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LETTER OF TRANSMITTAL

PDA
Cameron Village
2016 Cameron Street
P.O. Box 12844
Raleigh, NC 27605

Nancy M. Lane, MA
(919) 754-0303
Fax (919) 754-0328
nlane@pda-inc.net

To:

Kelli Fisk
Administrative Assistant
Medical Facilities Planning Branch
Division of Health Service Regulation

Date: 3/4/2015 **Job Number:** 11-7007-14

Attention:

RE: J. Arthur Dosher Memorial Hospital - MRI Policy Change Petition

WE ARE SENDING YOU: ☐ Shop Drawings ☐ Prints ☐ Plans ☐ Samples

☐ Specifications ☐ Change order ☐ Copy of letter ☐ Client Project Copy

☑ Spring 2015 Petition

Copies	Date	No.	Description
1	3/4/2015		Petition and Attachments

THESE ARE TRANSMITTED AS CHECKED BELOW:

☐ For approval ☐ Approved as submitted ☐ Resubmit copies for approval

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☐ As requested ☐ Returned for corrections ☐ Return corrected prints

☐ For review and comment ☐

Remarks: Sumbitted to Kelli Fisk at the 3.4.15 SHCC Meeting

Copy To: Dan Porter, CFO

Signed: KI

Petition to the State Health Coordinating Council Regarding Technology and Equipment Policy/ Methodology for Fixed Magnetic Resonance Imaging Equipment for *2016 State Medical Facilities Plan*

March 4, 2015

Petitioner:		***Contact:***	
Name:	J. Arthur Dosher Memorial Hospital	**Name:**	Dan Porter, CFO
Address:	924 North Howe Street Southport, North Carolina 28461	**E-mail:**	danporter@dosher.org
		Phone:	910-457-3912

STATEMENT OF REQUESTED ADJUSTMENT

PREFERRED ADJUSTMENT: NEW POLICY TE-2

J. Arthur Dosher Memorial Hospital (Dosher), requests the following Policy Adjustment and Change to Methodology in the *2016 State Medical Facilities Plan* (*SMFP*) regarding Magnetic Resonance Imaging equipment (MRI).

- Add a new policy, **Policy TE-2**, which should read as follows:

  "A certificate of need may be issued to a hospital which is licensed under GS 131E, Article 5, has only one MRI scanner, and offers MRI services on a full-time basis pursuant to a service agreement with an MRI provider, without regard to the MRI need shown in Chapter 9:Magnetic Resonance Imaging, if:

  1. *The hospital replaces the existing contracted service agreement with a fixed MRI scanner under the hospital's ownership and control.*
  2. *The existing service agreement can and will terminate prior to the date the new fixed MRI begins service.*
  3. *The acquisition and operation of the facility's own MRI scanner will allow the hospital to reduce its cost of providing the MRI service.*

- *The threshold tier of adjusted MRI scans for such a replacement shall equal that of a service area with no MRI scanners*

- With addition of **Policy TE-2**, remove from *SMFP* Chapter 9, "Magnetic Resonance Imaging," "Basic Assumptions of the Methodology, 4" (Assumption 4), thus eliminating redundancies.

ALTERNATIVE ADJUSTMENT DEEMED FEASIBLE: CHANGE THE MRI NEED METHODOLOGY

As an alternative to addition of proposed **Policy TE-2**, change the "MRI Need Determination Methodology" as follows:

- Add the following Basic Assumption:

    5. *If a hospital that operates only one MRI scanner on a full-time basis pursuant to a service agreement can demonstrate that owned equipment will be less costly than leased equipment, it should be permitted to replace the leased with owned equipment . The replacement MRI scanner should not be required to provide more MRI scans than an MRI scanner in a service area with no fixed MRI scanners, the lowest tiered planning threshold.*

- Add the following Steps:

    Step 13: *Identify hospitals with only one full time MRI operated pursuant to a service agreement.*

    Step 14: *For those hospitals identified in Step 13, identify a need for a replacement MRI for the service area in which the hospital is located.*

- Modify the need determination Table 9R as follows:

Table 9R: Fixed MRI Scanner Need Determination
(Scheduled for Certificate of Need Review Commencing in 2016)

It is determined that the service areas listed in the table below need additional fixed MRI scanners.

Service Areas	Fixed MRI Scanners Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
TBD	TBD	TBD	TBD
Service Areas	**Replacement MRI Scanner Need Determination**	**Certificate of Need Application Due Date****	**Certificate of Need Beginning Review Date**
Brunswick	1	TBD	TBD

* *Need determination shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).*

** *Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).*

REASONS FOR THE PROPOSED ADJUSTMENT

MRI is now an essential non-invasive diagnostic tool, particularly for soft tissues and organs. When the *SMFP* first included MRI Planning Threshold Tiers in 2005, use rates for MRI were growing rapidly and the State Health Coordinating Council (SHCC) wanted to provide a mechanism to both rationalize distribution of the technology and assure that community hospitals could obtain MRI scanners. For most hospitals and communities, the SHCC achieved its goal.

Nationwide and statewide, the health care system is under pressure to reduce cost. Policy GEN-3 and the Basic Principles of the *SMFP* encourage and require projects to reduce cost to the consumer. While not intended, the current *SMFP* MRI methodology holds a hospital that operates a single leased full time MRI hostage to a vendor contract. This arrangement has potential to limit competition and increase cost.

- *SMFP* Chapter 9, MRI Basic Assumption # 4 (pg. 146) states that "a facility that offers MRI services on a full-time basis pursuant to a service agreement with an MRI provider is not precluded from applying for a need determination in the North Carolina 2015 *SMFP* to replace the existing contracted service with a fixed MRI scanner under the applicant's ownership and control."
- This Basic Assumption requires that the respective *SMFP* first show a need in the MRI service area in question.
- There is no mechanism in the *SMFP* by which a hospital can successfully replace a full-time contracted MRI service with a full-time owned fixed MRI service. An MRI replacement of this nature would be a one to one swap that would not change the total inventory of MRI equipment in the service area.

In order to align the MRI Chapter with the spirit of the Basic Assumptions of the current MRI Methodology and the Basic Principles of the *SMFP*, the *2016 SMFP* should provide a limited option for cost-effective replacement of leased MRI equipment at community hospitals, independent of a forecast increase in the MRI equipment needed in a service area. Limitations should encourage efficient use of MRI equipment by honoring annual procedure thresholds. However, to enable eligible hospitals to replace a contracted MRI scanner with a less expensive owned MRI scanner, the threshold should be low. The lowest Tiered procedure threshold, currently 1,716 weighted scans, should be used to evaluate need and performance of a replacement scanner.

At this time, only one hospital in the state has only one full time fixed equivalent MRI and does not own the equipment. Thus, a policy or methodology that permits replacement would increase the statewide inventory of MRI equipment by only one, a change of less than four percent in the total inventory (1/261 = 3.8%). Consistent with rules for Replacement Equipment in 10A NCAC 14C .0303, the affected vendors of the replaced mobile unit or units should be required to remove the replaced equipment from the service area in question. The vendor would have the option to request a Declaratory Ruling to locate the equipment to a new service area. As a grandfathered unit, the MRI at Dosher is not subject to CON limitations on location, and could relocate anywhere in the state. Units in other counties may have location restrictions attached to their Certificates of Need.

STATEMENT OF ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS IF THE ADJUSTMENT IS NOT MADE

BRUNSWICK COUNTY

The current Policy and Methodology adversely affect Dosher Hospital in Southport, Brunswick County; and Dosher provides a good example of the potential adverse impact on others. The *SMFP* and related rules tie Dosher to a vendor agreement for MRI services, which has inherent obstacles to providing good customer service. To meet its requirements to maintain grandfathered status, the vendor established the leased scanner location and service hours. The MRI is not located on the hospital main campus, and is not easily accessible to Dosher Emergency Department or inpatients. As a result, physicians and emergency providers direct many hospital service area patients out of the county rather than risk delays associated with obtaining an MRI scan.

For residents of this publicly supported, critical access hospital, the goal of cost effective access to MRI service is out of reach. Dosher contracts for full time leased MRI services, but it cannot pursue more cost effective ownership of the MRI equipment. Rather, Dosher must wait until an *SMFP* shows that Brunswick County needs three full time scanners, one at Novant-Brunswick, the existing one at Dosher and one more. Then, Dosher could apply and compete with others for a Certificate of Need to replace its scanner. If awarded the CON, Dosher would be permitted to replace the existing scanner and remove it from the service area. However, to qualify for the CON award, Dosher would have to show that it could achieve 4,118 annual scans, almost four times its current workload[1]. This is both an unlikely and unachievable scenario.

Brunswick is a very large county; by land area, it ranks sixth largest in the state. It has two hospitals, Dosher in the southeast and Novant Brunswick in the west. According to the NC Office of State Budget and Management, Brunswick is the fourth fastest growing North Carolina County, with only Onslow, Hoke and Mecklenburg growing faster between 2009 and 2013. It has far and above the highest in-migration rate of the state's counties. With a median age of 49, it is among the top five oldest counties in the state. It is also very rural. Three population centers, Leland, Supply and Southport are almost equidistant from one another and they and their adjacent populations compose most of the 107,000 county residents. Leland is a suburb of Wilmington. Supply and Southport, located in the west and southeast, respectively, have small hospitals. The hospital in Supply has a fixed MRI scanner that it owns. The Southport area has only the one leased MRI.

Energy production, tourism, fishing and agriculture are the main county industries. Tourism and energy both produce slow travel along the county's main roads. Particularly in the summer, travel from Southport to Wilmington or Supply can take 45 minutes to an hour. Without a change in the methodology, residents in the Southport area will continue to operate with several disadvantages:

- No choice in mechanisms for reducing MRI cost or upgrading equipment,
- No opportunity to bring the MRI equipment inside the hospital, because the third party vendor is required to provide the equipment as a "movable unit."
- Added cost for MRI for hospital inpatients and emergency room patients associated with an additional charge for transportation to an off-site location approximately four miles away.

[1] 10A NCAC 14C.2703

- Limited control over options for increasing hours of service because vendor contracts require guaranteed service minima.

Brunswick County is too small to generate a need for three MRI scanners under the current MRI Methodology. Even in the unlikely scenario that the MRI Methodology were to generate a need for three scanners, Brunswick County is too small to generate enough need in the service area of that new scanner for it to provide 4,118 scans, while other MRI scanners in the service area continue to provide service, presumably at their current levels of operation. Yet, the current MRI Methodology and related Special Rules in 10A NCAC 14C .2703 (b)(3) and 10 NCAC 14C. 2701(13) mandate those performance standards. These requirements make sense when the goal is to slow growth of imaging technology, but they encourage high utilization of new equipment and run counter to current tenets of health reform and the CMS Triple Aim of Low Cost, High Quality and Good Customer Experience.

OTHER RURAL MRI SERVICE AREAS

Small hospitals in other counties, for example, Duplin, Bladen and Martin, have part-time MRI services and may reach full time. Presently, the *SMFP* MRI Methodology and related Rules could result in similar problems in these counties. All three would be at risk of unnecessary duplication of MRI services without one or the other of these proposed changes. Presently, these hospitals have less than one full time equivalent MRI, according to data in the *2015 SMFP.* These counties have no other MRI scanners, so they would not face a lower MRI Planning Tier Threshold problem.

- Duplin General: 0.44
- Bladen: 0.12
- Martin General:0.26

Hoke is an MRI Service Area according to Table 9P. It now has two hospitals. Because neither have MRI service at present, the *2015 SMFP* shows no MRI need in that MRI Service area. As those hospitals develop, they too will face similar problems.

PLAN CHANGES FOUND FEASIBLE

OVERVIEW

A change to either Policy or Methodology that permits substitution when a hospital can demonstrate that the replacement will be cost effective would resolve the unwarranted consequences.
Dosher has determined and multiple other applicants have demonstrated that it is possible to operate a fixed MRI scanner economically by providing only 1,716 adjusted scans. This criterion should apply to either a Policy or a Methodology change.

POLICY CHANGE

A Policy Change offers several advantages:

- A Policy change would require the least effort on the part of DHSR Planning and Certificate of Need Section staff. It would put the burden of proof on the applicant to demonstrate that it meets conditions.
- A Policy change would also adapt easiest to changes in relationships and arrangements that occur throughout the year. A hospital operating a leased MRI could apply at the time when it meets the condition of offering full time service. The community served by the hospital would not be required to wait for a need to appear in a subsequent year's *SMFP*, as would be required with the proposed Methodology change. We note here that service data lag the *SMFP* by two years. For example, the 2015 MRI Methodology uses 2013 information. So, the Methodology change will result in an even longer delay in meeting community needs.
- A Policy change would spare already burdened rural areas the expense associated with petitioning. All of the affected communities are small and/ or rural.
- A Policy change would spare the SHCC the expense and time of reviewing and responding to special need petitions each time the situation arises.

METHODOLOGY CHANGE

A methodology change achieves the same results, but is less flexible. It would permit changes only once a year; would require more staff time to investigate, document and program the database to show areas that meet the criteria and would put an extra one to two year lag in cost savings opportunities.

STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

OVERVIEW

Dosher considered and rejected:

- Status quo
- Waiting for the current methodology to show a need in the county
- Waiting and pursuing a special need petition
- Dropping MRI service all together

STATUS QUO

Dosher is operating under the status quo and finds it cost prohibitive and less than optimal for patient care. . The present arrangement limits service, because the scanner is located outside and geographically separate from the inpatients and emergency room patients. Although many MRI's can be scheduled on an outpatient basis, MRI still performs an important role in emergency care.[2][3] Dosher had 13,490 emergency room visits in 2014. Adding service hours under the current MRI lease arrangement requires the hospital to negotiate with the vendor. The contract is scaled to keep the vendor whole and profitable. It was ideal for start-up, but not so once the hospital built volume sufficient to support a full time service. Under the status quo, Dosher cannot bring the equipment into the hospital where it would better serve patients. Status quo is not a reasonable alternative.

WAIT FOR THE CURRENT METHODOLOGY TO SHOW NEED

The graduated scale in the current *SMFP* MRI Methodology would require the whole county to go from 5,548 adjusted total scans in FY 2013 to 8,895 scans (2.16 * 4118 = 8,894)[4] to receive a need determination for a new MRI. Note that a non-hospital provider has a mobile unit one day a week. Even with its rapid growth and aging, Brunswick County's population will not reasonably produce this level of demand. The county has approximately 107,000 people. Moreover, achieving a need in the *SMFP* under the current methodology and related Special Rules for MRI Scanners 10 NCAC .2700 would create a scenario in which Dosher or a comparable community would find it extremely difficult, if not impossible to reasonably project the required number of scans to justify the equipment. The Rules designed support the Methodology and would require Dosher to forecast 4,118 weighted scans in the third year of MRI operation. Dosher provided 1,262 weighted scans in 2014. Clearly, even with better schedule and access, this is not a reasonable alternative. Alternatively, with a fixed MRI at the hospital, it is reasonable for it to forecast 1,716 weighted scans by the third year.

[2] Weber, Marc-André , Biederer, J, Heidelberg University Hospital Magnetom Flash,Siemens, 2/2013

[3] Vogel-Claussen, J et al , Comprehensive Adenosine Stress Perfusion MRI Defines the Etiology of Chest Pain in the Emergency Room: Comparison with Nuclear Stress Test. J Magn Reson Imaging, 2009Oct 30®:753-762.

[4] Brunswick County has 2.16 full time equivalent scanners according to the *2015 SMFP*, Table 9P, page 152.

PURSUE A SPECIAL NEED ADJUSTMENT

A special need adjustment for Brunswick County MRI Service Area might provide an opportunity for Dosher to apply to replace its scanner, but such a change in the *SMFP* would not address the unreasonable productivity requirement. Moreover, it could result in more scanners than the county truly needs. Another applicant could pursue a CON for such a need and locate a scanner elsewhere in the county and Dosher's problem would remain. This approach would not serve residents of the Southport area well. Moreover, other hospitals located in rural counties, for example, Bladen, Martin, Duplin, or Hoke, could face the same dilemma in future years. Presently, none of these have full time MRI service. Three have part-time mobile service. Clearly, a special need adjustment is not a reasonable and complete alternative.

DROP MRI SERVICE ALTOGETHER

MRI services at Dosher are already located four miles from the hospital campus. Removing MRI services altogether would not only require ambulatory MRI patients to travel 30 to 60 minutes by car to the next closest MRI, it would eliminate the possibility that Dosher could provide MRI services to inpatients and emergency patients. Locating the closest diagnostic MRI 20 miles away from inpatient services at Dosher would create delays in care and increase costs. This is not a reasonable alternative for Dosher or residents of southeastern Brunswick County.

Other rural hospitals in this same situation would face a similar dilemma.

EVIDENCE OF NON-DUPLICATION OF SERVICES

Because either the proposed Policy change or the change in Methodology involves substitution of equipment, the proposed change would not involve duplication of services. Neither the applicant nor the contracted MRI service vendor would retain the replaced MRI unit in the service area.

The lapsed contract would put the mobile or grandfathered MRI unit back in play outside the affected service area. In the Dosher case, the mobile unit is a grandfathered unit that can respond to growing demand in larger markets anywhere in the state. If, in the case of another hospital, the mobile unit is tied to a geographic area, that vendor would have the option to petition the DHSR for a good cause change in material compliance of its service area location. DHSR has routinely granted such changes.

EVIDENCE OF CONSISTENCY WITH NORTH CAROLINA MEDICAL FACILITIES PLAN

BASIC GOVERNING PRINCIPLES

1. Safety and Quality

This basic principle notes:

> *"…priority should be given to safety, followed by clinical outcomes, followed by satisfaction.*
>
> *"…As experience with the application of quality and safety metrics grows, the SHCC should regularly review policies and need methodologies and revise them as needed to address any persistent and significant deficiencies in safety and quality in a particular service area*."

In the field of MRI, quality metrics are associated with the strength of the magnetic field, heat generated as magnetic strength increases and the heat impact on human tissue. Other metrics relate to assuring that the magnetic field associated with the MRI will not have an adverse impact on implants and other ferrous materials in the vicinity of the equipment.

Radiologists are studying appropriateness criteria and trying to develop metrics for such topics as exam appropriateness related to patterns of exam ordering, dose, adverse events, and communication time, and appropriateness of substituting x-ray or SPECT for MRI when MRI is not available.[5] Recent research favors MRI. Metrics for defining appropriate population utilization levels for MRI are under study, but the question of how much is appropriate remains unresolved.

Most of these relate to operation of the MRI. The one that emphasizes the importance of having MRI available to emergency rooms would support the arguments in this petition.

2. Access

This basic principle notes:

> *"…The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers.*
>
> *"…The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible under prevailing quality and value standards."*

The proposed changes would benefit a rural publicly funded hospital and its service area, would promote economic efficiency, and enable the hospital to bring the MRI on the hospital main campus close to the inpatients and its emergency department.

[5] Yeager, David, Quality Metrics – Forward-Looking organizations Are developing Their Own Performance Measures, Radiology Today, Vol 15 No7(12) , July 2014 http://www.radiologytoday.net/archive/rt0714p12.shtml

3. Value

This basic principle notes:

> *"The SHCC defines health care value as the maximum health care benefit per dollar expended.*
>
> *"…Cost per unit of service is an appropriate metric…*
>
> *"…At the same time overutilization of more costly and/or highly specialized low-volume services without evidence-based medical indication may contribute to escalating health costs without commensurate population-based health benefit."*

The proposed changes will have minimal impact on the statewide count of MRI technology, but will enable substitution of a less costly for a more costly service without placing unnecessary pressure on a health care provider to increase utilization.

CONCLUSION

The proposed changes are consistent with and support the Basic Principles that govern the *SMFP*.

ATTACHMENTS:

Attachment A

Section .2700 Criteria and Standards for
Magnetic Resonance Imaging Scanner -
10A NCAC 14C .2701: Definitions
10A NCAC 14C .2703: Performance Standards

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2701 DEFINITIONS

The following definitions apply to all rules in this Section:

(1) "Approved MRI scanner" means an MRI scanner which was not operational prior to the beginning of the review period but which had been issued a certificate of need.

(2) "Capacity of fixed MRI scanner" means 100 percent of the procedure volume that the MRI scanner is capable of completing in a year, given perfect scheduling, no machine or room downtime, no cancellations, no patient transportation problems, no staffing or physician delays and no MRI procedures outside the norm. Annual capacity of a fixed MRI scanner is 6,864 weighted MRI procedures, which assumes two weighted MRI procedures are performed per hour and the scanner is operated 66 hours per week, 52 weeks per year.

(3) "Capacity of mobile MRI scanner" means 100 percent of the procedure volume that the MRI scanner is capable of completing in a year, given perfect scheduling, no machine or room downtime, no cancellations, no patient transportation problems, no staffing or physician delays and no MRI procedures outside the norm. Annual capacity of a mobile MRI scanner is 4,160 weighted MRI procedures, which assumes two weighted MRI procedures are performed per hour and the scanner is operated 40 hours per week, 52 weeks per year.

(4) "Dedicated breast MRI scanner" means an MRI scanner that is configured to perform only breast MRI procedures and is not capable of performing other types of non-breast MRI procedures.

(5) "Existing MRI scanner" means an MRI scanner in operation prior to the beginning of the review period.

(6) "Extremity MRI scanner" means an MRI scanner that is utilized for the imaging of extremities and is of open design with a field of view no greater than 25 centimeters.

(7) "Fixed MRI scanner" means an MRI scanner that is not a mobile MRI scanner.

(8) "Magnetic Resonance Imaging" (MRI) means a non-invasive diagnostic modality in which electronic equipment is used to create tomographic images of body structure. The MRI scanner exposes the target area to nonionizing magnetic energy and radio frequency fields, focusing on the nuclei of atoms such as hydrogen in the body tissue. Response of selected nuclei to this stimulus is translated into images for evaluation by the physician.

(9) "Magnetic resonance imaging scanner" (MRI Scanner) is defined in G.S. 131E-176(14m).

(10) "Mobile MRI region" means either the eastern part of the State which includes the counties in Health Service Areas IV, V and VI (Eastern Mobile MRI Region), or the western part of the State which includes the counties in Health Service Areas I, II, and III (Western Mobile MRI Region). The counties in each Health Service Area are identified in Appendix A of the State Medical Facilities Plan.

(11) "Mobile MRI scanner" means an MRI scanner and transporting equipment which is moved at least weekly to provide services at two or more campuses or physical locations.

(12) "MRI procedure" means a single discrete MRI study of one patient.

(13) "MRI service area" means the Magnetic Resonance Imaging Planning Areas, as defined in the applicable State Medical Facilities Plan, except for proposed new mobile MRI scanners for which the service area is a mobile MRI region.

(14) "MRI study" means one or more scans relative to a single diagnosis or symptom.

(15) "Multi-position MRI scanner" means an MRI scanner as defined in the State Medical Facilities Plan, pursuant to a special need determination for a demonstration project.

(16) "Related entity" means the parent company of the applicant, a subsidiary company of the applicant (i.e., the applicant owns 50 percent or more of another company), a joint venture in which the applicant is a member, or a company that shares common ownership with the applicant (i.e., the applicant and another company are owned by some of the same persons).

(17) "Temporary MRI scanner" means an MRI scanner that the Certificate of Need Section has approved to be temporarily located in North Carolina at a facility that holds a certificate of need for a new fixed MRI scanner, but which is not operational because the project is not yet complete.

(18) "Weighted MRI procedures" means MRI procedures which are adjusted to account for the length of time to complete the procedure, based on the following weights: one outpatient MRI procedure without contrast or sedation is valued at 1.0 weighted MRI procedure, one outpatient MRI procedure with contrast or sedation is valued at 1.4 weighted MRI procedures, one inpatient MRI procedure without

contrast or sedation is valued at 1.4 weighted MRI procedures; and one inpatient MRI procedure with contrast or sedation is valued at 1.8 weighted MRI procedures.

(19) "Weighted breast MRI procedures" means MRI procedures which are performed on a dedicated breast MRI scanner and are adjusted to account for the length of time to complete the procedure, based on the following weights: one diagnostic breast MRI procedure is valued at 1.0 weighted MRI procedure (based on an average of 60 minutes per procedure), one MRI-guided breast needle localization MRI procedure is valued at 1.1 weighted MRI procedure (based on an average of 66 minutes per procedure), and one MRI-guided breast biopsy procedure is valued at 1.6 weighted MRI procedures (based on an average of 96 minutes per procedure).

History Note: *Authority G.S. 131E-177(1); 131E-183(b);*
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. February 1, 1994;
Temporary Amendment Eff. January 1, 1999;
Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;
Temporary Amendment Eff. January 1, 2000;
Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000;
Temporary Amendment Eff. January 1, 2001;
Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking originally proposed to be effective April 1, 2001;
Temporary Amendment Eff. January 1, 2002;
Amended Eff. August 1, 2002;
Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002;
Temporary Amendment Eff. January 1, 2003;
Amended Eff. August 1, 2004; April 1, 2003;
Temporary Amendment Eff. January 1, 2005;
Amended Eff. November 1, 2005;
Temporary Amendment Eff. February 1, 2006;
Amended Eff. November 1, 2006;
Temporary Amendment Eff. February 1, 2008;
Amended Eff. November 1, 2008;
Temporary Amendment Eff. February 1, 2009;
Amended Eff. November 1, 2009;
Temporary Amendment Eff. February 1, 2010;
Amended Eff. November 1, 2010.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:

(1) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;

(2) demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and

(3) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

(b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:

(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;

(2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];

(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or

(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

(4) if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or

(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

(5) demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and

(6) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

(c) An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:

(1) demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and

(2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

(d) An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:

(1) demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and

(2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

(e) An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:

(1) demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and

(2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

History Note: *Authority G.S. 131E-177(1); 131E-183(b);*
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. February 1, 1994;
Temporary Amendment Eff. January 1, 1999;
Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;
Temporary Amendment Eff. January 1, 2000;
Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000;
Temporary Amendment Eff. January 1, 2001;
Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking originally proposed to be effective April 1, 2001;
Temporary Amendment Eff. January 1, 2002;
Temporary Amendment Eff. January 1, 2002 amends and replaces the permanent rule effective, August 1, 2002;
Temporary Amendment Eff. January 1, 2003;
Amended Eff. August 1, 2004; April 1, 2003;
Temporary Amendment Eff. January 1, 2005;
Amended Eff. November 1, 2005;
Temporary Amendment Eff. February 1, 2006;

Amended Eff. November 1, 2006;
Temporary Amendment Eff. February 1, 2008;
Amended Eff. November 1, 2008.

Attachment B

Quality Metrics – Forward Looking Organizations are Developing Their Own Performance Measures

July 2014

Quality Metrics — Forward-Looking Organizations Are Developing Their Own Performance Measures
By David Yeager
Radiology Today
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A move to value-based care is one of the most highly anticipated changes wrought by the Affordable Care Act, but it's also one of the most poorly defined terms in health care today. That absence of value's definition is one reason why value-based care still largely is on the drawing board. Another is that the technology tools to measure value still are being developed.

To date, radiology has been on the periphery of the value-based care movement. While that's not likely to change soon, eventually it will, so the question becomes what do radiology departments and practices need to do to be ready?

Vijay M. Rao, MD, FACR, a professor and the chair of the department of radiology at Thomas Jefferson University Hospital in Philadelphia, says the sheer number of potential performance measures is daunting. For example, the consulting company The Advisory Board Company lists nearly 300 radiology-specific measures.

Perhaps of most interest to radiology departments and practices, though, is the Centers for Medicare & Medicaid Services' (CMS) Physician Quality Reporting System (PQRS), which started as a voluntary program but will begin assessing penalties in 2015. The PQRS includes numerous measures for radiology. The CMS also collects some radiology data for its Hospital Outpatient Quality Reporting program, which feeds the publicly available Hospital Compare website. With all of these competing guidelines, it's hard to know which metrics to track.

Identifying Measures
"It's not an easy topic," says Rao, who spoke about quality metrics in May at the Jornada Paulista de Radiologia Conference in São Paulo, Brazil. "Quality metrics have to be picked very carefully by a radiology group or a department so they can accurately measure them and then make a difference at the end of the day."

Teri Yates, founder and principal consultant of Accountable Radiology Advisors, who advises several companies in the health care industry on radiology-related matters, agrees that developing quality metrics will be a crucial task for radiology groups. Although accountable care organizations (ACOs) currently are prioritizing high-value targets such as diabetes and heart disease, and many ACOs still are paying radiology on a fee-for-service basis, she says now is the time to start proactively tracking quality metrics.

To do that, health care organizations need to assess the data and technical resources that are available to them. They also need to be specific about which clinical questions they want answered. In the era of Big Data, it's easy to focus on the trees and miss the forest.

"One of the big challenges that I see as we try to move down this path of analytics is we have so much data available to us. [But] do we have anybody who works for us who understands how to define quality, find the data in the systems, analyze it, and then knows what to do with it?" Yates says. "Organizations need a very strong vision at the beginning of what questions they are trying to answer and what good performance really looks like."

Rao says studying the life cycle of a radiology image can help identify a radiology department's or practice's most important metrics. She says that at every step of that cycle, there are opportunities to develop specific quality measures. Important areas of interest can be divided into "buckets" to make the process more manageable. She says measures of physician competence, patient satisfaction, operational efficiency, patient safety, and study appropriateness can provide valuable information, and she recommends choosing two or three measures from each bucket.

Appropriateness Criteria
Rao believes appropriateness criteria in particular will become highly important as value-based care works its way into medical practice. She says identifying which studies offer the best clinical value will put radiologists in a position to significantly affect care quality, but that's easier said than done. "Tracking some of these measures is really difficult. We need to develop tools," she says. "We need to identify which key performance indicators we want to track and then use the tools to collect the data, manage the data, and drive improvement."

There are four important areas that Yates believes represent quality in radiology. The first is exam appropriateness. Yates says clinical decision support can help determine exam appropriateness, but radiology practices and departments that don't use decision-support tools also can track variations in exam ordering among referring providers that suggest an atypical pattern. Additionally, they can look at more specific parameters, such as the number of patients who are having multiple CT scans in a short period of time without any clear clinical indication.

Yates says safety metrics such as radiation dose and adverse events also are important as well as measurements of report and interpretation accuracy. Peer review and medical outcomes audits, such as those used in mammography, are useful for measuring accuracy. Finally, she says communication metrics, such as turnaround time, critical results reporting, and consultations, should be tracked, too.

Yates adds that making the data user friendly is equally important. She says downloading information to a spreadsheet, which is sometimes done, isn't the best way to communicate information. Commonly used scorecards, or thumbnail sketches of relevant data points, are a

better option—but not optimum because they're drawn from historical data. Dashboards that provide real-time feedback on items such as turnaround time, for example, are the most effective way to monitor quality metrics. Yates believes dashboards will become increasingly popular tools.

Normalizing Data
With data being housed in various systems across the medical enterprise, normalizing data and integrating clinical systems is a must for developing and tracking quality measures. Unfortunately, that's often not the case. Gary Wendt, MD, MBA, a professor of radiology and the vice chair of informatics at the University of Wisconsin-Madison says effective data integration should be on the mind of anyone who's in the market for a new PACS. "Can your vendor either supply you with the tools to seamlessly integrate all of the data you need or will they actually develop something that's tailored to you?" he says. "If they at least provide you with the tools, you can develop something on your own. If the tools aren't even available, you're sort of out of luck."

Wendt says facilities' lack of system integration hampers the development of quality metrics in many ways. For example, most peer review systems aren't linked to a PACS, which means users need another workstation, another login, and another system to collect data. He says radiology departments and groups need a quality assurance and quality improvement system within their PACS to access quality metrics.

The University of Wisconsin uses a university-developed program that allows automatic quality assurance of certain exam types and protocols. The program also allows the radiology department to perform functions, including the following:

• collecting data as protocols are updated to validate the protocols;

• performing quality assurance reviews on technologists to ensure that they're correctly performing exams; and

• evaluating turnaround times on resident preliminary reads.

Without a single interface, those types of functions would be too cumbersome to be useful.

"I don't think you can start collecting that much data by using separate systems," Wendt says. "If you have to log in to a separate system to do every different function, it's practically unworkable."

Tracking Complications
Allen J. Rovner, MD, a radiologist at Aultman Hospital in Canton, Ohio, agrees with Wendt. Aultman Hospital is a 808-bed facility and a level 2 trauma center that uses Montage Search & Analytics to track various quality metrics. He says that prior to implementing Montage, staff already were tracking standard quality measures such as turnaround times for standard reports, critical results reports, certain types of procedures, and technologists arriving when called in. They also were tracking complications for certain procedures such as headaches following myelograms, pneumothorax following thorocentesis, and bleeding following a biopsy.

Now, Rovner says, they're beginning to use the data-mining software to take a deeper look at certain clinical details. One project currently under way is tracking hip fractures that aren't identified on initial X-rays. Rovner says the graying population in the region Aultman Hospital serves is driving up the incidence of hip fractures. Because many people are brought in late in the evening, it can be difficult to determine how to manage a patient with hip pain and a negative X-ray, especially if there isn't an MRI technologist on site.

"So what's the next step? Well, you can keep them overnight in the ER, but the ER's way too busy, and they don't have the time or the beds or the manpower to monitor people," Rovner says. "We've decided that we're going to look at the issue of what the risk is for patients who come in and have a negative X-ray and what our risk is as a health care provider. Sometimes they have an undisplaced fracture and they can walk on it, and they are, unfortunately, triaged home. That can be a big problem."

Aultman Hospital also is looking at utilization criteria. Rovner says the current trends to lower radiation dose and eliminate unnecessary studies are here to stay, and the Affordable Care Act will accelerate these trends. Aultman Hospital is working with its emergency department physicians to get a better handle on appropriate study utilization. Rovner says data-mining software makes it much easier to follow patients and monitor outcomes.

Additionally, Aultman Hospital has been looking for discrepancies in reports and soon will begin looking for instances of pulmonary emboli in CT angiograms. Aultman physicians have noticed a significant number of pulmonary embolisms in younger patients who had CT angiograms and wanted to keep tabs on the trend. Rovner says this is one example of how analytics can improve the quality of care, but he believes the possibilities for better care are vast.

Tear Down the Silos
Rovner says advanced analytics software allows physicians to do longitudinal studies with a mouse click. On the horizon, he sees the possibility of improving overall population health but doing that requires cooperative data mining. Sharing data among institutions and organization would allow access to a large enough patient population to accurately assess outcomes and develop relevant guidelines.

Rovner says cooperative data mining wouldn't be technically challenging, but current privacy regulations make it difficult. He says physicians currently are operating in data silos to patients' detriment. To improve care, Rovner says it would be helpful for physicians to know how other physicians are treating patients; the more complex the medical condition, the more important data sharing becomes.

"We've reached an age where the technology is there—the software, the computer power, the networking, it's all available. We should be able to aggregate our clinical experience," Rovner says. "I really think it's time for medicine to get into the data world."

Increased data sharing also may help radiology prove its value in a more measurable way. Because patient care is highly complex, it's difficult to determine how radiology affects overall outcomes. The most common strategy is to look at the cost of an exam, but Yates points out that noninvasive radiology exams can eliminate the need for more invasive—and typically expensive—procedures. She says to begin quantifying radiology's value, performance indicators will be important, but people in the health care system also will need to take a look at how radiology affects the care cycle.

Yates says she has advised one of her clients, Medicalis Corporation, to take a closer look at this question, and the company has developed a few reports to track certain measures. One report focuses on radiology's impact on emergency operations and highlights variations in ordering patterns. Another tracks turnaround times on studies required for patient discharge. Although these sorts of efforts are in the early stages, Yates says more work must be done in this area to put radiology in its proper health care context and improve overall care.

"Clearly, radiology impacts what happens with the rest of the patient experience, but determining how it affects the care cycle is a very advanced frontier," Yates says. "It's very complex, but it's the right thing to do."

*— David Yeager is a freelance writer and editor based in Royersford, Pennsylvania. He primarily writes about imaging IT for **Radiology Today**.*

Attachment C

Indications for 24 Hours / 7 Days Emergency MRI

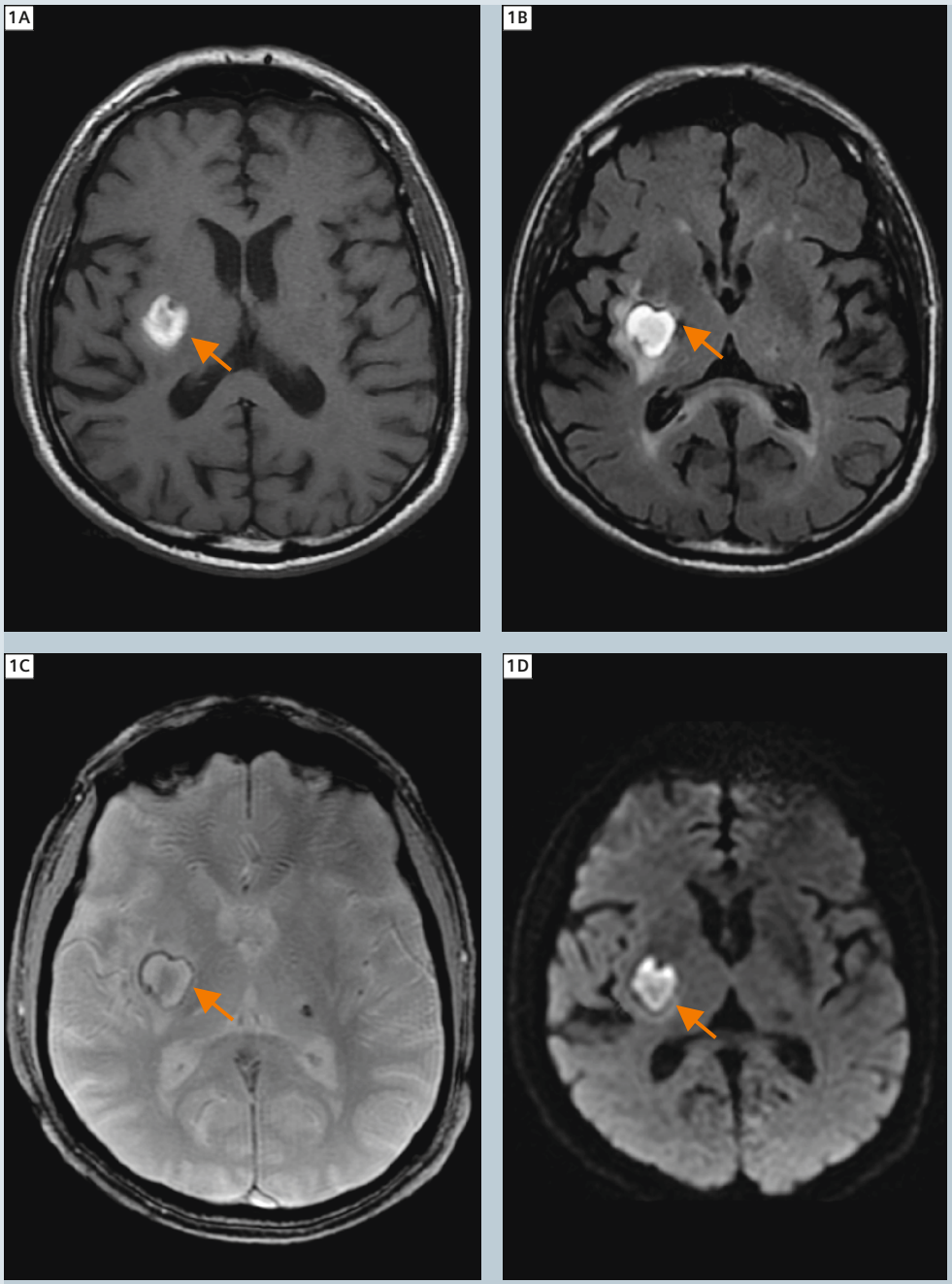
Indications for 24 Hours/7 Days Emergency MRI

Marc-André Weber, M.D., M.Sc.; Jürgen Biederer, M.D.

Heidelberg University Hospital, Diagnostic and Interventional Radiology, Heidelberg, Germany

Introduction

For many years MR imaging (MRI) has been considered a second-line procedure required for further diagnostic work-up after first-line imaging with x-ray, ultrasound or even computed tomography (CT) in the emergency room. However, the increasing performance of modern MR equipment and sequence design have broadened the range of indications, now making MRI the first-line imaging modality of choice for a number of clinical conditions. This is most obvious in neurovascular emergencies, but it also applies to a number of other indications. More and more, an 'emergency MRI' is being requested at night or during weekends. In most cases, the decision whether to perform it is taken according to the particular circumstances, such as the availability of sufficiently skilled staff and radiological expertise. The aim of this article is to suggest stratification criteria and to provide a list of clinical situations that might justify the performance of an MRI scan during night or weekend shifts based on the clinical relevance, i.e. immediate consequences. Conditions that do not require direct therapeutic intervention should not trigger an MRI scan outside the regular schedules. The limitation to only a small number of indications improves clinical decision-making and facilitates the preparation and training of the staff for these situations. The following suggestions have been developed at University Hospital Heidelberg in cooperation between the Department of Diagnostic and Interventional Radiology (Head: Hans-Ulrich Kauczor, M.D.), the Orthopedics and Trauma Surgery Clinic, the Spinal Cord Injury Center, the Vascular Surgery Clinic, the Department of Anesthesiology, and the Center

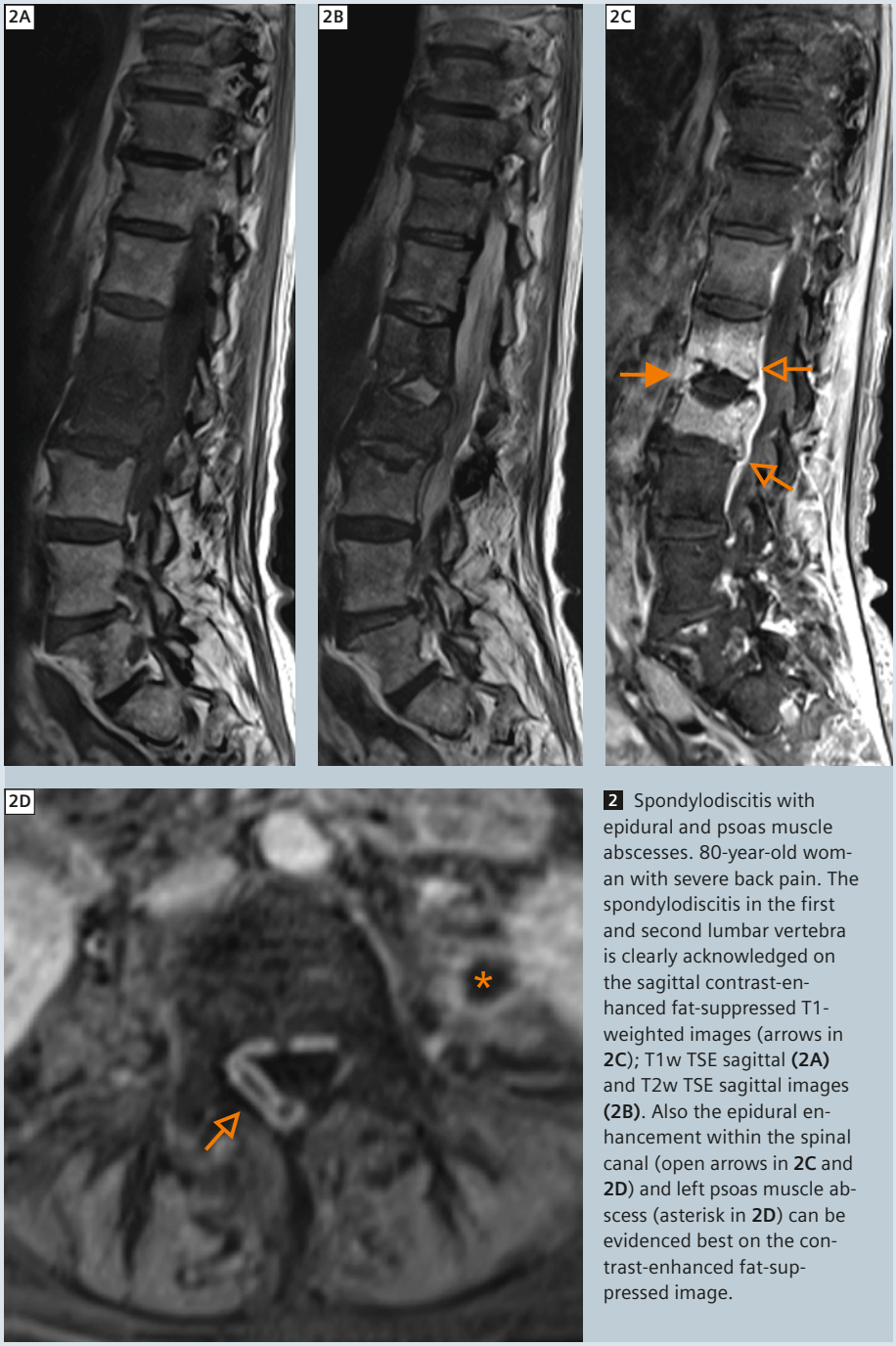


1 Intracranial hemorrhage in the right basal ganglia with small perifocal edema (arrows). 74-year-old man presenting with left sided hemiparesis since waking up 6 hours before. **(1A)** Axial unenhanced T1w, **(1B)** axial FLAIR, **(1C)** axial T2*w, **(1D)** axial diffusion-weighted image (*b*-value of 1000 s/mm²).

for Pediatric and Adolescent Medicine. Of course, the following suggestions are subject to ongoing discussion and refinement. The Department of Diagnostic and Interventional Radiology is the central service provider at the University Hospital Heidelberg in the field of diagnostic general radiological imaging and interventions. More than 91,000 examinations in out-patients and more than 71,000 in in-patients are performed annually, covering all indications and organ systems, with more than 210,000 imaging procedures every year. It should be noted that the following suggestions have been developed for a general radiological department. Dedicated neuroradiological departments may therefore develop additional suggestions regarding brain imaging.

List of indications for emergency MRI at the Department of Diagnostic and Interventional Radiology in Heidelberg

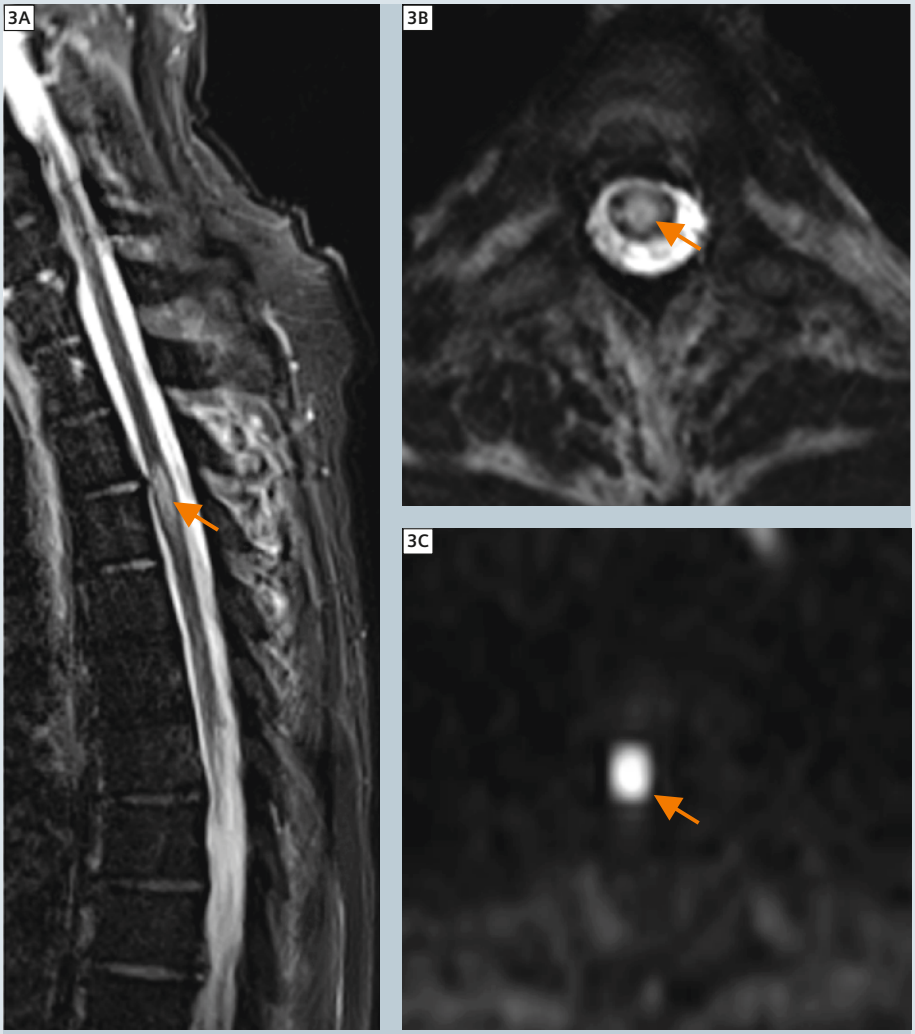
The list of indications differentiates between emergencies requiring immediate MRI (Category A, urgent care required as soon as possible day and night) and urgent cases with high priority but no need for immediate intervention (Category B, to be performed within 12 hours, e.g. next day). It was also considered important to define a third category (Category C) for situations that do not require an immediate MRI scan since equally diagnostic alternatives are available. Although such examinations may sometimes be urgently requested, it is strongly recommended to resist and to preserve the resources of the emergency MRI staff. This list represents the current stage of management and is intended to be regularly updated.



2 Spondylodiscitis with epidural and psoas muscle abscesses. 80-year-old woman with severe back pain. The spondylodiscitis in the first and second lumbar vertebra is clearly acknowledged on the sagittal contrast-enhanced fat-suppressed T1-weighted images (arrows in **2C**); T1w TSE sagittal **(2A)** and T2w TSE sagittal images **(2B)**. Also the epidural enhancement within the spinal canal (open arrows in **2C** and **2D**) and left psoas muscle abscess (asterisk in **2D**) can be evidenced best on the contrast-enhanced fat-suppressed image.

Category A Indications for an immediate emergency MRI

1. Cerebral and neurovascular emergencies (Fig. 1; e.g. acute cerebral ischemia or herniation syndromes in children): minimal protocol: T2-weighted TSE, dark-fluid imaging, diffusion-weighted imaging (DWI), time-of-flight (TOF) angiography, NO routine intra-venous (i.v.)-contrast medium administration.
2. Acute traumatic and non-traumatic syndromes with paraplegia and apparent neurologic deficits (such as paresis, sensory disturbances, disturbances in bladder or rectum function) that raise suspicion of a lesion of the myelon or the cauda equina. Examples include: Clinically suspected spondylodiscitis with epidural abscesses (Fig. 2; clinical relevance: immediate surgery indicated for epidural abscesses); acute spinalis



3 Spinalis anterior syndrome. 53-year-old man with acute paraplegia at level Th5 after surgical endovascular repair on an aortic dissection Stanford type B. At level of third thoracic vertebra there is swelling of the myelon with edema (arrows) on T2-weighted images (**3A**: STIR sagittal, **3B**: T2w SPACE) and restricted diffusion on the image with a *b*-value of 1000 s/mm² (arrow in **3C**).

anterior syndrome (Fig. 3); suspicion of epidural hematoma following spinal anesthesia or spinal surgery; suspected spinal cord contusion; clinical relevance: surgical decompression if edema of the spinal cord is detected). Minimal protocol: T2w TSE fat-saturated sagittal, T1w SE sagittal, T2w TSE transversal (non-fat-saturated) findings-centered. Optional: Diffusion-weighted imaging in case of suspected spinal ischemia. In case of suspected epidural abscess MRI with i.v.-contrast medium required.

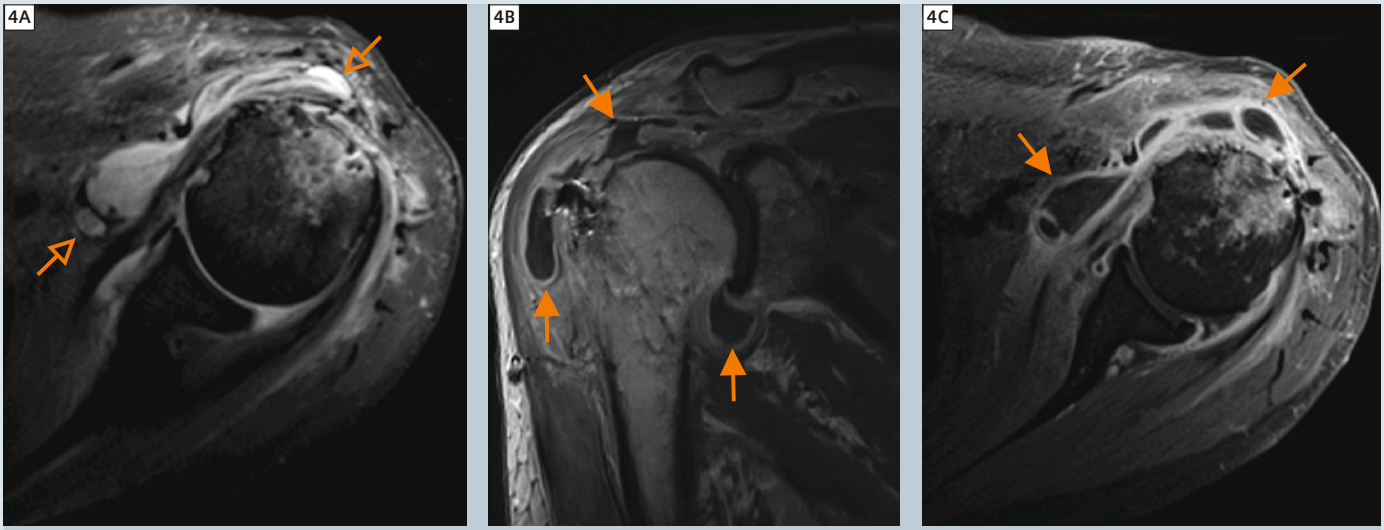
3. Strong clinical suspicion of septic arthritis (Fig. 4; clinical relevance: early joint lavage to prevent chondrolysis indicated). MRI with i.v.-contrast medium required.
4. Strong clinical suspicion of osteomyelitis in children. MRI with i.v.-contrast medium required.
5. Acute pulmonary artery embolism in pregnant women or very young patients (Fig. 5; pulmonary artery embolism protocol based on free breathing TrueFISP images. I.v.-contrast-enhanced TWIST perfusion and high spatial resolution MR angiography (MRA) only to be used, if exclusion of small peripheral emboli would be clinically relevant).

Category B Indications for an MRI within 12 hours include:

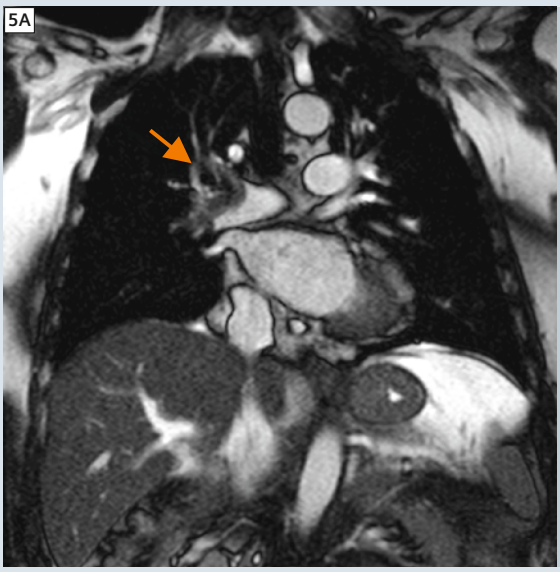
1. Spinal emergencies without neurological symptoms, e.g. to exclude spondylodiscitis or a ligamentous affection following a trauma of the spine, suspicion of a discoligamentous injury according to CT findings (use standard spine MR protocols).
2. In conventional radiography inconclusive findings or suspicion of occult fractures to prevent exposure to radiation in CT (especially in childhood).

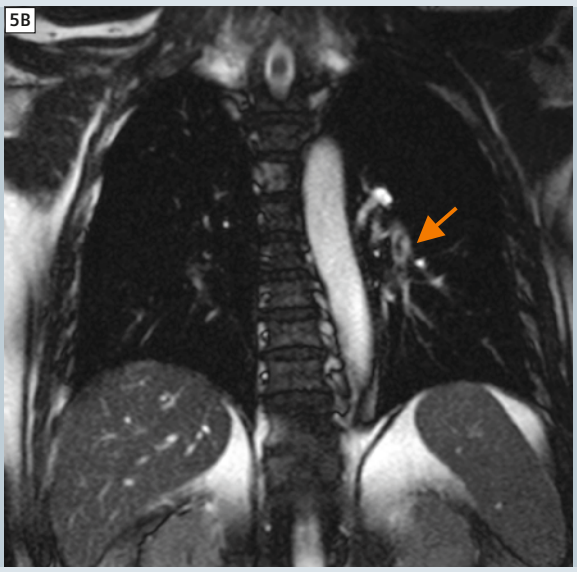
Category C Indications that do NOT justify an emergency MRI (=> e.g. CT as alternative emergency modality or MRI the next working day):

1. Run-off MRA for arteriosclerosis or acute occlusion of the lower limb (CT angiography as an alternative).
2. Suspicion or follow-up of intracranial hemorrhage (CT as an alternative) unless classified as neurovascular emergency according to Category A 1.
3. Suspicion of cerebral metastasis (CT with contrast medium as an alternative).
4. Urgent MRI requests due to organizational issues of the referring clinical partner or because of the patient's wish.



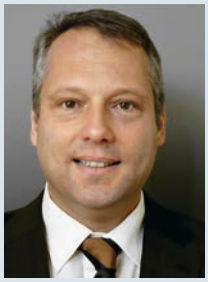
4 Septic arthritis of the shoulder joint in a 69-year-old man following shoulder arthroscopy and supraspinatus muscle refixation. The joint effusion is appreciated on the axial T2-weighted fat-saturated images (open arrows in **4A**). The strong synovialitis (arrows) is clearly evidenced on the contrast-enhanced coronal **(4B)** and axial **(4C)** MR images (**4B** without and **4C** with fat saturation).





5 Acute pulmonary embolism in both pulmonary arteries shown on T1/T2-weighted coronal TrueFISP images (arrows; this examination was obtained in a 64-year-old patient with renal insufficiency and suspected pulmonary embolism, being referred for non-contrast-enhanced MRI).

Contact
Marc-André Weber, M.D., M.Sc.
Professor of Radiology
Heidelberg University Hospital
Diagnostic and Interventional Radiology
Im Neuenheimer Feld 110
69120 Heidelberg
Germany
MarcAndre.Weber@med.uni-heidelberg.de



Contact
Jürgen Biederer, M.D.
Professor of Radiology
Heidelberg University Hospital
Diagnostic and Interventional Radiology
Im Neuenheimer Feld 110
69120 Heidelberg
Germany
Juergen.Biederer@med.uni-heidelberg.de

Attachment D

Comprehensive Adenosine Stress Perfusion MRI Defines the Etiology of Chest Pain in the Emergency Room: Comparison with Nuclear Stress Test

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Comprehensive Adenosine Stress Perfusion MRI Defines the Etiology of Chest Pain in the Emergency Room: Comparison With Nuclear Stress Test

Jens Vogel-Claussen, MD,[1,*] Jan Skrok, MD,[1] David Dombroski, MD,[1] Steven M. Shea, PhD,[2] Edward P. Shapiro, MD,[3] Mark Bohlman, MD,[1] Christine H. Lorenz, PhD,[2] Joao A.C. Lima, MD, MBA,[1,3] and David A. Bluemke, MD, PhD[1,4]

[1] Johns Hopkins University School of Medicine, Russell H. Morgan Department of Radiology and Radiological Science, Baltimore, Maryland
[2] Siemens Corporate Research, Inc., Imaging and Visualization, Princeton, New Jersey
[3] Johns Hopkins University School of Medicine, Department of Cardiology, Baltimore, Maryland
[4] National Institutes of Health, Department of Radiology and Imaging Sciences, Bethesda, Maryland
[*] Address reprint requests to: J.V.-C., Johns Hopkins University, Department of Radiology, Nelson Basement MRI 143, 600 N Wolfe Street, Baltimore, MD 21287. Email: jclauss1@jhmi.edu

Abstract

Go to:

Purpose

To compare standard of care nuclear SPECT imaging with cardiac magnetic resonance imaging (MRI) for emergency room (ER) patients with chest pain and intermediate probability for coronary artery disease.

Materials and Methods

Thirty-one patients with chest pain, negative electrocardiogram (ECG), and negative cardiac enzymes who underwent cardiac single photon emission tomography (SPECT) within 24 h of ER admission were enrolled. Patients underwent a comprehensive cardiac MRI exam including gated cine imaging, adenosine stress and rest perfusion imaging and delayed enhancement imaging. Patients were followed for 14 ± 4.7 months.

Results

Of 27 patients, 8 (30%) showed subendocardial hypoperfusion on MRI that was not detected on SPECT. These patients had a higher rate of diabetes ($P = 0.01$) and hypertension ($P = 0.01$) and a lower global myocardial perfusion reserve ($P = 0.01$) compared with patients with a normal cardiac MRI (n = 10). Patients with subendocardial hypoperfusion had more risk factors for cardiovascular disease (mean 4.4) compared with patients with a normal MRI (mean 2.5; $P = 0.005$). During the follow-up period, patients with subendocardial hypoperfusion on stress MRI were more likely to return to the ER with chest pain compared with patients who had a normal cardiac MRI ($P = 0.02$). Four patients did not finish the MR exam due to claustrophobia.

Conclusion

In patients with chest pain, diabetes and hypertension, cardiac stress perfusion MRI identified diffuse subendocardial hypoperfusion defects in the ER setting not seen on cardiac SPECT, which is suspected to reflect

microvascular disease.

Keywords: adenosine stress perfusion cardiac MRI, emergency room, chest pain, microvascular disease

The evaluation and triage of patients with chest pain is a common challenge for emergency room (ER) physicians. Fast and accurate assessment of myocardial ischemia in a patient presenting to the ER with chest pain is an essential component for further diagnostic and therapeutic decision making. Analysis of electrocardiograms (ECG) and cardiac enzymes are the first line tests to "rule out" acute myocardial infarction (1). In patients with a negative ECG, negative cardiac enzymes and an intermediate probability for coronary artery disease (CAD), nuclear stress perfusion tests (single photon emission computed tomography, SPECT) are well established means to evaluate for stress induced myocardial ischemia (2,3).

New technical developments over the past decade allow a comprehensive cardiac MRI examination, which includes myocardial perfusion, function, and viability assessment (4,5). Stress perfusion with MRI is an emerging noninvasive method for the evaluation of myocardial ischemia (6–9). Myocardial scar imaging with MRI aids in identifying small subendocardial myocardial infarctions that are not seen by cardiac SPECT (10). Furthermore, cardiac SPECT exposes the patient to 17–20 mSv of ionizing radiation (11) that is not present with MRI.

Some patients presenting to the ER with chest pain likely of cardiac origin may not have flow limiting stenosis of the coronary arteries, but instead have small vessel or other cardiac disease that could potentially be identified by MRI (12–14). Therefore, the aim of this study was to compare standard of care nuclear SPECT imaging with cardiac MRI for the evaluation of emergency room patients with chest pain and intermediate probability for coronary artery disease.

Materials and Methods

Go to:

Study Population

During a 12-month period, we prospectively and consecutively enrolled ER patients with chest pain, scheduled for a clinical cardiac SPECT who had negative cardiac enzymes and no signs of acute ischemia on ECG. The exclusion criteria were an internal pacemaker, defibrillator, positive cardiac enzymes, or contraindications for adenosine infusion. This study was approved by the institutional review board, and written informed consent was obtained from all patients.

Patients with a history of prior myocardial infarction and cardiac surgery were included in the study. All beverages containing caffeine were stopped at least 12 h before MRI examination.

Study Protocol

The MRI examination was performed within 24 h of presentation to the ER and within three hours of the nuclear SPECT stress test. During the MRI exam, blood pressure and ECG were monitored. Cardiovascular risk factors such as hypertension, diabetes mellitus, hypercholesterolemia, smoking, and family history of CAD were assessed. All patients were followed to assess for cardiac events for an average time period of 14 ± 4.7 months after noninvasive cardiac testing.

MR Imaging

Cardiac MRI was performed at 1.5 Tesla (T) (Siemens Avanto, Erlangen, Germany). A 6-element body matrix coil and 6 elements of a 24-element spine matrix coil were used for signal reception. For functional analysis, retrospectively ECG-gated steady state free precession (SSFP) cine MRI was performed in the short and long axis planes. The temporal resolution was 40 ms, with a slice thickness of 8 mm and 2-mm gap between slices on short axis images.

For the stress perfusion MRI, adenosine (Astellas Pharma US, Inc, IL) was infused intravenously at a rate of 140 (μg/kg per min over 6 min. At four minutes into the adenosine infusion, stress perfusion MRI was obtained with a Saturation Recovery (SR) SSFP sequence. Scan parameters per slice for the SR-SSFP perfusion images were repetition time/echo time (TR/TE) 2.4 ms / 1.0 ms, SR time 180 ms, flip angle 50°, FOV 36 × 27 cm, matrix 192 × 115, acquisition duration 150 ms, slice thickness 8 mm, and an acceleration factor of 2 (GRAPPA). Gadopentetate dimeglumine (Magnevist®, Bayer, Schering, Berlin, Germany) was injected at 5 cc/s followed immediately by a 20 cc of normal saline flush at 5 cc/s for the rest and stress perfusion MR images (0.075 mmol/kg each for rest and stress MR imaging, 0.15 mmol/kg total dose). Three evenly spaced short axis slices and one horizontal long axis slice were acquired with a temporal resolution of two ECG R-to-R intervals to cover the entire left ventricle for each patient. After 10 min, the perfusion examination was repeated to obtain rest perfusion images.

Following a delay of 5 to 10 min after rest perfusion imaging, gradient echo delayed enhancement (DE) MRI was obtained using an inversion recovery technique with nulling of the normal myocardium. Scan parameters per slice for the DE MRI were TR/TE 5.4 ms / 3.0 ms, flip angle 20°, field of view (FOV) 36 × 27 cm, matrix 256 × 160, slice thickness 8 mm with 2-mm spacing between each slice. Short axis images were acquired as well as one horizontal long axis image to cover the entire heart.

In addition, coronary sinus flow measurements were obtained at rest and during adenosine stress using breath hold two-dimensional (2D) phase contrast MR imaging as described by Koskenvuo et al in detail (15). The entire protocol was completed within 60 min.

SPECT Myocardial Perfusion Test

All patients underwent routine SPECT myocardial perfusion imaging using Tc^{99} sestamibi for rest and stress imaging. Of the 27 included patients, 13 underwent symptom-limited treadmill exercise testing (Bruce Protocol), 13 underwent a dobutamine stress protocol, and for 1 patient, adenosine stress protocol was used. Because the SPECT exam was part of the clinical routine, the type of stressor could not be influenced by the study team members. The SPECT exam is accepted as the clinical gold standard at our institution. Dobutamine was infused in incremental doses, starting at 5 μg/kg/ min for 3 min with increases to 10, 20, 30, and 40 (μg/kg/min until the stress end point was reached (e.g., target heart rate, chest pain with ECG changes, or hypotension). One patient received adenosine stress testing, with an identical stress regimen compared with the MRI stress protocol. Myocardial SPECT perfusion studies were performed using technetium 99m-sestamibi at rest and in the postexercise state according to widely accepted guidelines (16). The high-count rest scans were acquired as gated-SPECT studies (8 frames per cardiac cycle), and the left ventricular ejection fraction as well as end-diastolic volume were calculated.

Coronary Angiography

Patients with a positive SPECT and / or MRI stress test for reversible myocardial ischemia underwent conventional coronary angiography (n = 4) or coronary multi-detector computed tomography (n = 1) using a 256 detector scanner (Toshiba Aquilion, Japan). All angiography examinations were completed within 30 days (mean 15.5 ± 16.9 days) of the initial ER presentation.

MRI Analysis

Two experienced cardiac MRI physicians who were blinded to patient history (JVC and DD) evaluated all MRI studies separate from each other. If there was disagreement between the two readers, the cases were reviewed together and interpreted in consensus.

The analysis of the MRI perfusion examination was performed visually, as previously reported (17). We compared stress with rest perfusion to reduce the potential rate of artifacts. If a deficit was equally present at stress and rest, if it did not follow the subendocardial border, if ghosting artifacts could be seen or if it “blinked” bright and dark it was not regarded as an evident hypoperfusion, but as a potential artifact. Patients were classified according to

following criteria as previously described similarly by Pilz et al (13): (1) Patients with a reversible regional perfusion deficit in a coronary artery territory, lasting for more than six heart beats under adenosine stress, and without evidence of DE were classified as having significant obstructive CAD. (2) Patients with DE due to ischemic scar, history of coronary stent placement or coronary artery bypass graft without stress induced reversible perfusion deficit were categorized as "significant large vessel disease without reversible ischemia". (3) Patients with diffuse stress induced subendocardial hypoperfusion (<1/2 of the myocardial wall thickness) in at least two different coronary artery territories or circumferentially lasting for up to six heartbeats after the time of maximal signal peak intensity in the left ventricle were classified as having "small vessel disease" (13). (4) Patients without ischemic or nonischemic cardiac MR findings were categorized as "normal".

For the analysis, groups 1 and 2 were combined to a "large vessel disease" group. Additionally, other noncoronary findings that could explain the patients' chest pain were recorded.

Coronary sinus flow volumes in mL/min were calculated at rest and adenosine stress using dedicated flow software (Medis®, Netherlands). The coronary sinus was traced on the magnitude images. To compensate for the through-plane motion, a second region of interest was determined for each phase image on the myocardial tissue close to the vessel.

Coronary sinus blood flow (mL/min) was calculated by summing the flow per cardiac phase over the cardiac cycle and multiplying by the heart rate during the measurement. Coronary flow reserve was calculated by dividing the ratio of hyperemic to baseline coronary sinus flow.

SPECT Myocardial Perfusion Test

Cardiac SPECT studies were interpreted by an experienced nuclear medicine physician as part of routine clinical care for the patient. For this interpretation, the physician had access to the patients' medical records but not to the MRI results. Presence or absence of reversible or nonreversible stress induced perfusion deficits was recorded.

Statistical Analysis

Data are reported as mean ± standard deviation. The data were compared using Fisher's exact test or a two-tailed Wilcoxon signed rank test for matched pairs. In all cases, a P value < 0.05 was considered statistically significant. Interobserver agreement was measured using kappa statistics. Analyses were performed with commercially available statistic software (JMP®, SAS Institute, Cary, NC). The authors had full access to the data and take responsibility for its integrity.

Results

Go to:

Thirty-one patients were enrolled who were referred for SPECT stress test within 24 h after presentation with chest pain. Four patients (13%) were claustrophobic and did not complete the MRI exam. They were excluded from further analysis. The mean age of the remaining 27 patients (15 male) was 56.3 ± 13.2 years (Table 1). Five of 27 (19%) had a prior coronary revascularization procedure (one stent, four coronary artery bypass grafts).

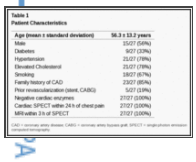


Table 1

Patient Characteristics

Image quality was sufficient for analysis in all patients, with reader consensus in 24/27 cases (kappa = 0.70). Of 27 patients, 8 (30%) showed diffuse subendocardial hypoperfusion with adenosine stress. Five of 27 patients (19%) had reversible large vessel ischemia on MRI (Fig. 1), confirmed by a ≥ 70% stenosis on angiography. One patient had both small and significant large vessel reversible ischemia.

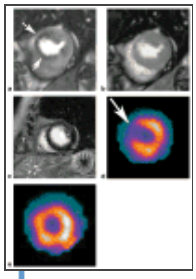


Figure 1

Short axis first pass adenosine stress perfusion MRI image shows a perfusion defect in the anterior-septal left ventricular wall (**a**, arrows), which is reversible at rest (**b**). Short axis delayed enhancement MR image shows no evidence of myocardial infarction **...**

All eight patients with subendocardial hypoperfusion on MRI (Fig. 2) were normal on cardiac SPECT. Of the five patients showing large vessel reversible ischemia on MRI, two patients also had corresponding transient ischemia on SPECT (Table 2). Of the three cases not detected by SPECT, two had a prior coronary artery bypass graft (CABG), one did not reach the target heart rate, and one had significant triple vessel disease (Table 2). Of 27 patients, 4 (15%) had an ischemic scar on MRI (Fig. 3). One patient had a small subendocardial scar that was not detected on SPECT.

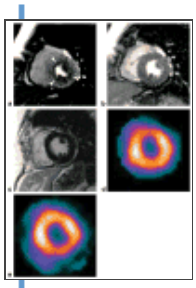


Figure 2

Short axis MR images (a–c) in a 53-year-old female with five traditional cardiac risk factors, chest pain, and negative cardiac enzymes show diffuse transient subendocardial hypoperfusion on the adenosine stress first pass perfusion image (**a**), **...**

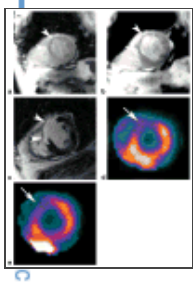


Figure 3

Short axis MRI images of a 75-year-old male patient with an old myocardial infarction and chest pain in the emergency room show thinning of the anterior septal wall with decreased first pass perfusion at adenosine stress (**a**), which persists at rest (**...**

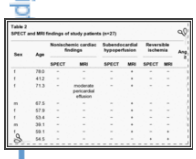


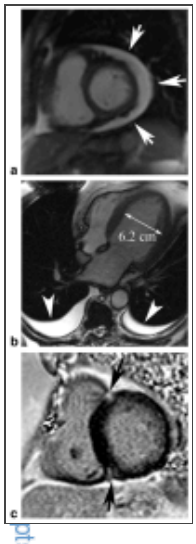
Table 2

SPECT and MRI findings of study patients (n=27)

Of 27 patients, 14 (52%) did not have small or large vessel disease on MRI and were also normal on SPECT. Of these 14 patients, 4 (29%) had nonischemic myocardial disease on MRI (Fig. 4), which was not detected on SPECT and may have contributed to the patients' chest pain: delayed enhancement at the right ventricular attachment site in a patient with pulmonary artery hypertension, moderate aortic regurgitation, mitral valve replacement with concomitant mitral valve stenosis, and alcohol related nonischemic cardiomyopathy (Table 2). One patient with subendocardial hypoperfusion also had a moderate pericardial effusion not identified at SPECT imaging.

Figure 4

Nonischemic cardiac findings identified on cardiac MRI in patients presenting with chest pain. **a**: Moderate pericardial effusion; (**b**) dilated nonischemic cardiomyopathy with absent LV scar (not shown), bilateral pleural effusions (arrowheads); (**c**) delayed **...**



Risk Factor Analysis

Patients with subendocardial hypoperfusion and the patient group with large vessel disease on MRI had a higher number of risk factors for cardiovascular disease (mean 4.4 and 4.0, respectively) compared with patients with a normal cardiac MRI (mean 2.5; $P = 0.005$ and $P = 0.03$, respectively). The group with large vessel disease (mean age, 58.9 ± 8.2 years) was significantly older compared with the group with normal MRI (mean age, 48.5 ± 8.9 years; $P = 0.01$).

Patients with subendocardial hypoperfusion had a significantly higher rate of diabetes ($P = 0.01$) and hypertension ($P = 0.01$) compared with patients with a normal cardiac MRI (Table 3). The majority (75%) of patients with subendocardial perfusion defects were women.

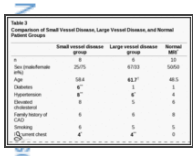


Table 3

Comparison of Small Vessel Disease, Large Vessel Disease, and Normal Patient Groups

Patients with subendocardial hypoperfusion had a significant lower coronary flow reserve (1.9 ± 0.44) assessed by coronary sinus flow measurements compared with patients with a normal perfusion MRI (3.0 ± 0.88; $P = 0.01$). The age of patients with normal MRI was not significantly different from that of patients with subendocardial hypoperfusion (48.5 ± 8.9 years versus 58.4 ± 13.8 years; $P = 0.17$).

Event Ascertainment

All patients were followed for an average period of 14 ± 4.7 months. During this time, there were no deaths, myocardial infarctions or strokes. One patient with a positive MRI stress test and negative SPECT for transient ischemia was found to have significant triple vessel disease on catheter directed angiography and underwent coronary artery bypass surgery 1 month after the initial admission. Three patients with chest pain, history of coronary artery bypass and reversible ischemia on MRI did not receive additional revascularization therapy, because the significant coronary artery disease was mainly affecting only coronary side branches on angiography.

During the follow-up period, 11 patients presented to the hospital with recurrent chest pain, but negative cardiac enzymes. All of these patients had abnormal findings on the initial cardiac MRI, including nonischemic findings, ischemic scar, subendocardial left ventricular (LV) hypoperfusion and transient ischemia (Table 2). None of the patients with a normal cardiac MRI had recurrent chest pain (n = 10; Table 2). Thus, patients with any abnormality on cardiac MRI (n = 17) were more likely to have recurrent chest pain than those with normal cardiac MRI (n = 10) ($P = 0.001$). Patients with subendocardial hypoperfusion on stress MRI were significantly more likely to return to

the ER with angina-like chest pain compared with patients with a normal cardiac MRI (4 of 8 patients, compared to 0 of 10 patients, respectively; $P = 0.02$). For recurrent presentations to the hospital with chest pain during the follow-up period, there was no significant difference between patients with (4 of 5 patients) or without (7 of 22 patients) reversible ischemia and/or myocardial scar on the initial SPECT exam ($P = 0.13$) (Table 2).

Discussion

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The results of this study suggest that cardiac MRI with stress evaluation may help define the etiology of chest pain in emergency room patients with a negative ECG, negative cardiac enzymes, and intermediate risk for ischemic heart disease. Patients with subendocardial hypoperfusion on MRI returned to the hospital more often with recurrent chest pain and had diabetes and hypertension more frequently compared with patients with a normal cardiac MRI. This same group of patients had a lower perfusion reserve measured by coronary sinus flow measurements compared with ER patients with a normal cardiac MRI and a normal cardiac SPECT examination.

Patients with angina pectoris but normal coronary arteries without coronary spasm have previously been described (18). There are 10% to 30% of patients diagnosed with ischemia who have normal angiograms, thought to be due to microvascular disease (19,20). In our study, 8 of 27 (30%) chest pain patients with negative cardiac enzymes in the ER showed diffuse subendocardial hypoperfusion on MRI. It seems likely that this could be caused by microvascular disease. In comparison, a multi center study in 159 women showed that coronary microvascular dysfunction was present in approximately half of women with chest pain in the absence of obstructive CAD (21).

Coronary microangiopathy, causing increased resistance in prearteriolar coronary vessels, consequently lowering myocardial perfusion and thus leading to impaired coronary flow reserve, has been suggested to be the underlying cause for the adenosine-induced diffuse subendocardial hypoperfusion (22,23). Pilz et al also reported adenosine-induced subendocardial hypoperfusion in the left ventricular myocardium, using first pass perfusion MRI (13). As in our study, patients with adenosine-induced diffuse subendocardial hypoperfusion had an increased frequency of hypertension or diabetes. Pilz et al showed that the subendocardial perfusion deficit as seen by cardiac MRI was highly correlated to lower coronary artery flow on catheter directed coronary angiography. In addition, in our study ER patients with diffuse stress induced myocardial hypoperfusion and chest pain had a lower perfusion reserve compared with symptomatic ER patients with normal first pass perfusion MRI.

In 222 participants of the MESA (Multi Ethnic Study of Atherosclerosis) study, coronary vasoreactivity was reduced in asymptomatic individuals with a greater coronary risk factor burden (24). In our study, patients with chest pain and adenosine-induced microvascular hypoperfusion also had significantly more traditional cardiovascular risk factors compared with the group without small or large vessel disease. The data suggest that the traditional risk factors not only affect the conductive coronary arteries but also myocardial microvascular vasoreactivity.

MRI findings of subendocardial hypoperfusion need to be carefully distinguished from hypoperfusion due to hemodynamically significant coronary artery stenosis. Both findings are seen only with adenosine stress perfusion. In general, perfusion defects due to coronary artery stenosis are more persistent and more focal than diffuse subendocardial perfusion defects. Both occur after the peak contrast bolus has reached the LV cavity at the time the myocardium starts to enhance. Dark rim artifacts typically start to occur earlier just before the peak bolus reaches the LV cavity. Dark rim artifacts may occur particularly with older perfusion sequences with lower spatial resolution, likely due to susceptibility differences between the blood pool and myocardium (25,26). Diffuse subendocardial hypoperfusion is located in the endocardium and is not confined to the blood pool/myocardial border as typically seen with dark rim artifacts. Dark rim artifacts are frequent (52% in our study) and are typically recognized on both resting and stress perfusion MRI studies and are usually more focal than subendocardial perfusion defects.

Three patients with CABG and reversible ischemia on MRI did not receive any additional revascularization therapy

in our study, as the coronary artery narrowing was affecting only coronary side branches on conventional angiography. In all three patients adenosine-induced regional reversible perfusion defects involved less than one-third of the myocardial thickness, but lasted longer than six heart beats. These perfusion deficits were not thought to be clinically significant for coronary revascularization; nevertheless, during the follow-up period, two of these patients presented to the hospital with recurring chest pain and negative cardiac enzymes. Dobutamine stress examinations may have higher specificity in this setting (27,28).

Compared with cardiac SPECT, PET, and CT, MRI does not expose patients to radiation, which is a strong motivation to further work on implementing cardiac MRI in the emergency room (29–31). Cardiac stress perfusion MRI has higher spatial resolution (2 mm in our study) compared with SPECT (10 mm) and PET (5–6 mm) (32), which is likely the cause for the detection of subendocardial perfusion defects on cardiac MRI in our ER patient cohort with normal SPECT exams.

Limitations

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A limitation of our study is that only a portion of our patients received conventional coronary angiography, because it was not routine clinical practice to perform catheter directed angiography after a negative SPECT examination. Patients in this category were instead followed for cardiovascular events. Nevertheless, reviewer agreement was high. Four patients (13%) were claustrophobic and did not complete the MRI exam, while all patients could tolerate the nuclear cardiac SPECT exam. Adenosine was used for all MRI cases but often different stress agents were used for the SPECT stress exam, which may have influenced the rate of discordant results. We acknowledge that this is a pilot study and future larger trials have to show if adenosine induced diffuse subendocardial hypoperfusion on first pass perfusion MRI is an independent predictor of future cardiovascular events.

In conclusion, chest pain patients presenting to the emergency room may have ischemic or nonischemic etiologies causing their pain. Cardiac stress perfusion MRI can identify subendocardial hypoperfusion that may represent microvascular disease in patients with chest pain and negative cardiac enzymes; these perfusion abnormalities are not otherwise detected on SPECT imaging. In our patient cohort, adenosine stress induced left ventricular diffuse subendocardial hypoperfusion found on MRI was associated with recurrent chest pain, diabetes, hypertension and decreased global myocardial perfusion reserve. It remains to be determined if patients with chest pain and adenosine-induced diffuse subendocardial hypoperfusion on MRI benefit from more aggressive cardiovascular risk reduction treatment.

Acknowledgments

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