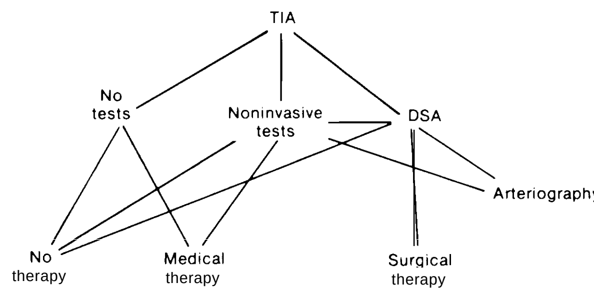
A possible fourth assumption, and one that is certainly true in many medical centers, is that radiologists and other physicians are reluctant to undertake tests with significant morbidity risks **(e.g.,** arteriography) without the opinion of a neurologist to determine that the patient's symptoms are due to TIA and therefore warrant the use of arteriography and/or surgical therapy.

Figure 5-1.— Clinical Alternatives Without DSA Available



SOURCE: Off Ice of Technology Assessment

Figure 5-2.—Clinical Alternatives With DSA Available



SOURCE: Office of Technology Assessment.

As DSA becomes increasingly available, the patterns of care associated with TIA are likely to undergo significant changes. It may be hypothesized that arteriography will less often be the initial diagnostic test, even in the case of patients with a history of definite TIA. As indicated in figure *5-2,* DSA may become the initial test of choice, or it may follow noninvasive testing of other types. On the output side, DSA maybe the final test before medical or surgical therapy, or it may lead to arteriography prior to medical/surgical intervention. The important assumptions underlying the hypothesized patterns of patient care diagramed in figure 5-2 are:

1. The sensitivity and specificity of DSA are generally much greater than for other noninvasive procedures under ordinary conditions of use.

2. The accuracy of DSA is somewhat less than arteriography, but DSA is much safer and less uncomfortable for the patient.
3. Arteriography is almost never performed (except in certain academic medical centers) without prior DSA examination, where the latter test is readily available.
4. Surgery may be undertaken without arteriography in selected cases.

Support for some of these assumptions is provided by Little and colleagues *(65):*

> In a previous study (19), . . . there was excellent correlation between the conventional angiogram and the intravenous [DSA] when the carotid bifurcation was well visualized (i.e., sensitivity, 95 percent; specificity, **99** percent; accuracy, 97 percent). When the carotid bifurcation was not well visualized by intravenous [DSA], there was a substantial chance of misinterpretation of the study results. The most common cause of misregistration was the patient's swallowing. Overall, the intravenous digital subtraction angiogram was found to accurately demonstrate the carotid bifurcations in 71 percent of the arteries evaluated. In the present study, 96 percent of the carotid bifurcations were adequately visualized.
>
> Although conventional angiography was usually recommended in patients treated surgically, intravenous [DSA] obviated the need for conventional studies in the evaluation of many patients. Some patients having extracranial and intracranial studies underwent carotid artery surgery without the need for further investigations.

The sponsors of the first outpatient ambulatory neurodiagnostic center in the State of New Jersey indicate anecdotally (45) that DSA has proven to be a significant advance in the evaluation of patients with cerebrovascular disease. According to Michael L. Gruber, M. D., a neurologist with this group:

> . . . Our experience indicates that of those patients who have surgically amenable abnormalities of the carotid bifurcations, no further studies are indicated in the majority (approximately 80 percent). In other words, the surgeon will operate on the basis of the digital subtraction angiogram. In the other 20 percent of cases, further study is required . . . because of technical problems with the DSA; because (the test revealed) total occlusion on the DSA; (in such cases the) standard procedure is to follow this with a conventional angiogram; and lastly the reluctance on the part of some surgeons to accept this new modality of investigation (45).

As a further indication of the extent to which DSA may substitute for conventional angiography as the diagnostic test establishing the need for carotid artery surgical therapy, Little and colleagues (64) summarized the experience with DSA at the Cleveland Clinic:

> DSA examinations frequently obviated the need for conventional angiography. Some patients having satisfactory extracranial and intracranial studies underwent carotid endarterectomy without further contrast studies. The number of patients undergoing carotid surgery without conventional arteriography continues to increase.

Because DSA has not yet gained widespread use as a diagnostic procedure, the data do not exist by which to accurately predict the patterns of use which will develop for the diagnosis and treatment of cerebrovascular disease. It is possible, however, to speculate on some of the ways in which DSA might be used, given current patterns of practice in disciplines such as neurology and primary care specialities. The following six assumptions are made as the basis of a cost effectiveness analysis of DSA:

1. **The technical proficiency of DSA is expected to rapidly improve as a result of the intense competition among the major imaging equipment manufacturers.**
2. **As the speed and spatial resolution of DSA studies improve and the quality of ancillary technology improves, more and more patients will have only a DSA procedure before undergoing cerebrovascular surgery.**

Detmer and colleagues (24) estimated that if no more than 5 percent of positive DSA examinations were followed by conventional arteriography for confirmation purposes, a savings of approximately $1,100 per discovered lesion would result.

3. **It is unlikely that only one DSA study will be performed per discovered lesion. It seems more likely that a minimum of two DSA ex-**

aminations (one before and one after therapy) will become the pattern of care.

This would especially be the case for all surgically treated patients, since the postoperative DSA examination would serve as a new "baseline" for the future. Among medically treated patients, it seems reasonable to assume that many will receive repeat examinations at yearly intervals to determine whether the pathology has progressed and to learn whether the stenosis of the carotid arteries has become more serious. Hence, only among patients where the DSA exam did not find a lesion can one assume that a single examination will suffice.

4. **The population of patients receiving DSA examinations in the future is likely to be much larger than the current number who receive in-hospital arteriography.**

Freedman (33), and Detmer and colleagues (24) both estimate the number of patients who will receive DSA examinations as twice the number presently having conventional arteriography. The 1977 Cooperative Study of TIA (102) reported an average of 5,4 definite TIAs per 100 acute care beds per year (the highest rate being 8.8 TIAs per 100 beds per year). Freedman (33) and Detmer (24) assumed that 95 percent of the higher prevalence estimate (or 8.5 per 100 beds) would receive arteriograms. Thus, previous studies and their assumptions suggest that as many as 17.4 DSA examinations per 100 acute care beds will be performed annually in U.S. hospitals.

Because DSA is an ambulatory care procedure, however, the "burden of illness" in the total population may be a more reasonable guide for the estimation of potential utilization, rather than the frequency of relevant diagnoses per 100 acute hospital beds. Available data (62) suggest that the incidence of TIA is 30 per 100,000 population per year with an average episodic duration of 5 years, or a prevalence of 150 per 100,000. Physicians are likely to "follow" patients with recurrent TIAs with repeated examinations, especially as the imaging quality improves.

In addition, virtually all patients with a completed stroke would likely receive a DSA examination. The incidence of stroke is *150* per 100,000 per year with an average duration of 4 years. Since a completed stroke is considered to be a relative contraindication for surgical intervention, few such patients now receive arteriography unless subsequent TIAs occur, or the treating physician finds evidence that a major stroke might subsequently occur after a minor stroke that has left relatively little intellectual and motor impairment. Since DSA is much safer than arteriography, it is assumed that many stroke patients will receive this examination. A DSA exam following a stroke may help the physician determine prognosis for family counseling, even though relatively few demonstrated lesions in stroke patients will receive surgical therapy.

If one assumes that 90 percent of new TIAs, 70 percent of new strokes, 30 percent of old TIAs, and 10 percent of old strokes receive a DSA examination annually, then 237 (27 + 105 + 45 + 60) DSA examinations for carotid artery disease per 100,000 population would seem a reasonable estimate. This figure is much larger than one based on hospital data from New Haven, Connecticut, that was estimated at 33 per 100,000 population (34).

5. **The prevalence of asymptomatic extracranial occlusive vascular disease will further increase the volume of DSA procedures performed.**

It has been estimated that in asymptomatic individuals, there is a *22* percent prevalence of arterial stenosis of the extracranial and major intracranial vasculature sufficiently severe to compromise the arterial lumen by at least 50 percent (96,97). Many of these patients have abnormal clinical signs on examination, even though no symptoms were present before the exam. These signs include bruits (murmurs) audible through a stethoscope placed adjacent to a compromised artery, diminished arterial pulsations, and an abnormally low blood pressure recorded distal to (beyond) a stenotic vessel. Many of these patients will likely receive a DSA examination, especially prior to administration of general anesthesia for a surgical procedure elsewhere in the body, because of a concern that a stroke might occur during surgery even in the absence of prior symptoms. Except under unusual circumstances (such as prior to prolonged surgery) patients with asymptomatic occlusive vascular disease do not now receive arteriograms. With the ready availability of a safe and effective diagnostic tool such as DSA, many asymptomatic patients with abnormal signs on clinical examination will likely receive a diagnostic evaluation. It appears to be a safe assumption that the indications for surgical therapy may be expanded to include asymptomatic patients with severe stenosis discovered by DSA examinations. This will result in an overall increase in the number of surgically treated lesions.

6. **The increasing availability of DSA, its technical quality and its extremely low morbidity will significantly alter the pathway through which patients with TIA are evaluated and/or referred by primary care physicians.**

Because of the risk of complication associated with conventional arteriography and the relatively large radiation exposure (20 roentgens per examination for arteriography vs. 3.6 for DSA), patients are now carefully screened by their physicians before arteriography is scheduled. This screening occurs in two ways: First, as shown in figure 5-1 above, preliminary noninvasive tests (e.g., ultrasonography) are often performed in order to reduce the likelihood of a “true negative” arteriographic examination. Most experienced clinicians prefer to screen all but the most urgent patients before performing an arteriogram. Thus, patients for whom arteriography is the first and only examination are a minority of those receiving this examination.

Second, the screening process includes a neurologist’s opinion that a patient’s symptoms are likely to come from extracranial occlusive vascular disease. Many primary care physicians diagnose TIA for symptoms that necrologic specialists would place in other categories. For example, dizziness is a common symptom among the elderly, especially when one first arises from a seated or lying position. Neurologists know that most dizzy patients do not suffer the types of stroke that would signal the occurrence of TIAs even if they have symptoms of dizziness and vertigo (without other symptoms and signs). Furthermore, symptoms in the extremities may represent focal seizures (localized to one part of the body), and these may be misdiagnosed as TIAs by the less experienced non-neurologist. Many patients with acute confusional states, due to a variety of toxic and metabolic causes, are also falsely labeled as having had TIAs. For these and other reasons, many radiologists will not accept patients for arteriographic examinations of the extracranial vasculature unless a neurologist has been consulted.

It maybe hypothesized that DSA may significantly alter the pathway through which patients with suspected cerebrovascular disease are managed. It is possible that both primary care physicians and radiologists may become convinced that the superior quality of DSA images and the lower morbidity risk of the procedure itself can allow some proportion of patients with suspected TIA to be managed without neurology specialty consultation. However, the American Neurological Society strongly suggests that appropriate neurological advice should be sought even in the most straightforward of cases.

QUANTITATIVE ESTIMATES OF THE COST EFFECTIVENESS OF DSA

Measuring the cost effectiveness of DSA in the diagnosis of patients with carotid artery disease is a complex task. Because several factors which influence the acquisition, use, and efficacy of DSA are variable, a *range* of costs must be incorporated into the analysis.

The data presented in the tables that follow represent the variability in cost effectiveness which can be expected in the operation of DSA under different institutional and clinical circumstances. These data are largely based on secondary information in previous studies of DSA (see principally

24,33). These studies provide important indicators of the specific cost parameters of DSA. Because their methods are limited in scope, these studies also pose certain limitations for these analyses.

Estimates of the cost effectiveness of DSA reported in this case study are based on the predicted patient charges necessary to cover the costs of operation of a DSA unit. The use of billed charges in the calculation of cost effectiveness indicators does not identify the actual flow of resources (revenues) to the production of DSA examinations, since patient or insurance payments will most likely fall below the level of billed charges. The primary concern here, however, is comparing the *relative* amount of outlays for a specific set of medical procedures—the diagnostic imaging of carotid artery disease—as a new technology (DSA) is introduced into the field of diagnostic radiology. Since data on the costs of conventional carotid arteriography are unavailable in the literature, DSA *charges* have been estimated for comparison with charges for conventional arteriography reported by Freedman *(33)* and Detmer and colleagues *(24)*.

Another issue is the appropriateness of the cost effectiveness indicators employed in this analysis. It may be argued that the indicator used in prior studies, cost per lesion found, is an incomplete measure of the costs of cerebrovascular diagnosis. Because arteriograms are assumed to follow only positive DSA tests, the costs of further diagnostic evaluation following negative DSA tests are missing.

Hypothetically, the costs associated with negative DSA results may be of two kinds: 1) costs of arteriography or other testing ordered by conservative clinicians who want to confirm the negative DSA results, and 2) costs of patient disability or death due to false negative DSA tests, where the failure of DSA to show arterial disease prevented timely medical or surgical intervention. Realistically, technical improvements in DSA imaging and physician experience with the technology should reduce followup testing of negative DSA findings to insignificant levels. Indeed, it is likely that positive DSA exams will be a sufficient basis for making decisions regarding surgical intervention *(45,64,65)*. Furthermore, clinical tests of DSA show that when a good (i. e., diagnostically useful) image is produced (approximately 85 percent with an experienced radiologist), the sensitivity of the procedure is close to 95 percent in the examination of the carotid arteries (19). In other words, only 5 percent of all patients with actual arterial disease will have a negative DSA finding.

It is reasonable, therefore, to assume that nearly all the costs of carotid artery imaging are incorporated into the measures of "charges per lesion found" and "charges per patient examined" as estimated in this case study. These measures are not ideal, because they do not indicate the effectiveness of DSA in improving clinical therapy or patient outcomes, but they do estimate an important unit of analysis, the cost of diagnosing carotid artery disease.

DSA charges must reflect: 1) fixed capital costs of the DSA equipment and facility; 2) semi-fixed costs for radiological personnel, equipment maintenance, administration, and utilities; 3) costs of supplies; and 4) professional fees. Total annual fixed costs are estimated by Freedman *(33)* to be from $274,000 to $448,000. Table 5-2 shows the charges which are necessary to cover the costs of DSA operation at a volume of 1,500 and 2,000 cases per year at several levels of fixed costs for a DSA facility.[1] These charges range from *$446* to *$648* per examination.

The most important determinants of the cost effectiveness of DSA, as calculated in tables 5-3 through 5-7, are charges and yield rates for DSA exams and charges for arteriograms which may be ordered to followup DSA findings. By varying the values of these three parameters, it is possible to conduct a sensitivity analysis of the cost effectiveness of DSA under various clinical and institutional patterns of operation.

Yield rates for DSA—the number of lesions identified per 100 DSA exams performed—are predicted to reach 80 percent for the examination of patients who previously would have received an arteriogram. This figure is comparable to the

[1]This case study, following Freedman (33), assumes that patient revenues will be approximately 80 percent of billed charges due to bad debts and cost-based reimbursements.

Table 5-2.—Estimated Charges for DSA Examinations

Total annual fixed costs[a]	supply Costs[a] per exam	Exams/year	Total cost/exam	Breakeven charge[b]	Professional fees[a]	Total charges/exam
$274,000	$100	1,500	$283	$353	$150	$503
		2,000	237	296		446
$318,000	100	1,500	312	390	150	540
		2,000	259	323		473
$360,000	100	1,500	340	425	150	575
		2,000	280	350		500
$404,000	100	1,500	369	462	150	612
		2,000	302	377		527
$448,000	100	1,500	399	498	150	648
		2,000	324	405		555

[a]Levels of fixed costs, supply costs, and professional fees are estimated on basis of information provided by Freedman (1982). Current supply costs are estimated in 1982 to average approximately $100 per DSA examination, allowing for a 20 percent waste and repeat study factor.
[b]Also following Freedman (1982), it is assumed that patient revenues will be approximately 60 percent of billed charges due to bad debts and cost-based reimbursements. If receipts after bad debt and acceptance of assignment (of fees by third-party payers) are expected to equal 60 percent of charges, the breakeven charge equals 1.25 times costs.

SOURCE: Office of Technology Assessment, following G. S. Freedman, "Economic Analysis of Outpatient Digital Angiography," *Applied Radio/ogy* 11(3): 29-38, 1982.

Table 5-3.—Estimates of the Cost Effectiveness of DSA
(with fixed charges for arteriography)[a]

Protocol	DSA exams	Lesions found	Arteriography exams	Total charges billed[b]	Cost-effectiveness indicators: Charge per lesion found	Cost-effectiveness indicators: Charge per patient examined
1 (arteriogram only)	0	80	100	$120,000	$1,500	$1,200
II (arteriogram if DSA positive)	100	80	80	(a) 140,600	1,758	1,406
				(b) 153,500	1,919	1,535
				(c) 160,800	2,010	1,608
III (arteriogram only for 50% of positive DSAs)	100	80	40	(a) 92,600	1,158	926
				(b) 105,500	1,319	1,055
				(C) 112,800	1,410	1,128
IV (arteriogram only for 10% of positive DSAs	100	80	8	(a) 54,200	678	542
				(b) 67,100	839	671
				(c) 74,400	930	744

[a]Arteriography charge: $11200
[b]DSA charges: a) S446, b) $575, c) $648.

SOURCE: Office of Technology Assessment. Arteriography charge estimated by G. S. Freedman, "Economic Analysis of Outpatient Digital Angiography," *Applied Radiology* 11(3): 29-38, 1982

yield of positive findings from conventional arteriography. The safety and efficacy of DSA in patient diagnosis will allow or encourage a much larger population to be examined than could be done previously with arteriography, however. It is estimated in the literature that the population at risk for carotid artery diseases is two to three times larger than that which can currently be screened by arteriography **(24,33,102).** Earlier, the argument for estimating the annual volume of DSA procedures at or near *237* per **100,000** population was made. This figure is more than seven times higher than the 33 per 100,000 estimated to be receiving arteriography at the present time. For this larger group, the yield of positive DSA findings is likely to be considerably less than the current yield of arteriography or DSA.

The yield rates of DSA for this expanded population are estimated to range from 25 percent upward (24,33). Tables 5-5 through 5-7 incorporate yield ratios of 25, 50, and 80 percent in the new populations to be screened with DSA.

Arteriography charges are set at $1,200 in Freedman's (33) study of the cost effectiveness of DSA. This corresponds closely with the charge of $1,120 at the University of Wisconsin reported by Detmer and colleagues (24). Therefore, in the

Table 5-4.—Estimates of the Cost Effectiveness of DSA
(with variable charges for arteriography)[a]

Protocol	DSA exams	Lesions found	Arteriography exams	Arteriography charge	Total charges billed[b]	Cost-effectiveness indicators: Charges per lesion found	Cost-effectiveness indicators: Charges per patient examined
I (arteriogram only)	0	80	100	$1,200	**$120,000**	**$1,500**	**$1,200**
II (arteriogram if DSA positive)	100	80	80	1,232	(a) 143,160	1,790	1,432
					(b) 156,060	1,951	1,561
					(C) 163,360	2,042	1,634
III (arteriogram only for 50% of positive DSAs)	100	80	40	1,306	(a) 96,840	,211	968
					(b) 109,740	,372	,097
					(c) 117,040	,463	,170
IV (arteriogram only for 100/0 of positive DSAs)	100	80	8	1,379	(a) 55,632	695	556
					(b) 68,532	857	685
					(C) 75,832	948	758

aThe variable charges for arteriography reflect the following assumptions:
1 Patient charges are set at a level such that actual patient receipts will just offset, or break even with, the costs of patient care at the current volume of procedures If patient receipts, after bad debts and acceptance of assignment, average 60 percent of billed charges, then the estimated breakeven cost per arteriogram is $960 (0.60 x $1200 current charge)
2 The cerebrovascular studies in which DSA may effectively replace arteriography represent about one-quarter of the current volume of arteriograms.
3 Approximately 50 percent of the long-run costs of arteriographic facilities are fixed
Given these assumptions, the estimated breakeven charge per arteriogram at any new volume of arteriography is equal to:

$$(0.80)\ \text{Breakeven arteriography charge} = \frac{\left(\text{100\% current volume}\right)\left(\text{\$480 fixed cost per exam}\right) + \left(\bar{x}\text{\% new volume}\right)\left(\text{\$480 variable cost per exam}\right)}{\text{\% new volume procedures}} \quad \text{—or—}$$

$$\text{Breakeven arteriography charge}\ (1.25) = \frac{\left(\text{100\% current volume}\right)\left(\text{\$480 fixed cost per exam}\right) + \left(\bar{x}\text{\% new volume}\right)\left(\text{\$480 variable cost per exam}\right)}{\text{\% new volume procedures}}$$

Where the new volume of arteriography is equal to the current volume of arteriography minus one-quarter the percentage reduction in cerebrovascular arteriography due to DSA substitution
bDSA charges a) $446, b)$575, c) $648

SOURCE: Office of Technology Assessment

calculations in tables 5-3 and 5-5, a fixed charge of $1,200 for arteriograms is used in calculating total imaging charges per patient examined and per lesion found.

It is reasonable to assume the DSA will replace a certain percentage of arteriography. As the volume of arteriograms changes, the charges necessary to cover the fixed capacity of arteriographic facilities must also vary. Fineberg (31) notes that only 5 to 15 percent of the costs of CT scanning are variable with volume, and variable costs of DSA appear to range from *25* to 35 percent of total costs. For arteriography, high fixed costs may be lowered considerably by the combination of DSA and arteriographic facilities and personnel. Thus, tables 5-4, 5-6, and 5-7 assume that 30 percent of all costs of arteriography are fixed and calculate the measures of cost effectiveness on the basis of anticipated new (reduced) charges for arteriograms.

It should be noted that utilization of arteriography may not decrease in terms of the absolute numbers of examinations performed. The use of arteriography depends on the acceptance of DSA by radiologists and clinicians as a substitute imaging procedure. Data in table 5-7 show that if the population examined for carotid artery disease expands to four times its current volume (i.e., from 100 to *400* DSA exams), it is very likely that the demand for arteriography will rise (and its cost per exam will fall). The clinical protocols developed by Freedman (33) are used in tables 5-3 through s-7 to estimate the “charges per lesion found” and “charges per patient examined” as DSA is partially substituted for arteriography in the diagnosis of carotid artery disease. At this time

Table 5-5.—Estimates of Cost Effectiveness of DSA for Expanded Population At Risk[a] With Variable Yield Rates for Positive Findings

					Cost-effectiveness indicators	
Protocol	DSA exams	Lesions found[b]	Arteriography exams	Total charges billed[c]	Charges per lesion found	Charges per patient examined
II (arteriogram if DSA positive)	200	A. 160	160	(a) $281,200	$1,758	$1,406
				(b) 307,000	1,919	1,535
				(C) 321,600	2,010	1,608
	200	B. 130	130	(a) 245,200	1,886	1,226
				(b) 271,000	2,085	1,355
				(C) 285,600	2,197	1,428
	200	c. 105	105	(a) 215,200	2,050	1,076
				(b) 241,000	2,295	1,205
				(C) 255,600	2,434	1,278
Ill (arteriogram only for 50% of positive DSAs)	200	A. 160	80	(a) 185,200	1,158	926
				(b) 211,000	1,319	1,055
				(C) 225,600	1,410	1,128
	200	B. 130	65	(a) 167,200	1,286	836
				(b) 193,000	1,485	965
				(C) 207,600	1,597	1,038
	200	c. 105	53	(a) 152,800	1,455	764
				(b) 178,600	1,701	893
				(C) 193,200	1,840	966
IV (arteriogram only for 10% of positive DSAs)	200	A. 160	16	(a) 108,400	678	542
				(b) 134,200	839	671
				(C) 148,800	930	744
	200	B. 130	13	(a) 104,800	806	524
				(b) 130,600	1,005	653
				(C) 145,200	1,117	726
	200	c. 105	11	(a) 102,400	975	512
				(b) 128,200	1,220	641
				(C) 142,800	1,360	714

[a]Assumes th. population at risk which can be safely studied will double in size (24). This is regarded as a minimum level of additional volume Of DSA procedures Performed.
[b]DSA yield ratios:
(A) 60 percent (if volume of procedures is assumed at current level)
(B) 50 percent
(C) 25 percent (Yield ratios of those procedures beyond the current volume, e.g., 100 procedures in this example. Hence, yield ratios in (B) and (C) are calculated at 60 percent for the first 100 procedures performed and at 50 percent and 25 percent, respectively, for all procedures performed beyond the initial 100,)
[c]DSA charges: a) $446, b) $575, c) $648. Arteriography charge: $11200

SOURCE: Office of Technology Assessment.

there is no simple level of substitution that seems most likely; instead, it appears that over time, substitution of DSA for arteriography will increase, but with no predictable upper limit.

Because the patterns of clinical use of DSA are difficult to predict, it is also difficult to estimate accurately the cost effectiveness of this new technology. Certain trends are evident from the data presented in tables 5-3 through 5-7, however:

- As DSA substitutes for arteriography in the diagnosis of carotid artery disease, the cost effectiveness of DSA increases, and total costs of diagnostic imaging are reduced.
- As the yield of positive findings with DSA decreases due to the application of this technology to a larger population of cases, the costs per patient decline, but the cost per lesion found rises.
- As the population examined for carotid lesions increases, total costs per diagnostic imaging are virtually certain to increase regardless of how effective DSA is or how much it replaces arteriography. That is, the intro-

Table 5.6.—Estimates of the Cost Effectiveness of DSA for a Population At Risk[a] With Variable DSA Yield Rates and Variable Arteriography Charges

Protocol	DSA exams	Lesions found[b]	Arteriography exams	Arteriography charge	Total charges billed[c]	Cost-effectiveness indicators: Charges per lesion found	Cost-effectiveness indicators: Charges per patient examined
II (arteriogram only if DSA positive)	200	A. 160	160	$1,122	(a) $268,720	$1,680	$1,344
					(b) 294,520	1,840	1,473
					(C) 309,120	1,932	1,546
	200	B. 130	130	1,158	(a) 239,740	1,844	1,199
					(b) 265,540	2,043	1,328
					(C) 280,140	2,155	1,401
	200	c. 105	105	1,193	(a) 214,465	2,043	1,072
					(b) 240,265	2,288	1,201
					(C) 254,865	2,427	1,274
III (arteriogram only for 500/0 of positive DSAs)	200	A. 160	80	1,232	(a) 187,760	1,174	939
					(b) 213,560	1,335	1,068
					(C) 228,160	1,426	1,141
	200	B. 130	65	1,258	(a) 170,970	1,315	855
					(b) 196,770	1,514	984
					(C) 211,370	1,626	1,057
	200	C. 105	53	1,280	(a) 157,040	1,496	785
					(b) 182,840	1,741	914
					(c) 197,440	1,880	987
IV (arteriogram only for 100/0 of positive DSAs)	200	A. 160	16	1,359	(a) 110,944	693	555
					(b) 136,744	855	684
					(c) 151,344	946	757
	200	B. 130	13	1,367	(a) 106,971	823	535
					(b) 132,771	1,021	664
					(c) 147,371	1,134	737
	200	c. 105	11	1,372	(a) 104,292	993	521
					(b) 130,092	1,239	650
					(C) 144,692	1,378	723

[a] Assumes the population at risk which can be safely studied will double in size (24) This is regarded as a minimum level of additional volume of DSA procedures performed
[b] DSA yield ratios
(A) 80 percent (if volume of procedures is assumed at current level)
(B) 50 percent
(C) 25 percent (Yield ratios of those procedures beyond the current volume, e g., 100 procedures in this example Hence, yield ratios in (B) and (C) are calculated at 80 percent for the first 1 00 procedures performed and at 50 percent and 25 percent. respectively, for all Procedures Performed beyond the initial 100)
[c] DSA charges a) $446 b) $575, c) $648

SOURCE Off Ice of Technology Assessment

duction of DSA is likely to represent an addition to the costs of health care in the treatment of carotid artery diseases.

- The variations in cost effectiveness and total costs of DSA due to changes in costs (and charges) of DSA and arteriographic facilities are often small relative to the variations caused by the patterns of DSA utilization.

Table 5-7.—Estimates of the Cost Effectiveness of DSA for a Population At Risk Expanded Four-Fold With Variable Yield Rates for Baseline Findings (with fixed charges for arteriography)[a]

Protocol	DSA exams	Lesions found[b]	Arteriography exams	Arteriography charge	Total charges billed[c]	Cost-effectiveness indicators: Charges per lesion found	Cost-effectiveness indicators: Charges per patient examined
II (arteriogram only if DSA is positive)	700	A. 560	560	$1,200	(a) $ 984,200	$1,758	$1,406
					(b) 1,074,500	1,919	1,535
					(C) 1,125,600	2,010	1,608
	700	B. 380	380	1,200	(a) 768,200	2,022	1,097
					(b) 858,500	2,259	1,226
					(c) 909,600	2,394	1,299
	700	C. 230	230	1,200	(a) 588,200	2,557	840
					(b) 678,500	2,950	969
					(c) 729,600	3,172	1,042
III (arteriogram only for 50% of positive DSAs)	700	A. 560	280	1,200	(a) 648,200	1,158	926
					(b) 738,500	1,319	1,055
					(c) 789,600	1,410	1,128
	700	B. 380	190	1,200	(a) 540,200	1,422	772
					(b) 630,500	1,659	901
					(c) 681,600	1,794	974
	700	C. 230	115	1,200	(a) 450,200	1,957	643
					(b) 540,500	2,350	772
					(c) 591,600	2,572	845
IV (arteriogram only for 10% of positive DSAs)	700	A. 560	56	1,200	(a) 379,400	678	542
					(b) 469,700	839	671
					(c) 520,800	930	744
	700	B. 380	38	1,200	(a) 357,800	942	511
					(b) 448,100	1,179	640
					(c) 499,200	1,314	713
	700	C. 230	23	1,200	(a) 339,800	1,477	485
					(b) 430,100	1,870	614
					(c) 481.200	2.092	687

[a]The fixed charges for arteriography correspond to current charges for the procedure in 1982-83 (33), assuming that arteriographic facilities are Operating at full Capacity or efficiency, The population examined with DSA, then referred for arteriography, will expand by a factor of 2 to 6 This will require additional arteriographic facilities which would also presumably operate at full capacity or efficiency in the long run

[b]DSA yield ratios:

(A) 80 percent (if volume of procedures is assumed at current level)

(B) 50 percent

(C) 25 percent (Yield ratios of those procedures beyond the current volume, e.g , 100 procedures in this example. Hence, yield ratios in (B) and (C) are calculated at 60 percent for the first 100 procedures performed and at 50 percent and 25 percent, respectively, for all procedures performed beyond the initial 100)

[c]DSA charges a) $446, b) $575, c) $648

SOURCE Off Ice of Technology Assessment

Appendixes

Appendix A. – Acknowledgments and Health Program Advisory Committee

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Appendix B.—Glossary of Terms and Acronyms

Glossary of Terms

Accuracy: The number of correct test results divided by the total number of tests performed. Diagnostic accuracy may vary with the prevalence of the disease in the population.

Aneurysm: A permanent abnormal blood-filled dilation of a blood vessel resulting from disease of the vessel wall.

Arterial lumen: The cavity of a tubular organ.

Arteriography: Visualization of an artery using photographs made with X-rays after the injection of radiopaque (impervious to the rays) material into the bloodstream.

Atherosclerosis: A chronic disease characterized by the deposition of fatty substances in the inner layer of the arteries.

Bruit: A sound or murmur heard in an organ, especially an abnormal one.

Carotid bifurcation: The division into two branches of the principal artery in the neck.

Cerebral infarction: An area of dead tissue in the cerebrum caused by a deficiency of blood due to functional constriction or actual obstruction of a blood vessel.

Cerebrovascular disease: A disease affecting or pertaining to the blood vessels of the cerebrum or brain.

Cholesterol: A steroid alcohol present in animal cells and body fluids, important in physiological processes, and implicated experimentally as a factor in arteriosclerosis.

Digital subtraction angiography (DSA): A radiologic tool used for the diagnosis of conditions pertaining to the internal structure of blood vessels. The procedure involves injecting a contrast medium into the veins and then monitoring the change of the medium as it passes through the veins. The computer subtracts the images before the injection from the images after the injection to attain a numerical representation of the arterial structure.

Diplopia: A vision disorder in which two images of a single object are seen because of unequal action of the eye muscles (also called "double vision").

Doppler device: A radar-like device used to measure the velocity of blood flow through the arteries.

Duplex scanning: The combination of the B-scan and the Doppler device. Using this method both the image of the blood vessel and the flow pattern at a given location can be determined.

Effectiveness: Same as efficacy except that it refers to "... average or actual conditions of use."

Efficacy: The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use.

Endarterectomy: Surgical removal of the inner layer of an artery when thickened and obstructed.

Energy subtraction: Using digital subtraction angiography to show changes in the contrast appearance of the artery at varying X-ray intensities.

Fibrin: A white insoluble protein formed from fibrinogen during the clotting of blood.

Hemorrhagic: Of or pertaining to a copious discharge of blood from the blood vessels,

Microemboli: A microscopic abnormal particle circulating in the blood.

Noninvasive technique: A diagnostic method that does not involve the penetration (by surgery or hypodermic needle) of the skin.

Occlusion: The blocking off or obstruction of blood flow through a vessel.

Periorbital ultrasonography: A diagnostic technique using ultrasonic waves to examine the orbit or the eye socket.

Peristalsis: Successive waves of involuntary contraction passing along the walls of the intestine or other hollow muscular structure and forcing the contents onward.

Platelet: A disk-shaped structure found in the blood of all mammals. It is known for its role in blood coagulation.

Prophylaxis: Measures designed to preserve health (as of society) and prevent the spread of disease.

Real-time ultrasound (B-scan): A device used to measure the anatomical structure of vessels by vibrations of the same physical nature of sound, but with frequencies above the range of human hearing.

Risk: A measure of the probability of an adverse or untoward outcome and the severity of the resultant harm to health of individuals in a defined population and associated with use of a medical technology applied for a given medical problem under specified conditions of use.

Safety: A judgment of the acceptability of risk in a specified situation.

Sensitivity: The number of positive test results divided by the number of patients that actually have the disease.

Specificity: The number of negative test results divided by the number of patients that actually have the disease.

Stenosis: A narrowing or constriction of a bodily passage or orifice.

Stroke: A condition caused by sudden lesions in the blood vessels of the brain. The lesions could be caused by hemorrhage, embolism or thrombosis. This condition is often followed by permanent neurological damage.

Temporal subtraction: Using digital subtraction angiography to show changes in the contrast appearance of the artery over time.

Transient ischemic attacks: A deficiency of blood in a part of the body, due to functional constriction or actual obstruction of a blood vessel.

Ulcerated plaques: Breaks in the yellowish plaque which is formed within the intima and inner media (innermost and middle coats of the blood vessels) of large and medium-sized veins.

Yield rates: The numbers of lesions found per population screened.

Glossary of Acronyms

DSA digital subtraction angiography
DHHS -- Department of Health and Human Services
TIA – transient ischemic attacks
CT scan — computer axial tomography
DRG – diagnosis related group
R&D – research and development

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