Advanced MRI in renal tumours

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To evaluate the diagnostic performance of diffusion weighted MR imaging (MRI) techniques by using apparent diffusion coefficient (ADC) maps and Diffusion Tensor Imaging (DTI) on 3 tesla MRI in assessing the nature of renal masses.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON40717

Source
ToetsingOnline

Brief title
MRI in renal tumours

Condition

- Renal disorders (excl nephropathies)

Synonym
Kidney cancer, renal tumours

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Europese unie

Intervention

Keyword: Diffusion tensor imaging, Diffusion weight imaging, MRI, Renal mass

Outcome measures

Primary outcome

To assess the discriminative value of diffusion weighted MR imaging for

malignant versus benign lesions.

Secondary outcome

To assess the discriminative value of DTI for histological subtype of renal

tumours using DTI and Fractional Anisotrophy (FA) values.

Study description

Background summary

About 2-3% of newly diagnosed cancer concerns renal cell carcinoma (RCC). Approximately 85-90% of all diagnosed renal malignancies is accounted for by RCC. The three major subtypes of RCC are clear cell (80-90%), papillary (10-15%) and chromophobe (4-5%).

In solid renal masses, presence of enhancement in CT or MR imaging is used for detecting malignant lesions. However, differentiation between histological subtypes of renal tumours (malignant versus benign and subtypes of malignant tumours) on imaging is not yet proven to be unequivocal. Because CT and MRI cannot reliably distinguish malignant renal tumours from oncocytoma and (fat-free) angiomyolipoma false positive scans do occur. When reviewing surgical series regarding partial nephrectomy, up to 20% of all resected lesions of suspected malignant nature on imaging, are shown to be benign. Even higher percentages have been reported for radical nephrectomy. Identifying these benign lesions in an early stage through imaging may avoid invasive diagnostics such as biopsy, and eventually unnecessary surgery. Also when patients are unsuitable for surgery but histological confirmation of a renal mass is needed, for instance with the intended purpose of starting systemic therapy, additional information regarding subtype obtained by MRI may be of value.

Diffusion weighted imaging (DWI) is based on the Brownian motion of water molecules. When the environment is totally unrestricted, the motion of water molecules is completely random (Brownian motion or free diffusion). Within tissue however, the movement is not random but restricted by interactions with tissue compartments, cell membranes and intracellular organelles. The amount of

restriction of the movement of the water molecules within tissue is measured using DWI sequences. The strength of the sequence used (diffusion sensitizing gradient) is characterized by the b value. Three different factors affect the b value: gradient amplitude, duration of the applied gradient and the time interval between paired gradients. The unit of the b value is seconds per square millimeter. Using linear regression, an apparent diffusion coefficient (ADC) can be calculated using the images obtained at different b values. The images can be reviewed qualitatively by visually assessing DW and ADC images, but also qualitatively by measuring the ADC value of the lesion. Impeded diffusion will appear bright on DW images even at higher b values due to maintained signal. Restricted diffusion can be observed on the ADC map as it appears as a dark area in relation to the surrounding structures. When measuring a reduced ADC value, this indicates impeded diffusion which is associated with increased cellularity.

As malignant tissue is associated with impeded diffusion, DWI using ADC measurements has been shown to be able to discriminate between benign and malignant renal tumors. A recent meta analysis concluded that identification of oncocytoma by ADC value might be the greatest advantage in DWI. However, differentiating angiomyolipoma*s (AMLs) from malignant tumors was not possible using ADC values, as AMLs showed comparable results with RCCs.

Diffusion tensor imaging (DTI) is based on the principles of DWI. For ADC imaging using DWI usually 3 gradient directions are be applied. Meaning that ADC measurements are performed along three axes and are integrated thereafter, leading to an image based on mean ADC values along 3 axes. However, the calculated ADC values are still very dependent on the direction of the diffusion encoding because diffusion can occur in an infinite amount of directions. To better assess the true direction of diffusion DTI is developed. This system measures mean ADC values along different axes that fit to a 3D ellipsoid. By assessing 6 parameters (the length and orientation of the three axes) of the ellipsoid, its properties can be assessed. Because of these measurements, with DTI it is possible to assess the speed of movement of the water molecules (as in regular DWI) but also the direction in which the molecules move and thereby fully characterising the diffusion in 3D instead of only 3 directions.

Unrestricted diffusion in all directions is referred to as isotropic, anisotropy means that diffusion along certain axes are not equal. Using anisotropy DTI enables to calculate in which direction the diffusion occurs. A widely used metric of diffusion anisotropy is fractional anisotropy (FA). The current soft- and hardware is enabled to provide FA images and values, thus showing in which direction diffusion is more or less restricted. Higher FA values indicate more anisotropy within the tissue. Anisotropy data can be used in for instance brain imaging to assess the orientation of fibers along brain tissue. For examples also see Appendix C. DTI has previously been studied in patients with chronic kidney disease (CKD), showing decreasing ADC an FA values

with more severe stages of CKD. Kidney tumours also have previously been studied using DTI, conclusions regarding ADC and FA values of this study however are based on a very small group.

Study objective

To evaluate the diagnostic performance of diffusion weighted MR imaging (MRI) techniques by using apparent diffusion coefficient (ADC) maps and Diffusion Tensor Imaging (DTI) on 3 tesla MRI in assessing the nature of renal masses.

Study design

Single center, prospective, observational.

Study burden and risks

The only risks consist of additional risk by MRI (burden of heating and noise, risks of adverse reactions against gadolinium). Patients with previous allergic reaction to gadolinium based contrast agent are at higher risk to develop a subsequent allergic reaction upon administration, therefore they are excluded in order to minimize the risk of an adverse reaction.[19] The overall frequency of acute adverse events after an injection gadolinium based contrast agent ranges from 0.07% to 2.4%. The vast majority of these reactions are mild: coldness at the injection site, nausea, headache, warmth or pain at the injection site, paresthesias, dizziness and itching. Allergic reactions are very unusual and vary in frequency from 0.004% to 0.7%. Rash, hives, or urticaria are the most frequent, and very rarely there may be bronchospasm. Life-threatening anaphylactoid or nonallergic anaphylactic reactions are exceedingly rare (0.001% to 0.01%). [20]

Gadolinium agents are considered to have no nephrotoxicity at approved dosages for MR imaging. Gadolinium based contrast agent administration to patients with severe impairment of renal function (eGFR <30 mL/min) can result in a syndrome of nephrogenic systemic fibrosis (NSF). Therefore no contrast will be administered to this group of patients. [20]

By screening all patients as in clinical use before undergoing MRI, and by additionally assessing previous adverse reactions to gadolinium based contrast agents and renal function, the risk on adverse reactions is minimized.

With minimal burden for the studied group with good applicability towards the study endpoint, the objective of the study outweighs the individual risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Planned to undergo (partial) tumour nephrectomy of at least one untreated tumour of one kidney;
- Signed IRB-approved informed consent form.

Exclusion criteria

- Relative contra indications for MR imaging (metal device/foreign bodies, claustrophobia);
- Known hypersensitivity / previous allergic reaction to gadolinium based contrast agent;
- Active renal or perirenal infection;
- Minor and/or incapacitated adult.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2014
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	15-09-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-01-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49616.091.14