related to the initial treatment strategy. . .; and (3) local Medicare administrative contractors will have discretion to cover (or not cover) within their jurisdictions any additional FDG PET scan for the therapeutic purposes related to the initial treatment strategy. . . .” The memo went on to state that “For any individual beneficiary the usefulness of any additional FDG PET scan for initial treatment planning might be affected by the beneficiary’s specific medical problem, the availability of results of other diagnostic tests, and the expertise of the interpreting physician. We believe in such situations that our local administrative contractors, who may more readily obtain this information, can make these determinations about any additional FDG PET scan for initial treatment planning within their jurisdictions. We do not believe that a national coverage determination is the most appropriate way to address coverage for any additional FDG PET scans for the therapeutic purposes related to the initial treatment strategy at this time.”

Centers for Medicare & Medicaid Services

FROM THE LITERATURE

Each month the editor of Newsline selects articles on diagnostic, therapeutic, research, and practice issues from a range of international publications. Most selections come from outside the standard canon of nuclear medicine and radiology journals. These briefs are offered as a monthly window on the broad arena of medical and scientific endeavor in which nuclear medicine now plays an essential role. We have added a special section on molecular imaging, including both radionuclide-based and other molecular imaging efforts, in recognition of the extraordinary activity and promise of diagnostic and therapeutic progress in this area. The lines between diagnosis and therapy are sometimes blurred, as radiolabels are increasingly used as adjuncts to therapy and/or as active agents in therapeutic regimens, and these shifting lines are reflected in the briefs presented here. We have also added a small section on noteworthy reviews of the literature.

MOLECULAR IMAGING/THERAPY

Imaging of Gene Therapy in NSCLC

Singh et al. from the University of Texas M.D. Anderson Cancer Center (Houston) reported on July 23 ahead of print in *Human Gene Therapy* on a study assessing whether a human somatostatin receptor subtype-2 (SSTR2)–based reporter gene can be used as a marker of gene transfer into non–small cell lung cancers (NSCLC), which account for 85% of lung cancer–related deaths in North America. In in vitro studies, SSTR subtype expression was assessed in 3 NSCLC cell lines using reverse transcription polymerase chain reaction. Lines were infected with an adenovirus containing hemagglutinin-A-tagged-SSTR2 (Ad-HA-SSTR2) or a control insert, and expression was assessed by immunologic techniques and binding to ^{111}In-octreotide. In in vivo studies, intrathoracic H460 tumors in mice were imaged at baseline with MR and, using ultrasound guidance, injected with Ad-HA-SSTR2 or a control virus. ^{111}In-octreotide was injected on d 2, and the mice underwent planar and SPECT imaging. Biodistribution was assessed with MR and γ-camera imaging as well as by assessment of excised organs/tumors. All 3 NSCLC cell lines expressed different SSTR subtypes, but none expressed SSTR2. However, after Ad-HA-SSTR2 infection, HA-SSTR2 expression was seen in all 3 cell lines using antibodies targeting the HA domain or ^{111}In-octreotide targeting the receptor domain. Intrathoracic tumors infected with Ad-HA-SSTR2 were clearly visible on γ-camera imaging, with expression quantified by biodistribution studies. Immunohistochemistry found that 78% of NSCLCs were negative for and 13% had low levels of SSTR2 expression. The authors concluded that “SSTR2-based reporters can serve as reporters of gene transfer into NSCLCs.” It is noteworthy that the study included the effective use of a combination of several nuclear techniques and MR imaging.

Human Gene Therapy

Peptides for Osteosarcoma Imaging

Sun et al. from the National Institutes of Health (Bethesda, MD), the Fourth Affiliated Hospital (Harbin Medical University, China), and the Jiangsu Institute of Nuclear Medicine (Wuxi, China) reported in the August 15 issue of *Clinical Cancer Research* (2010;16:4268–4277) on a study of phage display screening for peptides that bind specifically to osteosarcoma cells. From a phage display peptide library of 2.7×10^9 displayed peptides, 1 peptide was enriched after 4 rounds of in vitro selection in 143B osteosarcoma tumor cells. Both the peptide and a phage clone displaying the peptide were conjugated with fluorescent dyes for in vitro cell and ex vivo tumor tissue staining. The peptide was labeled with ^{18}F for PET imaging, and cell uptake and biodistributions studies were performed with an ^{18}F-labeled osteosarcoma-specific peptide. The dominant sequence isolated was ASGALSPSRLDT, which was named OSP-1. OSP-1 was found to have significant similarities to the heparinase II/III family protein, which binds and reacts with heparan sulfate proteoglycans. Fluorescence staining indicated that fluorescein isothiocyanate-OSP-1-phage or Cy5.5-OSP-1 had high binding with a panel of osteosarcoma cell lines, much greater than binding observed in several other experimental cell types. ^{18}F-OSP-1 had significantly higher ac-

cumulation in 143B tumor cells both in vitro and in vivo than did ^{18}F-OSP-S. The authors concluded that these data suggest that "OSP-1 peptide is osteosarcoma specific, and the binding site of OSP-1 might be related to heparan sulfate proteoglycans," so that "appropriately labeled OSP-1 peptide has the potential to serve as a novel probe for osteosarcoma imaging."

Clinical Cancer Research

Angiogenic Therapy Imaging with Nanoparticles

In the August issue of *Magnetic Resonance in Medicine* (2010;64:369–376), Winter et al. from Washington University (St. Louis, MO) reported on a study investigating whether MR molecular imaging with $\alpha_v\beta_3$ integrin–targeted perfluorocarbon nanoparticles can detect neovascular response in angiogenic therapy. The study was conducted in hypercholesterolemic rabbits that underwent femoral artery ligation, followed in 1 group of animals by no treatment and in the other by angiogenic therapy with dietary L-arginine. At d 10, all rabbits underwent MR imaging that showed increased signal enhancement in L-arginine–treated animals. Specifically targeted nanoparticles showed MR signal enhancement 2 times higher than nontargeted particles, effectively showing improved identification of angiogenic vasculature with biomarker targeting. Angiography performed at d 40 showed that L-arginine treatment increased development of collateral vessels, results that were confirmed by histologic staining of muscle capillaries showing a denser pattern of microvasculature in L-arginine–treated animals. The authors concluded that "the clinical application of noninvasive molecular imaging of angiogenesis could lead to earlier and more accurate detection of therapeutic response in peripheral vascular disease patients, enabling individualized optimization for a variety of treatment strategies."

Magnetic Resonance in Medicine

Biomarker of Response to Radiation

Wang et al. from Vanderbilt University (Nashville, TN) reported on August 11 in the online journal *PLoS One* on a study expanding previous work on a hexapeptide (HVGGSSV) that showed potential as a molecular imaging probe to distinguish tumors responding to ionizing radiation and/or tyrosine kinase inhibitor treatment from those that do not show a response. The current in vivo and in vitro studies looked at the biological bases of the HVGGSSV peptide binding within irradiated tumors. Initial results indicated that Tax interacting protein 1 (TIP-1) is a molecular target that enables selective binding of the HVGGSSV peptide within irradiated xenograft tumors. Optical imaging and immunohistochemistry indicated that a TIP-1 specific antibody showed biodistribution similar to that of the peptide in tumor-bearing mice. The TIP-1 antibody blocked the peptide from binding within irradiated tumors. In vitro studies on both human and mouse lung cancer cells showed that intracellular TIP-1 relocated to the plasma membrane surface within the first few hours after radiation exposure and before onset of treatment-associated apoptosis. TIP-1 relocation onto the cell surface was associated with reduced proliferation and enhanced susceptibility to subsequent radiation treatment. The authors concluded that these results suggest "that imaging of the radiation-inducible TIP-1 translocation onto the cancer cell surface may predict the tumor responsiveness to radiation in a time-efficient manner and thus tailor radiotherapy of cancer."

PLoS One

THERAPY

RIT as Antifungal Treatment

In the August 15 issue of the *Journal of Infectious Diseases* (2010;202:633–637), Bryan et al. from the Albert Einstein College of Medicine (Bronx, NY) and the Institute for Transuranium Elements (Karlsruhe, German) reported on a comparison of the antifungal efficacy of radioimmunotherapy (RIT) with that of amphotericin B in experimental cryptococcal infection. The study was conducted in AJ/Cr mice injected intravenously with either nonmelanized or melanized C. neoformans cells. One group of infected mice was left untreated for 24 h after infection, and the other was treated with ^{213}Bi-18B7 antibody, amphotericin B, or both. Melanization before infection was not found to increase resistance of C. neoformans to RIT. ^{213}Bi-18B7 treatment was found to almost entirely eliminate colony-forming units from lung and brain; amphotericin B did not decrease the number of colony-forming units compared with controls. The authors concluded that "RIT is more effective than amphotericin B against systemic infection with C. neoformans."

Journal of Infectious Diseases

^{90}Y RIT in NHL

Morschhauser from the Universitaire de Lille (France) and an international consortium of researchers reported in the August 10 issue of the *Journal of Clinical Oncology* (2010;29:3709–3716) on a multicenter phase I/II study of anti-CD22 fractionated radioimmunotherapy (RIT) in non-Hodgkin lymphoma (NHL). The study included 64 patients with relapsed/refractory NHL (including 17 who had undergone previous autologous stem cell transplantation [ASCT]) who underwent 2 or 3 weekly infusions of ^{90}Y-epratuzumab tetraxetan (humanized anti-CD22 antibody). Results were characterized as objective, complete, and complete but unconfirmed responses, and progression-free survival was determined. The authors found that at a maximum total ^{90}Y dose of 45 mCi/m^2, grade 3 and 4 hematologic toxicities were reversible to grade 1 in patients with <25% bone marrow involvement. The overall objective response rate was 62%, and progression-free survival was 9.5 mo. Patients who had not undergone previous ASCT had higher objective response rates of 71% across all NHL

subtypes and the range of ^{90}Y doses, even in those who had been refractory to their last anti-CD20-containing treatments. Patients who had undergone previous ASCT received lower RIT doses and achieved objective response rates of 41%. Patients with follicular lymphoma saw objective response rates and median progression-free survival times increase directly with ^{90}Y dose, reaching 100% and 24.6 mo, respectively, at the highest dose levels. Patients with follicular lymphoma refractory to previous anti-CD20-containing therapy achieved 90% objective response rates and a median progression-free survival of 21.5 mo. These data led to the conclusion that in future studies of fractionated anti-CD22 RIT with high total doses of ^{90}Y, the recommended dose should be 20 mCi/m^2 × 2 wk.

Journal of Clinical Oncology

EGFR-Targeted RIT

In the August issue of *Molecular Cancer Therapeutics* (2010;9:2297–2308), Liu et al. from Peking University (China) reported on mouse studies of epidermal growth factor receptor (EGFR)–targeted radioimmunotherapy (RIT) of human head and neck cancer xenografts using ^{90}Y-labeled fully human monoclonal antibody panitumumab. Panitumumab was recently approved by the U.S. Food and Drug Administration for treatment of patients with metastatic colorectal cancer. The authors conducted biodistribution and planar γ imaging studies using ^{111}In-DOTA-panitumumab in a UM-SCC-22B tumor model. Tumor uptake of ^{111}In-DOTA-panitumumab was 26.10 ± 4.93, 59.11 ± 7.22, 44.57 ± 9.80, 40.38 ± 7.76, and 14.86 ± 7.23 %ID/g of tissue at 4, 24, 72, 120, and 168 h after injection, respectively. Immunotherapy with unlabeled panitumumab resulted in no significant antitumor effect. RIT with even a single dose of 100 μCi ^{90}Y-DOTA-panitumumab caused significant tumor growth delay and improved survival times. A single dose of 200 μCi ^{90}Y-DOTA-panitumumab resulted in almost complete tumor regression by d 46 after treatment. Histopathology confirmed this efficacy and documented limited systemic toxicity. The authors concluded that the "high tumor uptake and prolonged tumor retention, as well as effective therapy, reveal that ^{90}Y-DOTA-panitumumab may be a promising radioimmunotherapeutic agent to treat EGFR-positive solid tumors."

Molecular Cancer Therapeutics

^{90}Y-RIT in Pretreated B-Cell Lymphoma

Zinzani et al. from the University of Bologna (Italy) reported in the August 1 issue of *Clinical Lymphoma, Myeloma, and Leukemia* (2010;10: 258–261) on a retrospective long-term outcomes study of ^{90}Y-ibritumomab tiuxetan as a single agent in patients with pretreated B-cell lymphoma. The authors reviewed their hospital's clinical database and identified 57 patients previously treated with at least 1 rituximab-containing chemotherapy who were subsequently treated with ^{90}Y-ibritumomab tiuxetan radioimmunotherapy (RIT). The median number of pretreatments was 3 (range, 1–9). Forty-six patients had stage III/IV disease (31 with bone marrow involvement), and 6 had bulky disease. Histologic results indicated that 53 patients had follicular lymphoma, 2 had marginal zone lymphoma, and 2 had small lymphocytic lymphoma. The overall response rate to ^{90}Y-ibritumomab tiuxetan RIT was 93% (53/57), with a complete response rate of 70% (40/57). At the time of publication, 65% (26/40) of patients with a complete response rate remained in continuous complete response at a median follow-up of 20 mo (range, 10–42 mo). All patients who achieved a continuing complete response had follicular lymphoma. Twenty-one of these had stage III/IV disease, 12 of the 26 had been heavily pretreated (≥3 times), and 2 had undergone autologous stem cell transplantation. No grade 4 extrahematologic toxicity was noted. The authors concluded that this study confirmed "the safety and high efficacy of ^{90}Y-ibritumomab tiuxetan RIT in heavily pretreated follicular lymphoma patients, with the possibility of having a subset of long-term responders."

Clinical Lymphoma, Myeloma, and Leukemia

^{213}Bi RIT in NHL

In an article e-published on August 11 ahead of print in *Blood*, Park et al. from the University of North Carolina (Chapel Hill) reported on ^{213}Bi RIT to target and treat minimal residual disease in non-Hodgkin lymphomas (NHLs) expressing CD20. Mice were injected with anti-CD20 1F5(scFv)(4)SA fusion protein or a control fusion protein, followed by a dendrimeric clearing agent and ^{213}Bi-DOTA-biotin. After 90 min, tumor uptake for 1F5(scFv)(4)SA was 16.5 ± 7.0 %ID/g compared with 2.3 ± 0.9 %ID/g for the control fusion protein. Mice treated with anti-CD20 pretargeted radioimmunotherapy (RIT) and 600 μCi ^{213}Bi-DOTA-biotin showed marked tumor growth delays at 19 d compared with controls. Median survival for the 1F5(scFv)(4)SA-treated group was 90 d and for the control fusion group was 23 d. No treatment-related mortalities were noted. The authors concluded that this study demonstrated "the favorable biodistribution profile and excellent therapeutic efficacy attainable with ^{213}Bi-labeled anti-CD20 pretargeted RIT."

Blood

DIAGNOSIS

PET and PET/CT in Papillary Thyroid Carcinoma

Miller et al. from the University of California at Los Angeles reported on July 27 ahead of print in *Head and Neck* on the results of a statistical metaanalysis and literature review of PET and PET/CT evaluation for recurrent papillary thyroid carcinoma. The authors found that using a fixed effect model, the combined sensitivity of PET and PET/CT was 77%, a figure that rose to 82% using the random effects model. Specificity was 85% and 84% with the 2 models, respectively. Meta-regression

was performed and determined that ^{131}I negativity was not correlated with PET sensitivity or specificity. The authors described this as the "first study to examine papillary thyroid carcinoma independently of other subtypes of well-differentiated thyroid carcinoma."

Head and Neck

Cardiovascular Irregularities in Young Diabetics

Naskret et al. from the Poznan University of Medical Sciences (Poland) reported ahead of print in the July 24 issue of *Microvascular Research* on a study of albuminuria and vascular endothelial growth factor (VEGF) as early markers of cardiovascular disturbances in young type-1 diabetic patients. The authors assessed myocardial perfusion by means of noninvasive diagnostic methods and measurement of plasma concentrations of VEGF in 41 patients (23 females, 18 males; ages 30 ± 7.6 y) with a duration of type 1 diabetes of 15.2 ± 5.5 y. Initial testing indicated that 17 patients (10 females, 7 males) showed microalbuminuria and 24 (13 females, 11 males) did not. All participants underwent 24-h ECG evaluation, an exercise treadmill test, echocardiologic evaluation with dobutamine and atropine challenge, and SPECT at rest and after dipyridamol induction of ischemia. All exercise and stress ECG tests were negative. The authors found significant differences between microalbuminuric and normoalbuminuric participants in duration of exercise tests (586.9 ± 110.5 and 664.9 ± 133.2 s, respectively), performed work (11.4 ± 1.6 and 12.6 ± 1.8 METs, respectively), achieved pulse limits (89.1 ± 3.6 and 92.6 ± 5.2%, respectively), rest ejection fraction (55.8 ± 8.7 and 62.0 ± 4.4%, respectively), abnormal changes in SPECT (53% and 21%, respectively), and VEGF concentrations (101.5 ± 7.8 and 75.15 ± 16.5 pg/mL, respectively). The presence of retinopathy increased 12-fold the probability of significant changes on SPECT and in nephropathy. The authors concluded that "asymptomatic patients with long-lasting type 1 diabetes may have disturbances in myocardial perfusion" especially when these patients have microalbuminuria.

Microvascular Research

^{11}C-PIB PET and AD Staging

In an article e-published on August 6 ahead of print in the *Journal of Alzheimer's Disease*, Hatashita and Yamasaki from the Shonan-Atsugi Hospital (Japan) reported on a study designed to determine whether ^{11}C-PIB PET can detect amyloid deposition at different clinical stages of Alzheimer disease (AD) and preclinical dementia. The study included 214 individuals (56 with AD, including 11 with moderate AD, 22 with mild AD, and 23 with very mild AD; 58 with mild cognitive impairment; and 100 healthy control participants) who underwent cognitive testing and 60-min dynamic ^{11}C-PIB PET imaging 35–60 min after injection. Co-registered MR imaging was used to define regions of interest, and distribution volume ratios (DVRs) of tracer retention were determined. All patients with AD showed a significant increase in tracer retention in cortical areas. Mean DVRs in patients with moderate AD indicated significantly higher tracer retention than in amyloid-negative healthy participants. DVRs in patients with very mild and mild AD were 2.32 ± 0.45 and 2.34 ± 0.42, respectively, similar to rates in moderate AD. By contrast, 48% of individuals with mild cognitive impairment showed a typical AD-like pattern with DVR values of 2.07 ± 0.34. Eighteen percent of controls had typical AD-like patterns with DVR values of 2.06 ± 0.28. The incidence of AD among the 53 amyloid-positive patients aged 75 y or older increased significantly to 74%, whereas that of amyloid-positive healthy participants decreased by only 9% and that of amyloid-positive patients with mild cognitive impairment decreased by 17%. The authors concluded that the study was able to identify prodromal AD and AD dementia based on cognitive function and amyloid deposition by ^{11}C-PIB PET imaging. Of note, "cortical amyloid deposition could be detected at preclinical stages of AD."

Journal of Alzheimer's Disease

SPECT and Neuronal Viability in TBI

Koizumi et al. from Yamaguchi University School of Medicine (Japan) reported on August 4 ahead of print in the *Journal of Cerebral Blood Flow and Metabolism* on the use of ^{123}I-iomazenil SPECT to assess recovered neuronal viability in patients after traumatic brain injury (TBI). The study included 12 patients with cerebral contusion who underwent ^{123}I-iomazenil SPECT within 1 wk after TBI. After conventional treatment, patients underwent repeat imaging to investigate changes in tracer distribution in the cortex in the chronic phase. A decrease in accumulation of the radioligand for the central benzodiazepine receptor in the cortex corresponded to the contusion as assessed by CT and MR imaging in the acute phase in all patients. In 9 of 12 patients, SPECT images in the chronic phase showed that areas with a decreased distribution of ^{123}I-iomazenil were "remarkably reduced" in comparison with images obtained in the acute phase. Both CT and MR in the chronic stage showed a normal appearance of the cortex morphologically in those areas in which the binding potential of ^{123}I-iomazenil recovered. Reduced binding potential of the radioligand for the central benzodiazepine receptor has been considered to be an irreversible reaction; however, in this study, ^{123}I-iomazenil accumulation in the cortex after TBI was found to recover in the chronic phase in several patients. The authors concluded that ^{123}I-iomazenil SPECT "may have a potential to disclose a reversible vulnerability of neurons following TBI."

Journal of Cerebral Blood Flow and Metabolism

REVIEWS

Review articles provide an important way to stay up to date on the latest topics and approaches by providing

valuable summaries of pertinent literature. The Newsline editor recommends several reviews accessioned into the PubMed database in late July and August. In an article e-published on August 12 ahead of print in *Antiviral Research*, Bray et al. from the National Institutes of Health provided an overview of "Radiolabeled antiviral drugs and antibodies as virus-specific imaging probes" using PET and SPECT techniques. van Dongen and Vosjen from the VU University Medical Center (Amsterdam, The Netherlands) reviewed on August 14 ahead of print in *Cancer Biotherapy and Radiopharmaceuticals* "Immuno-positron emission tomography: shedding light on clinical antibody therapy." Heidenreich et al. provided an article on "Imaging studies in metastatic urogenital cancer patients undergoing systemic therapy: recommendations of a multidisciplinary consensus meeting of the Association of Urological Oncology of the German Cancer Society" in the July issue of *Urologia Internationalis* (2010;85:1–10). In a review e-published on August 3 ahead of print in *Bone*, Snoeks et al. from Leiden University Medical Center (The Netherlands) reviewed "Optical advances in skeletal imaging applied to bone metastases." Cerchia and de Franciscis from the Istituto per l'Endocrinologia e l'Oncologia Sperimentale del CNR (Naples, Italy) on August 16 reported ahead of print in *Trends in Biotechnology* on advances in "Targeting cancer cells with nucleic acid aptamers." Hu et al. from Northwestern University (Evanston, IL) summarized advances in "High-performance nanostructured MR contrast probes" on August 6 ahead of print in *Nanoscale*. Tolmachev et al. from Uppsala University (Sweden) described on July 26 ahead of print in *Lancet Oncology* the prospects and challenges of "Radiolabelled receptor-tyrosine-kinase targeting drugs for patient stratification and monitoring of therapy response."

Erratum

In the August issue of Newsline, the final sentence of the literature brief summarizing an article in the *British Journal of Cancer* by Ströbel et al. on sunitinib in metastatic thymic carcinomas should have ended with the following sentence: "The authors concluded that 'sunitinib is an active treatment for metastatic thymic carcinomas' and that 'a panel of molecular analyses may be warranted for optimal patient selection.'" The Newsline editor thanks sharp-eyed reader Ted Silberstein, MD, for pointing out the erroneous substitution of the word "thyroid" in that sentence.

(Continued from page 16N)

Conclusion

PET utilization increased substantially after expansion of insurance coverage in Taiwan. However, PET examinations still accounted for only a small fraction of noninvasive diagnostic imaging studies performed. Although regional levels of PET utilization were commensurate with oncologic burden, significant regional variations in patterns of utilization were noted.

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