

# INTERNET NEWS

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## FDA approves Lu-177 PSMA-617 for prostate cancer treatment

by Will Morton, AuntMinnie.com staff writer

March 23, 2022 -- The U.S. Food and Drug Administration (FDA) has approved lutetium-177 (Lu-177) prostate-specific membrane antigen radioligand therapy (Pluvicto, Novartis) for the treatment of patients with metastatic prostate cancer.

The radiopharmaceutical drug is indicated for adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer who have previously received other anticancer therapies, such as androgen receptor therapy or taxane-based chemotherapy.

In addition, the FDA approved Novartis' kit (Locametz) for the preparation of the radiotracer gallium-68 (Ga-68) PSMA, which is used in PET imaging to identify metastatic prostate cancer tumors.

Prostate cancer is the second most common cancer in men. More than 248,000 cases of prostate cancer and approximately 34,000 deaths are projected in the U.S. in 2022.

Lu-177 PSMA-617 was tested in a phase III clinical trial in 800 men with PSMA-positive prostate cancer that had progressed despite standard treatments.

Approximately 38% of men had a reduced risk of death and a 60% reduced risk of progression when treated with Lu-177 PSMA-617, according to the company.

Lu-177 PSMA-617 is a radioligand therapy that consists of a targeting compound (PSMA-617) that binds to prostate cancer cells and a radioactive isotope (lutetium-177) that inhibits tumor growth.

The Society for Nuclear Medicine and Molecular Imaging (SNMMI) applauded the FDA's approval of the drug, noting that the new therapy relies on PET scans to identify and treat patients whose metastatic prostate cancers express PSMA.

"We are proud of the society members who contributed substantially to this new theranostic paradigm, as well as all of the authors who published articles on this therapy in *The Journal of Nuclear Medicine*," said SNMMI President Dr. Richard Wahl in a news release.

The FDA granted priority review for Lu-177 PSMA-617 in September 2021 based on positive data from the multicenter phase III VISION study, which measured overall survival and progression-free survival in metastatic castration-resistant prostate cancer patients whose disease progressed despite treatment.

The SNMMI will provide guidance and support to physicians and patients as Lu-177 PSMA-617 becomes readily available, Wahl added.



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## **A issues warning on iodinated contrast use in young kids**

Brian Casey, AuntMinnie.com staff writer

March 30, 2022 -- The U.S. Food and Drug Administration (FDA) has added a new warning to the prescribing information for iodinated contrast media, advising of the health risk of contrast use in children younger than 3 years who have thyroid issues.

Effective March 30, the FDA's warning pertains to the use of iodinated contrast media in young children with an underactive thyroid or a temporary decrease in thyroid hormone levels. The health risk specifically pertains to children who are given contrast as an injection through an artery or vein.

The FDA's warning notes that certain young children are at an increased risk from the use of iodinated contrast, including those who are newborns or have very low birth weight, prematurity, or the presence of cardiac or other conditions such as those requiring care in neonatal or pediatric intensive care units.

What's more, the agency said that children with cardiac conditions could be at the highest risk because they often require high doses of contrast during invasive cardiac procedures.

The FDA advised that clinicians administering iodinated contrast media to children younger than 3 consider monitoring thyroid function within three weeks after administration, in particular for the possibility of hypothyroidism or a temporary decrease in thyroid hormone levels. This advisory applies to term and preterm neonates and children with certain underlying conditions.

If thyroid dysfunction is detected in these children, clinicians should treat the patients and monitor thyroid function to avoid cognitive and developmental problems in the future. The FDA also advised that adverse events be reported to its database.



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## **CT shows that antithrombotics don't boost brain bleed frequency**

By Kate Madden Yee, AuntMinnie.com staff writer

March 25, 2022 -- Head CT shows that antithrombotics don't boost incidence of brain bleeds in patients who have sustained a ground-level fall -- though they may cause the hematoma to expand, according to March 24 research published in the [\*American Journal of Roentgenology\*](#).

The findings could help clarify whether follow-up CT is indicated in patients who have fallen and are also on antithrombotics, wrote a team led by Dr. Zeynep Vardar of the University of Massachusetts Medical Center in Worcester.

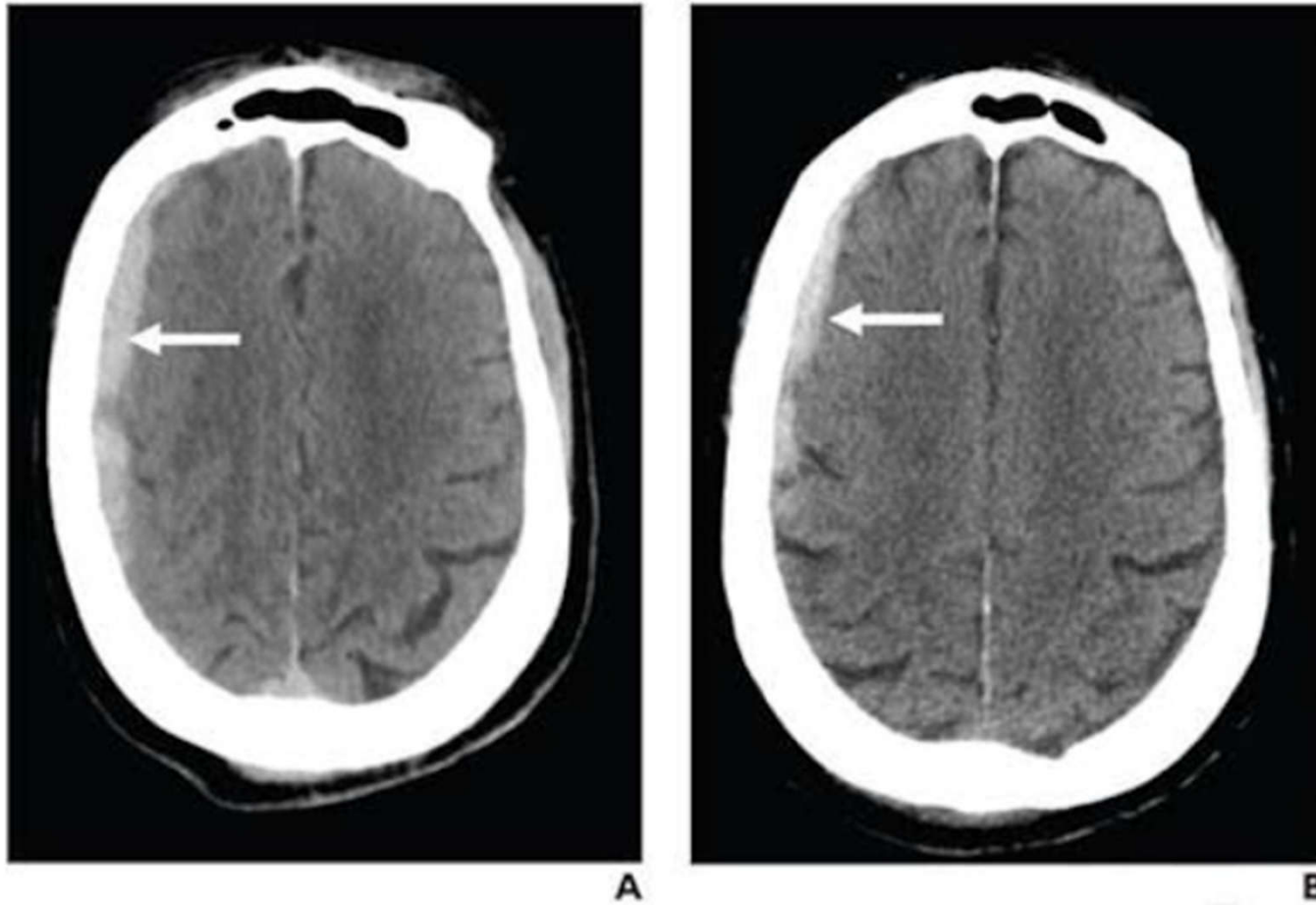
Various imaging recommendations have been suggested for patients with antithrombotic use who present with trauma," the team wrote. "Some authors recommend imaging regardless of whether the patient experiences loss of consciousness or amnesia, while others suggest avoiding imaging in anticoagulated patients who have normal Glasgow coma scale and no focal neurologic deficit."

Ground-level falls are common in older people, with an incidence of 30% per year in those over 65 and 50% in those over 80, the team explained. Combine this propensity with the fact that elderly people are also more likely to be taking antithrombotic medication, and it's no wonder that emergency departments are treating more patients who have fallen and are also on antithrombotics.

Ground-level fall is traditionally considered to represent low-energy trauma that is potentially associated with minor head trauma," the researchers wrote. "However, minor head trauma may lead to substantial head injuries in patients on antithrombotic therapy, for example causing traumatic intracranial hemorrhage (tICH) by either direct impact or indirect force."

Vardar and colleagues sought to assess the frequency of traumatic head injury in patients on antithrombotic medication presenting in the emergency department after a ground-level fall (Glasgow Coma Scale  $\geq$  14 and no nerve, spinal, or brain function deficit). The study included 1,630 patients who underwent head CT scans due to a fall between January and December 2020. The head CT exams were reviewed for brain bleeds; any follow-up exams were reviewed for hematoma expansion.





*15-year-old patient, not on antithrombotic therapy, presenting to emergency department after ground-level fall (Glasgow Coma Scale of 15). Patient had no focal neurological deficit. (A) Axial slice from initial noncontrast head CT shows right frontoparietal subdural hematoma (arrow); hematoma was classified as exhibiting both regional mass effect and midline shift (not shown). (B) Axial slice from noncontrast head CT performed eight hours later shows stable size of hematoma (arrow). Patient was discharged home in stable condition two days later. Images and caption courtesy of the American Roentgen Ray Society.*

The group found that frequency of brain bleeds in patients who had experienced these types of falls but had good neurological status on presentation to the emergency department did not differ significantly between individuals on antithrombotic therapy and those not on it (4.4% vs. 3.1%,  $p = 0.24$ ). But patients on antithrombotic medication did have increased incidence of hematoma expansion on follow-up head CT compared to those who were not on the medication (26.2% vs. 4.8%,  $p = 0.04$ ).

The results may help clarify which patients need follow-up head CT in this situation, the authors noted.

[Our] findings suggest adopting similar strategies for initial imaging evaluation by head CT in the two groups [i.e., those patients who are on antithrombotics and those patients who are not]," they wrote. "However, while early follow-up head CT should be routinely performed in patients on antithrombotic therapy with tICH systemic early imaging follow up may not be required in patients with tICH not on antithrombotic therapy."



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## Preoperative MRI benefits women with triple-negative breast cancer

by Kate Madden Yee, AuntMinnie.com staff writer

March 25, 2022 -- Women with triple-negative breast cancer who undergo preoperative MRI before breast-conserving surgery have lower rates of disease recurrence and reexcision, according to a study published March 18 in the [\*Annals of Surgical Oncology\*](#).

The findings are good news for women dealing with this particular type of aggressive cancer, wrote the research team led by Dr. Laura Burkbauer, who was at the University of Pennsylvania in Philadelphia at the time of the study and is now at University of North Carolina in Chapel Hill.

"Preoperative MRI has not been found to improve surgical outcomes in patients undergoing breast-conserving surgery," the group wrote in a statement it shared with *AuntMinnie.com*. "However, previous studies have not examined the utility of preoperative MRI in patients with aggressive tumor subtypes such as triple-negative breast cancer, and there is some suggestion that MRI may improve local control in these patients."

Some consider breast MRI to be the modality with the highest sensitivity for identifying breast cancer, performing better than mammography or ultrasound -- a particular benefit for women with triple-negative breast cancer, which mammography can miss. In fact, compared with receptor-positive breast cancers, "mammography is less effective at detecting triple-negative breast cancer with 9% to 18% showing no mammographic evidence of disease," the group wrote.

And women with triple-negative breast cancer have local recurrence rates of 8.8% (median follow-up, 61 months) -- seven times higher than the rate for hormone receptor-positive breast cancers.

"There is reason to think that patients with triple-negative breast cancer, in particular, may benefit from use of preoperative MRI," Burkbauer and colleagues explained.

The team conducted a study that included 648 women with triple-negative breast cancer who had breast-conserving surgery between 2009 and 2018. It then compared demographic and clinical characteristics between women who had preoperative MRI (292, or 45.1%) and those who did not (356, or 54.9%).

- Both local recurrence and re-excision rates were lower in the cohort of women who had preoperative MRI compared with those who did not undergo MRI before surgery.

**Recurrence and re-excision rates in women with triple-negative breast cancer depending on preoperative MRI**

Measure	No preoperative MRI	Preoperative MRI
Local recurrence rate	21.6%	3.4%
Re-excision rate	27.2%	3.7%

These study results are promising. Yet questions persist regarding the utility of preoperative MRI in patients with aggressive cancers, such as triple-negative breast cancer, and include the following, according to Burkbauer's research team:

- Is preoperative MRI better at tumor staging and selecting patients for breast-conserving surgery versus mastectomy compared to conventional breast imaging?
- Is there a role for preoperative abbreviated-MRI?
- How can reexcision rates be further reduced in breast-conserving surgery?

These questions are being explored by the Alliance A11104 Clinical Trial from the American College of Radiology Imaging Network (ACRIN), the authors reported.

Whether these findings -- as well as those from the Alliance trial -- will influence clinical practice remains to be seen, the authors wrote.

"The data demonstrated that re-excision rates are affected by myriad factors, including surgeon-specific variables that may not routinely be captured in databases," Burkbauer and colleagues concluded. "Such data may add nuance to result interpretation in prior and future studies."



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 **Digital X-Ray** *Sponsored by Carestream Health*



## EXA predicts mortality in heart failure patients

March 23, 2022 -- Measuring arm muscle mass on dual-energy x-ray absorptiometry (DEXA) scans can help predict mortality in older hospitalized patients with heart failure, according to a study published March 17 in [Archives of Gerontology and Geriatrics](#).

A group of Japanese researchers compared the prognostic values of arm and leg muscle mass measured using DEXA in hospitalized elderly patients with heart failure. They found that upper arm muscle mass offers incremental prognostic value, and they suggested the scans could be useful for identifying high-risk patients in daily clinical practice.

"Low [muscle mass], diagnosed based on the arms and not the legs, was associated with poor prognosis in patients with heart failure," wrote corresponding author Dr. Yuya Matsue, PhD, of Juntendo University Graduate School of Medicine in Tokyo.

DEXA is one of the most widely accepted methods in clinical settings for measuring muscle mass, and muscle wasting (sarcopenia) is a known predictor of frailty and reduced survival in heart failure patients.

However, heart failure patients experience high rates of edema, particularly in the lower extremities, which can limit DEXA results. The researchers hypothesized that muscle mass of the upper arms is more accurate than lower leg measurements and subsequently has a better prognostic value.

Matsue and colleagues analyzed DEXA scans acquired on a commercially available system (QDR-Horizon A, [Hologic](#)) of 271 elderly ( $\geq 65$  years) patients who underwent imaging to measure muscle mass as part of a clinical trial that ended in 2018. Patients were included if they could walk or move about at discharge. The endpoint of the study was all-cause mortality, with data relating to patient status collected up to May 2021.

During a median follow-up of 690 days, 54 patients (19.9%) died. Only measurements of the lower arms (hazard ratio [HR]: 2.05,  $p = 0.026$ ), in contrast to measurements of the lower legs (HR: 1.15,  $p = 0.663$ ), were associated with poor prognosis after adjusting for preexisting risk factors, according to the findings.

In addition, analysis using net reclassification improvement (NRI) metrics revealed that low arms muscle mass index (NRI: 0.353,  $p = 0.018$ ), in contrast to a lower legs index (NRI: 0.219,  $p = 0.153$ ), provided incremental prognostic predictability when considered with preexisting risk factors at discharge, the authors reported.

"Our study results demonstrated that extremity [muscle mass], specifically upper arm muscle mass, measured using DEXA has an incremental prognostic value in elderly patients with heart failure," the authors wrote.

Japan is becoming a superaging society, with the number of patients with heart failure and sarcopenia increasing rapidly. Considering that low muscle mass is one of the main components for diagnosing sarcopenia associated with poor prognosis in these patients, accurate assessment of muscle mass is essential, the authors wrote.

This study suggests arm muscle mass may be more useful for screening patients with heart failure than leg muscle mass, and "it may be useful to measure the arm [muscle mass] of patients with heart failure in daily clinical practice," they wrote.

Yet further research is warranted, the researchers stated.

Future prospective studies are needed to investigate the mechanism underlying the discrepancy in prognosis between arm and leg [muscle mass] evaluated using DEXA in patients with heart failure," Matsue and colleagues concluded.





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 **MRI** *Sponsored by Fujifilm Healthcare Americas*



## **MRI can identify complications from total knee surgery**

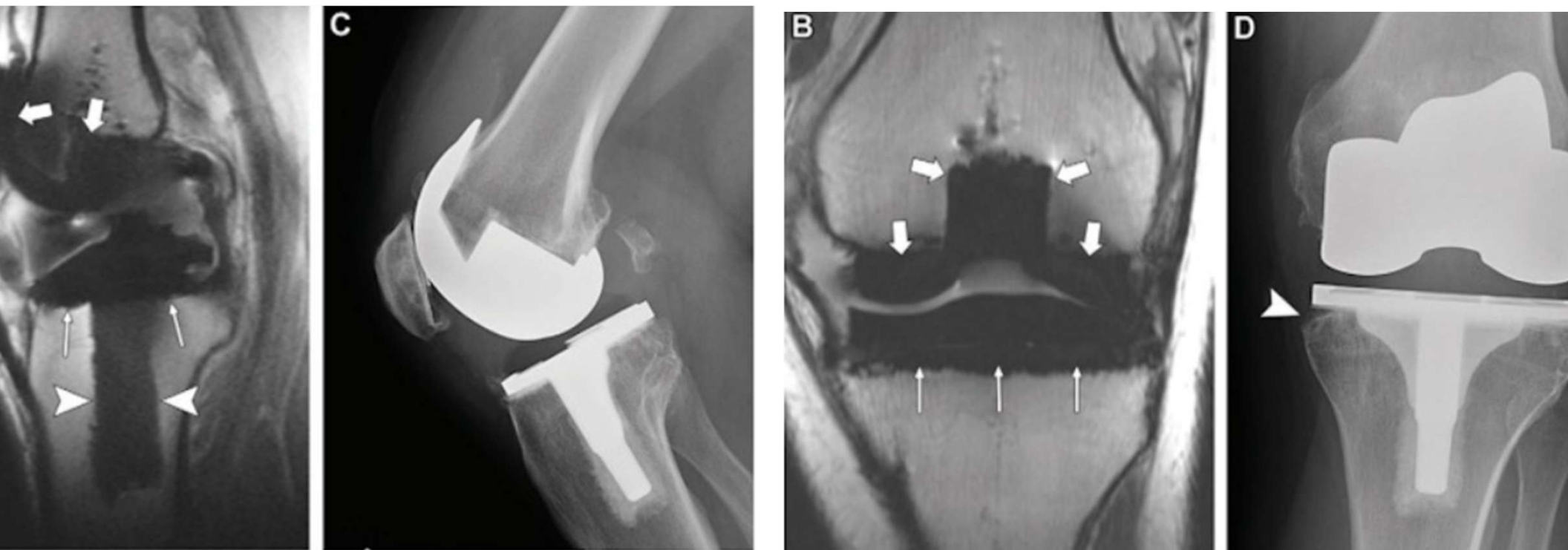
By Kate Madden Yee, AuntMinnie.com staff writer

March 23, 2022 -- MRI shows higher sensitivity than x-ray when it comes to identifying complications from replacement of the patellar component of the knee, according to a study published March 22 in [\*Radiology\*](#).

The findings offer clinicians and their patients a more effective way to evaluate the success of total knee replacement, wrote a team led by Dr. Yoshimi Endo of the Hospital for Special Surgery in New York City.

"In addition to the superb depiction of soft tissue including synovial abnormalities at MRI, the ability to evaluate the implant-bone interface and assess loosening are additional compelling reasons why an MRI examination should be considered for all problematic total knee arthroplasty," the group noted.

Loosening of knee replacement components can cause pain, and it may indicate that additional surgery is needed, Endo's group explained. But which imaging modality can best evaluate knee replacement component loosening has remained unclear.



*axial noncontrast-enhanced intermediate-weighted multiacquisition variable resonance imaging combination selective*  
*an (repetition time msec/echo time msec, 4000/7.9) in the midline knee and (B) coronal noncontrast-enhanced*  
*mediate-weighted fast spin-echo MRI scan (4057/32) in the anterior knee in a 51-year-old man show normal interfaces*  
*the patellar component (yellow arrows), femoral component (thick white arrows), and the tibial component, including*  
*tray (thin white arrows) and the keel (arrowheads). (C) Lateral and (D) anteroposterior radiographs in the same knee*  
*normal appearance of the components except for minor bone resorption along the medial tibial tray (arrowhead). Im*  
*ation courtesy of the RSNA.*

o and colleagues sought to compare the performance of x-ray and MRI for identifying knee replacement component loosening via a study that included 114 patients who had undergone knee replacement surgery (116 knees) between July 2011 and June 2019.

Patients were imaged with both MRI and x-ray, and of the total number of knees, 52% had at least one loose component, the team noted. The researchers assessed the type of interface between the knee replacement component and bone (normal, fibrous, synovial membrane, fluid, or osteolysis), the percentage integration of this connection (less than 33%, 33% to 66%, or more than 66%), and the presence of any bone marrow edema; they then compared the sensitivity and specificity of MRI to x-ray for these measures against surgical findings as reference.

The investigators found that knee replacement component loosening was associated with the following characteristics:

- Poor (less than 33%) bone integration (odds, 20.4)

- Fluid interface (odds, 20.1)

- Lack of any normal interface (odds, 11.8)

The study also demonstrated that MRI showed higher sensitivity that was statistically significant compared to x-ray for identifying patellar component loosening, although specificity was lower

**X-ray vs. MRI for identifying knee replacement patellar component loosening**

	<b>X-ray</b>	<b>MRI</b>	<b>p-value</b>
<b>Sensitivity</b>	31%	84%	< 0.001
<b>Specificity</b>	96%	85%	0.003

ally, interreader reproducibility between MRI and x-ray for identifying knee replacement component loosening was "substantial to excellent" (0.67 to 0.96), the group found.

The study results highlight the role MRI can play in monitoring the success of total knee replacements, according to the authors.

The higher sensitivity of MRI for patellar component loosening compared with radiography, together with its superb soft-tissue evaluation, make it an ideal imaging modality for assessing the problematic total knee arthroplasty," they concluded.



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## Can dark-field chest x-ray diagnose COVID-19 pneumonia?

by Will Morton, AuntMinnie.com staff writer

April 14, 2022 -- German researchers have tested a new prototype dark-field chest x-ray imaging device, and are finding that the system may be valuable for diagnosing COVID-19 pneumonia, according to a preprint article published April 7 on [Research Square](#), an open-access site for sharing manuscripts under peer review.

A research group at the Technical University of Munich (TUM) conducted a reader study by having 10 radiologists who tested images acquired from healthy patients and patients diagnosed with moderate COVID-19. Images assessed included standard chest x-rays alone, dark-field chest x-rays alone, or both images displayed simultaneously.

"We found that dark-field imaging has a higher sensitivity for COVID-19 pneumonia than attenuation-based imaging, and that the combination of both is superior to one imaging modality alone," wrote corresponding author Manuela Brack, a doctoral candidate in biomedical physics at TUM, and colleagues.

The work is based on recent technological advancements on a human-scale dark-field chest x-ray imaging prototype that enables the acquisition of quantitative dark-field x-rays with diagnostic image quality at a radiation dose comparable to conventional x-rays, the authors noted.

Dark-field x-ray imaging has been proposed by the TUM group as a new diagnostic tool for the assessment of microstructural changes in lung parenchyma. It has shown promise imaging various lung diseases in mouse models and in [first studies in humans](#).

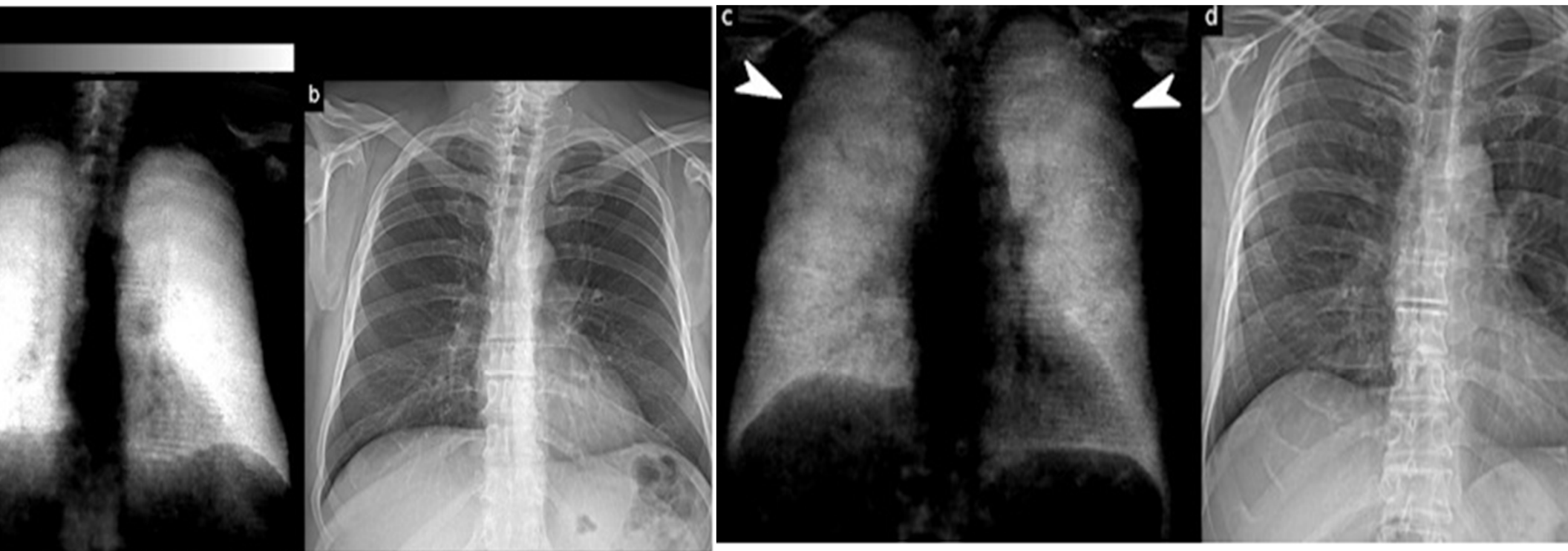
In this study, the researchers enrolled volunteers who underwent chest CT scans for suspected COVID-19 infection at their hospital in Munich between May 2020 and December 2020. The final study group consisted of 40 healthy patients and 60 with COVID-19 pneumonia.

Patients are positioned within the beam path of the prototype via a lifting platform inside of the patient cabin. The prototype acquires both attenuation-based and dark-field chest x-rays simultaneously at a time window of about 17 ms per frame. One scan consists of a maximum of 195 single frames taken in about seven seconds, the authors wrote.

Four radiologists with different levels of experience in dark-field imaging (two, five, seven, and nine years) assessed only attenuation-based radiographs, only dark-field radiographs, and both displayed simultaneously for all patients. Values 1 to 3 were counted as negatives, while values 4 to 6 were counted as positives.

Overall rating values by the readers for the presence of COVID-19-pneumonia in suspected patients were substantially higher for dark-field imaging (4.84) compared with attenuation-based imaging (3.16). Additionally, rating values for infected patients were higher for the combination of dark-field-based and conventional imaging (5.04) compared with dark field-based imaging alone, according to the findings.





*Dark-field and (b) conventional (attenuation-based) chest radiographs of a healthy subject. The dark-field radiograph exhibits a strong, homogeneous dark-field signal. The respective attenuation-based radiograph shows no apparent pathology. (c) Dark-field and (d) attenuation-based chest radiographs of a patient infected with COVID-19. Compared with the healthy subject, the infected patient shows an overall decrease of signal intensity. While the signal of the healthy subject is homogeneous, the dark-field signal of the infected patient appears inhomogeneous and patchy, especially in the periphery of the lung (white arrowheads). Image courtesy of Research Square.*

receiver operating characteristic (ROC) analysis for the differentiation between infected patients and healthy subjects, the effect size expressed as area under the ROC curve (AUC) was 0.78 for standard radiographs, 0.91 for dark-field images, and 0.93 for the combination of both.

In this study we present the first application of the recently developed dark-field lung imaging technology for the assessment of COVID-19-pneumonia and demonstrate its superiority over conventional radiography," the authors wrote.

Ultimately, the researchers are aiming to introduce a low-radiation, medical imaging alternative to CT imaging for COVID-19 pneumonia detection and follow-up. Although the sensitivity radiologists achieved when reading both dark-field chest x-rays and conventional chest x-rays together in this study was not as high as seen in CT imaging, it is still reasonably high and comes with only a fraction of the CT radiation dose, according to the authors.

However, further technological improvements are required, as well as clinical studies to evaluate the prototype's potential for lung imaging, the researchers wrote.

"Dark-field imaging might be a low-radiation alternative for disease monitoring especially in patients where repetitive CT scans should be avoided," Frank and his colleagues concluded.

**THE END**