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Introduction and Summary

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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.