The American College of Radiology Strategy for Managing Incidental Findings on Abdominal Computed Tomography

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KEYWORDS

• Computed tomography • Incidental findings • Committee
• Recommendations

BACKGROUND: NEED FOR INCIDENTAL FINDINGS PROJECT

Incidental findings on radiographic studies have been available since the origin of diagnostic radiology. The discovery of such findings was often accepted as simply an unwanted, but unavoidable, byproduct of an important test. With the advent of cross-sectional imaging, the discovery of such findings became more frequent, and their recognition was usually believed to be beneficial by leading to early detection of subclinical disease, and probably to better outcomes.[1–3] However, in recent years, incidentalomas have generated heightened concern and even alarm.[4,5]

It is important to understand the meaning of the term incidental finding. An incidentaloma, as it is also known, may be defined as "An incidentally discovered mass or lesion, detected by CT, MRI, or other imaging modality performed for an unrelated reason."[6] Essentially, these masses or lesions represent findings that are detected but are unrelated to the primary objectives of the examinations.[7–10] However, many such incidental findings are of little importance because they are immediately recognized as unrelated to any condition that would threaten the patient's health. For example, an anomalous retroaortic left renal vein is a common anatomic variant. Many patients have findings indicating prior surgery or trauma but are unlikely to have any acute clinical significance. Although these findings may warrant reporting because they could affect future surgical planning or potentially be mistaken for more important abnormalities, they are not the subject of the remainder of this discussion.

There are several reasons why incidentalomas have evolved from a perceived advantage to a perceived problem. The frequency of incidental findings has markedly increased. The number of computed tomographic (CT) examinations performed in the United States skyrocketed from an estimated 21 million in 1998 to 61 million in 2006, which resulted in several factors, including self-referral by nonradiologists. As has been shown by several studies, nonradiologists tend to refer their patients for more radiographic tests when they have a direct or indirect financial interest in the revenue from the sites to which they refer.[11]

Another cost concern is that some radiologists see the identification of incidentalomas as an opportunity to increase referral business for CT, magnetic resonance (MR) imaging, or other expensive radiological tests, providing financial benefit in a fee-for-service environment that incentivizes increased workload.[12,13]

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Another reason for the increased frequency of incidental findings is that the spatial and contrast resolution of CT has improved substantially over the past 10 to 15 years. Therefore, incidental findings may be more likely to be observed on any single examination as well because many more CT scans are being performed. There has also been a markedly increased awareness of the costs of medical care, which has been associated with heightened political pressure to limit these costs. The increase in the use of CT itself has led to CT becoming a target of regulators and insurers. For example, in many regions, health insurers have implemented preauthorization for CT, MR imaging, and other expensive medical tests. Depending on the location and the insurer, this practice has measurably limited the approval for CT examinations, causing the use of this technique to decline or at least level off in number.[14] Nevertheless, this leveling off is still occurring at a rate higher than just 10 years ago.

The concern about incidental findings has also gradually increased because of support by many for using CT for screening for conditions such as lung cancer and colon polyps. For example, CT colonography has raised the concern among insurers and the federal government that its use, and therefore costs, will increase. The Center for Medicare and Medicaid Services, in a decision memorandum, indicated that one of the reasons that they were declining to approve CT colonography for screening for colon polyps in the Medicare population was the concern that the pursuit of extracolonic findings would substantially increase cost with uncertain benefits.[15]

Because of the paucity of data regarding the importance of reporting and following up incidental findings and the paucity of guidance for managing such findings, there is marked inconsistency in the approach to such findings. One of the few studies in which the performance of multiple experienced radiologists was tested regarding the reporting of incidental findings suggested only modest agreement.[16] There were substantial disagreements in this blinded study regarding both the detection of these findings and the beliefs regarding their need to be further evaluated. In addition, anecdotally, many primary care physicians and other clinicians have found that pursuing incidental findings has come to occupy more of their time and has distracted them from attending to activities that could provide greater benefits. Also, determining how to manage such findings can be confusing for referring physicians unless specific guidance is offered by the interpreting physician.

The fear of medicolegal consequences from underreporting incidental findings has been cited as an important source of requests for evaluating or following them. Because of the uncertainty about the importance of many of such findings, performing extra tests follows a philosophy of "better safe than sorry." In addition, reinforcing this perception is a prevalent belief within the medical culture itself, particularly within the United States, that medical uncertainty is unacceptable, especially because now there are more sophisticated tests to decrease that uncertainty.[17,18] However, with the limited information currently available and the great array of diagnostic possibilities, it is virtually impossible to calculate the probability that a given finding (eg, a mildly increased attenuation 2-cm liver lesion on a noncontrast CT examination) is likely to represent the early manifestation of a disease for which early intervention could improve the outcome.

The level of experience of readers as well as their philosophy is also likely to influence the nature and frequency of recommendations of the physician interpreting the CT study for additional studies, although the nature and magnitude of this effect is unclear. It is a common experience among academic body-imaging radiologists to encounter an excessive number of recommendations for further studies from radiology residents, who understandably do not have the experience to conclusively characterize incidental findings or appreciate their importance (or lack thereof). At the other end of the spectrum, highly experienced academic subspecialists in tertiary referral centers have often encountered cases in which initially subtle findings led to serious medical consequences. These findings heighten their concern and perhaps even falsely elevate their perception of the probability that an incidental finding encountered in a similar situation may be important. Again, although these effects of such differences in experience are unclear, it is highly probable that the level of experience of the interpreter plays a substantial role in the approach that radiologists take to how they report and make recommendations for managing incidentalomas.

COSTS AND CONSEQUENCES OF MANAGING INCIDENTAL FINDINGS

Supporting all these concerns are anecdotal observations and some retrospective and prospective studies on the benefits and costs of working up or following incidental findings. Among the largest populations of patients who have been studied for incidental findings are patients undergoing CT colonography for screening, for failed colonoscopy, or for symptoms or other medical findings suspicious for colonic disease.[7,10] There

is a wide variation in the projected costs of following such findings and there is little data to suggest how detecting and following such findings have affected outcome.

One example of the difficulty in understanding these effects is renal cell carcinoma (RCC). This condition has increased markedly in incidence since the advent of cross-sectional imaging, with about 61% of all cases of RCC being detected incidentally on CT scans performed for another indication. However, the overall death rate from RCC has changed little, despite a marked increase in early detection.

One of the reasons for this apparent discrepancy is the problem of overdiagnosis,[19,20] which is the occurrence of histologically confirmed cancerous masses, for which their natural behavior is unknown. Statistics suggest that in many cases, such cancers would never become symptomatic or clinically apparent in another way or would never cause the patient's life span or health to be altered. These cancers are commonly termed as those that "you would die with, rather than die from." For example, although approximately 0.5% of all patients die of RCC, studies suggest that RCC is found in as many as 2% of all autopsies. The problem is that when these masses are biopsied or removed and cancer is diagnosed histologically, it is not known which of them represent cancers that would grow to become symptomatic or to metastasize and which would remain indolent and asymptomatic. Therefore, by necessity, all such cancers must be treated as if they were potentially fatal. This problem of overdiagnosis is found not only with renal cancers but also with breast, lung, prostate, and thyroid cancers as well as other conditions.

Although it is a common public perception that early detection of disease, before the onset of symptoms, is highly desirable, it depends greatly on both the specific condition and at what stage the disease is detected. For example, there is no available data suggesting that early detection of lymphoma affects outcome. Detecting metastatic cancer of many types before the onset of symptoms is also unlikely to change the course of disease. Multiple attempts to achieve early detection of ovarian cancer with imaging has suggested that finding it at both an asymptomatic and curable stage with imaging is exceedingly difficult.[21,22]

Considerations of costs cannot be limited to the costs of the extra tests performed alone. In many cases, these tests have potential side effects and may lead to more invasive and risky procedures, such as biopsies or surgery. Naturally, in a small number of cases, complications from these procedures occur, which may lead to very high costs. A phenomenon termed "cascade syndrome" occurs in which one examination may lead to one or multiple incidental findings, which in turn lead to multiple other examinations and procedures sequentially. One example of this phenomenon was published in the *journal Radiology*,[23] described by the former Chairman of the Department of Radiology at Emory University as having occurred to himself. The investigator underwent a CT colonography; had renal, hepatic, and lung masses detected; and underwent additional CT scans, a positron emission tomography scan, a liver biopsy, and a video-aided thoracoscopy with wedge resection. He experienced excruciating postoperative pain, 5 weeks of recuperation, and charges more than $50,000. Fortunately, all findings were benign.

Another difficulty in interpreting the benefits from detecting disease before the onset of symptoms is that this detection may lead to a false impression of increased longevity. The period of detection before the onset of symptoms may be added to the overall survival time, suggesting that early detection has been beneficial. This phenomenon is termed "length bias."

Many believe that the value of early detection is primarily in the early detection of cancer. However, at least one study using a Monte Carlo simulation technique, suggests that most of the benefit may be in the early detection of abdominal aortic aneurysms (AAAs).[24] Although ruptured AAAs represent a relatively small percentage of total deaths, the value of early detection of AAAs is high because they are usually asymptomatic, and treatment with surgical bypass or endostent placement is highly effective in reducing deaths.[25]

FORMATION OF THE INCIDENTAL FINDINGS COMMITTEE OF THE AMERICAN COLLEGE OF RADIOLOGY

In 2005, I was appointed as the Chair of the Committee on Body Imaging under the Body Imaging Commission (at that time under the leadership of Dr N. Reed Dunnick) of the American College of Radiology (ACR). One of the core responsibilities of this committee is the development and ongoing review and revision of radiological guidelines documents in multiple areas. Because I began to hear presentations at national meetings from radiology leaders such as Dr Richard Gore and others on incidental findings in the abdomen, this helped reinforce my perception from my own busy academic practice that such incidental findings had not received adequate attention. I also appreciated from my

participation in these guidelines reviews awareness of the ACR Appropriateness Guidelines and from the efforts of organizations such as the Fleischner Society (which released guidelines for managing pulmonary nodules in 2005[26]) that an effort to generate a consensus on managing incidental findings on abdominal imaging could also be valuable.

In 2006, with the support of Dr Dunnick and the ACR, we organized an Incidental Findings Committee under the Body Imaging Commission, which is now led by Dr James A. Brink. We were able to assemble a group of thought leaders within radiology to address this problem, and we began to contemplate how such an effort could be organized and what its objectives would be. We agreed that there were little data on how incidental findings should be reported and managed and agreed that some method of consensus development would be a reasonable objective. In addition, the committee believed that although the primary product of the committee would be practical guidance for radiologists for managing incidental findings, other objectives might also be desirable, which included the development of common terminology and providing baseline parameters and recommendations for researchers to test.

PROCESS OF DEVELOPING RECOMMENDATIONS

Although it was believed that using a modified Delphi technique (such as used for the ACR Appropriateness Criteria) might be worthwhile, after discussion among the committee members and representatives of the ACR, it was concluded that such an approach might not be applicable to this effort and would require resources not available to us. Additional discussions occurred regarding whether physicians outside radiology would be included in this effort. It was agreed that acceptability of recommendations that might come from this committee was likely to be enhanced by the participation of nonradiologists. However, after considering this option, the committee agreed that to include nonradiologists would be difficult and time consuming and might also hinder progress by requiring the review and approval of nonradiology subspecialty professional organizations. Therefore, although considered important, we agreed that the involvement of nonradiologists should be deferred until the committee had produced its initial set of recommendations.

As the Chair of the Renal Subcommittee, Dr Stuart Silverman decided to approach the task of developing recommendations by developing an article reviewing and summarizing the available literature, which was completed and published in the *journal Radiology*.[27] This article provided the basis for the final recommendations released in the ACR Incidental Findings Committee White Paper.[28] Although this project was initiated within the ACR, multiple organizations have an interest in incidental findings in the abdomen. Therefore, in addition to the ACR, the Society of Computed Body Tomography and Magnetic Resonance (SCBT-MR), the Society of Gastrointestinal Radiology (SGR), and the Society of Uroradiology (SUR) were consulted. Most members of the committee are fellows or members of more than one of these organizations. Through the involvement of these societies, it was hoped that once recommendations were developed, the societies would actively endorse and assist in disseminating these recommendations.

Unfortunately, the progress of the committee was initially slow because of several obstacles of commitment and support and extended deliberations regarding the appropriate methods with which to proceed. However, in mid-2008, the issue of the potential approval of CT colonography for widespread reimbursement was attracting increased attention. It had already been perceived that the concern about the implications regarding incidental findings could potentially affect decisions in this area. At about this time, Dr James A. Brink assumed the leadership of the Body Imaging Commission. The concern about the effect of incidentalomas on CT colonography was expressed by Dr Elizabeth McFarland as the Chair of the ACR CT Colonography Committee and subsequently Dr Judy Yee, who succeeded as the Chair of this committee. All agreed that the effort to develop recommendations on incidental findings should be prioritized and accelerated.

WHITE PAPER TO COMMUNICATE RECOMMENDATIONS

If the committee were to develop formal guidelines analogous to the ACR Appropriateness Criteria, it would require a lengthy review and approval process by the ACR. Therefore, the commissioner, representatives of the ACR, and the committee agreed that the most efficient vehicle for codifying and disseminating guidance on incidental findings is a white paper.

Among the challenges facing the development of these recommendations was the concern that these recommendations should be broadly acceptable, easy to access, and straightforward

to understand and apply. To accomplish this objective, it was agreed that the white paper should illustrate recommendations in the form of tables or flowcharts, supported by more detailed text. Such tables proved difficult to construct, and the committee eventually decided to develop flowcharts. These flowcharts were patterned after flowcharts developed for managing incidental adrenal masses designed by Dr Boland and colleagues.[29]

The large potential scope of the project also required that the effort be narrowed. The organ systems that may contain incidental findings include the kidneys, liver, adrenal glands, pancreas, aorta, spleen, lymph nodes, gallbladder, biliary system, ovaries, and others. To optimize value, while keeping the task manageable, the committee decided to address the 4 organs with the largest number of potentially important incidental findings, the kidneys, liver, adrenal glands, and pancreas.

Also, to assure that the submission of the white paper is not excessively delayed, it was investigated whether the article could be submitted under the auspices of the ACR without having to go through the formal approval process of the college. It was determined that publishing such a white paper was acceptable, provided it was not claimed to represent formal guidelines or other type of formal statement of the ACR.

DISSEMINATING THE WHITE PAPER AND ENCOURAGING ITS USE

Among the core advantages of adopting these recommendations is the improved consistency of the approach among various practitioners. It has been well demonstrated in many environments in medicine and business that quality is enhanced by decreasing variations of practice. Therefore, it is hoped that by broadly distributing this scheme for managing incidental findings, greater uniformity can be achieved.

This article[28] has been published in the *Journal of the American College of Radiology*. Based on the participation of the ACR, the SCBT-MR, the SGR, and the SUR, these societies are being requested to actively endorse and promote the use of these recommendations to their membership. We also hope to increase awareness of this white paper through articles in appropriate newsletters and Web sites. We expect this work to attract attention and hope to solicit both positive and constructive critical comments to help refine these recommendations and possibly modify the process of their development.

POSSIBLE FUTURE TASKS FOR THE COMMITTEE

Improving Accessibility and Usability

Even when radiologists become aware of these recommendations, facilitating their integration into practice is challenging. Distilling this management scheme into flowcharts is intended to make this guidance more accessible and usable. It is hoped that in addition to having the entire white paper available near workstations, it is expected that the flowcharts will be printed and posted for easy reference. We will also encourage the participating societies to place links on their Web sites to the white paper or post other summary materials as we prepare them.

The complexity of these subjects makes even the graphic representation of the management scheme potentially confusing. Therefore, one consideration is to attempt to summarize recommendations in other formats that can be accessed online or provide a reorganized structured Web-based method to access the recommendations for patients.

Soliciting Comments and Formalizing the Process of Developing Recommendations

As discussed, this white paper is not intended to be a final document but a step in an evolving process. We will evaluate comments from users but also plan to enroll other interested clinical physicians in the process of revision. For example, we would expect to include nephrologists and urologists in addressing renal masses, hepatologists for liver masses, and so forth. At some point, it might also be reasonable to solicit the opinions and endorsement of nonradiology specialty societies. How the inclusion of nonradiologists proceeds will partly depend on the resources available through the ACR and other involved radiology societies.

Another avenue for promoting the use of these recommendations and guidance would be to attempt to acquire the formal approval of the ACR. As part of this effort, the ACR may wish to establish a specific consensus technology, such as the modified Delphi technique used for the ACR Appropriateness Criteria.

Although the white paper addresses several of the key organ systems in which incidental findings are found, there are many other potential types of incidental findings. These findings include ovarian cystic masses, lymphadenopathy, biliary dilation, abdominal aortic and other aneurysms, various gastrointestinal findings, and others. The committee, or another group, may wish to tackle such findings.

Encouraging Research to Test Our Recommendations

As noted, one of the core problems in managing incidental findings is the severe paucity of scientific research on the nature and natural history of these findings. The committee is well aware of the gaps and potential flaws in the approach we have proposed. One of the often-repeated desires of the committee has been that our efforts result in further research. We believe that by disseminating our recommendations for specific management approaches based on specific mass sizes and characteristics, researchers could test the parameters we propose for their efficacy. In addition, we believe that providing this structure for studying this problem could also help encourage various organizations to materially support research in this area.

SUMMARY

There has been a dramatically increased awareness of the substantial clinical challenges posed by incidental findings found on cross-sectional imaging. We believe that the efforts of the ACR Incidental Findings Committee are advancing the ability to create a consistent and rational approach to these findings. However, the committee also appreciates that our level of knowledge about the importance of these findings and how to appropriately manage them remains embryonic, and we are prepared to keep this issue in the consciousness of medical professionals and to assist in furthering knowledge about incidental findings.

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