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Database integration of protocol-specific neurological imaging datasets

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Abstract

For many years now, Magnetic Resonance Innovations (MR Innovations), a magnetic resonance imaging (MRI) software development, technology, and research company, has been aggregating a multitude of MRI data from different scanning sites through its collaborations and research contracts. The majority of the data has adhered to neuroimaging protocols developed by our group which has helped ensure its quality and consistency. The protocols involved include the study of: traumatic brain injury, extracranial venous imaging for multiple sclerosis and Parkinson's disease, and stroke. The database has proven invaluable in helping to establish disease biomarkers, validate findings across multiple data sets, develop and refine signal processing algorithms, and establish both public and private research collaborations. Myriad Masters and PhD dissertations have been possible thanks to the availability of this database. As an example of a project that cuts across diseases, we have used the data and specialized software to develop new guidelines for detecting cerebral microbleeds. Ultimately, the database has been vital in our ability to provide tools and information for researchers and radiologists in diagnosing their patients, and we encourage collaborations and welcome sharing of similar data in this database.

Introduction

The wealth of information embedded in any given set of neuroimaging data is well beyond what is usually extracted in a single study. While the acquisition scheme itself might be fixed for different protocols, the data can be processed (either immediately or in a subsequent analysis) in many ways to look for different imaging biomarkers based on the study's objectives. Our own work has focused on neurological diseases, and over the years, we have established a number of protocols for detecting microbleeds and imaging iron in traumatic brain injury (TBI) and more recently, stroke patients. We began by collaborating with sites both nationally and internationally, and it became critical to design a data sharing repository to allow proper storage and extraction of data as needed for data analysis. In 2005, we were awarded state funding from the State of Michigan Technology Tri-Corridor

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fund to build a robust database to allow safe data storage and easy access to what is currently an expensive process to collect and maintain data if done by grant funding. Our goal was to establish several specific protocols and begin collecting data for diseases such as Alzheimer's disease (AD), specifically vascular dementia, multiple sclerosis (MS), Parkinson's disease (PD), stroke and TBI.

Our focus in the past has been to develop new MR technology via novel imaging sequences and image processing methods. The biggest challenge has been to test these ideas clinically with sufficiently large number of cases to have an impact on the field. We envisioned this repository to serve as a national database repository of de-identified data for the best possible MR data from different imaging centers, hospitals and research institutions (all shared and protected following the Health Insurance Portability and Accountability Act (HIPAA) regulations). Once the database was established, it could then be made available for reproduction of the same study anywhere, as well as for reprocessing and re-analyzing, data mining, and more in-depth statistical analysis as new image processing methods were developed (Greicius et al., 2004). This database was further expanded in 2010 to include collaborations with national and international investigators, who agreed to share their data as part of the current MR imaging repository. To date, based on images from this database, our group has published more than 100 papers, which otherwise would not have been possible.

MR Innovations employs its MR imaging patents, MR image processing software, and expert knowledge to provide quantitative and diagnostic data analysis tools and services to hospitals, neuroradiologists, and imaging centers, offering consulting, protocol optimization, collaborations, technical reporting for imaging centers, and original research publications. More recently, MR Innovations is taking advantage of the availability of this database by doing large-scale contract research for pharmaceutical companies. Over the past few years, our group has collaborated with many sites, many of whom have signed an agreement allowing us to store, use and share the data for future studies.

The database: Current status

Generally, the purpose of the database is to: a) keep large quantities of standardized data organized; b) maintain original and processed data in an easy to use format; and c) encourage sharing and research collaborations both publicly and privately. Our “Process Scheme for MR Innovations” (Fig. 1), in general, closely resembles the “Stages of Electronic Data Capture” as graphically described by Poline et al. (Poline et al., 2012): First the experiment is established and imaging protocols are designed or used with fixed acquisition parameters, images are collected from subjects from the MR scanner, or the data are transferred to us by a vendor who has adopted our protocol and ultimately stored on our servers. Then the raw data is de-identified and converted to a usable DICOM (digital imaging and communications in medicine) format. The server then pre-processes the data with myriad algorithms which may include sorting, anonymization, brain extraction, etc. After that, the database is populated with the acquisition parameters and remaining patient information on the server. The individual processors or researchers then perform any further processing on their workstations if needed and the quantified data are analyzed, reviewed, and prepared for technical reports or for research publications. The final processed de-

identified data are uploaded back to the server for storage and potential future analysis. Any publications are then distributed through web services and databases such as PubMed Central or ScienceDirect.

The data

The database was originally developed to store MRI data that were collected for many different neuroimaging studies. This data was composed of a wide range of MRI sequences including conventional (heavily used in clinics – such as T1 and T2 – weighted imaging, Fluid Attenuated Inversion Recovery (FLAIR), proton density) and non-conventional approaches (such as susceptibility weighted imaging (SWI), perfusion weighted imaging (PWI), diffusion tensor imaging (DTI), functional MRI (fMRI), phase contrast flow quantification (FQ) and MR angiography and venography (MRV)) for imaging the brain's structure, function, and composition. After this initiative, more data was added to the database from different centers outside our direct collaborations who adopted our image acquisition protocols, creating a large source of re-usable data (with proper permissions).

The current database holds MR data from more than 3000 cases, covering a spectrum of neurodegenerative diseases (dementia, migraine, AD, MS, PD, stroke and TBI) as well as a repository of data from healthy controls. Most of the collected data followed a single protocol for each disease, which made the quality and format of the data and processed results consistent and reliable between sites. For instance, in 2010, we developed a protocol to collect MRI data to best diagnose the damage in TBI. This paper resulted from a special workshop sponsored by the National Institutes of Health (NIH) and the United States military which is published in the Journal of Magnetic Resonance Imaging (Haacke et al., 2010) and has been adopted as the standard imaging protocol by the United States military (DCoE Clinical Recommendation, 2013).

The resurgence of a vascular hypothesis for MS occurred in 2009 (Zamboni et al., 2009). Demand by both researchers and patients for MRI scans (as well as ultrasound and selective catheter venography) to investigate extracranial venous structure and function (flow) increased. Though shorter MRI protocols with conventional MR imaging already existed for MS, we created a specialized venous imaging protocol which included phase contrast flow quantification, 2D time-of-flight venography, 3D contrast-enhanced Time Resolved Imaging of Contrast Kinetics (TRICKS) angiography, and SWI (Utriainen et al., 2012a, 2012b). More advanced tiers for this protocol included DTI and PWI using a T1-shortening contrast agent. Numerous institutions worldwide have adopted these protocols and have sent their standardized data to MR Innovations for flow processing and angiography review for venous anomalies (Table 1). This unique repository has grown to over 2000 cases all collected with a similar protocol. Several papers have been published related to the data from these sites (Utriainen et al., 2012a, 2012b; Dake et al., 2011; Feng et al., 2012a, 2012b; Haacke, 2011; Haacke et al., 2012a, 2012b; Liu et al., 2014; Rahman et al., 2013; Sethi et al., 2014) (for more specific protocol information, visit <http://mrinnovations.com/index.php?site=protocols>). Collaborators from all the major vendors have participated in this program. Table 1 shows a list of de-identified data from some institutions that we have data from with a list of disease type, subject count, and associated publications.

Data collection and subject descriptors

At the start of new site collaboration, we review test scan data from the collaborating institution to ensure its quality, and to make sure the right set of images are output. Our quality control consists of reviewing the images for any acquisition problems or errors in post-processing. Scans with artifacts which severely affect the structures of interest are excluded from any future data analyses.

The information pertaining to the patient is determined by the nature of the study. Generally, with database administrator permissions and Institutional Review Board (IRB) approval if we are collaborators, we have access to all the header information, recording fields such as age and sex, while other details such as medical history, smoking and history of cardiovascular or neurological problems can be requested from the provider (assuming they in turn have the subject's consent). In some diseases such as MS, we often have expanded disability status scores (EDSS), disease duration and symptoms; for TBI, we often have information related to the injury and symptoms such as whether the trauma was caused from a motor vehicle accident, the patient lost consciousness, or has vertigo. In the studies where we have collected data from our own research in subjects and healthy controls, patients are screened for history of diabetes, chronic renal disease, a prior known psychiatric or neurological disorder, or substance abuse; currently receiving chemotherapy, on dialysis or any known contraindication to MRI such as a pacemaker or implanted device; or if females were pregnant or nursing. For any subjects who undergo contrast-enhanced (CE) venography, subjects were excluded if they were allergic to MRI contrast, or had moderate to severe kidney disease with impaired ability to filter contrast agents (serum creatinine > 1.8 mg/dL). For those sites where we were not collaborators, no information is available about the patients at all (except perhaps for sex and age) and all personal information is de-identified using different techniques that automatically traverse all the patient's data and overwrite each file with a new anonymized header without keeping the personal information. The de-identification and post processing tools are executed using different command lines with well-established parameters. Scanned copies of different documents can be present within the patient's data, containing personal information, but only for in-house IRB approved investigators. Otherwise, these are automatically detected and permanently deleted using our algorithms. We are currently developing a brain extraction algorithm that will work on all types of data, leaving behind no facial characteristics that can lead to face recognition.

Regarding data contribution, anybody who is interested in collaborating can contribute new data. After registrations and data usage agreements have been signed, a new site is set up on our end, followed up with instructions on how to upload data. The data can come in different archive forms (zip, rar, 7z, gz, etc.) or uncompressed formats. After the automatic extraction takes place (if required by the format), data is anonymized and sorted by sequence type. After these processes are completed, the sorted data will be made available for the designated database users. Sorted data is kept in the same format to maintain a consistent input and make it easier to develop processing tools that work for the whole database's data in the same way.

The storage

The data acquired is stored in its raw format after being assigned a unique identifier. Each institution is assigned 3 initials. The subsequent data coming from these institutions will be assigned continuing unique identifiers in the following format: institution's initials followed by an automatically generated number with a maximum 6 characters in length, e.g., ABC_123456. Data is transferred to us using different modalities, such as SFTP (secure FTP-File Transfer Protocol over SSH-Secure Shell protocol using multiple simultaneous transfers for an efficiently bandwidth use and increased speed), a picture archiving and communication system (PACS) to PACS using a DICOM router behind a virtual private network (VPN) established connection, web upload behind a secure socket layer (SSL) encryption, listed in the preferred order due to their simplicity, speed and security characteristics or in rarer occasions via disk or an external drive. We handle large data uploads by using a dedicated internet line and multiple concurrent transfers for the SFTP transfer. Due to multiple geographical locations for many of our clients, we are planning to enable load balancing for uploads using multiple locations to host our servers. The interruptions that may occur are usually handled by the client's software. Most of the current file transfer protocol (FTP) client softwares handle resumed connections, the same applies to the PACS systems. The data undergoes a series of processes that are designed to automatically populate the database with well-established details about patient, visit, study, series, image, procedure, equipment and magnetic field strength data fields that are extracted from the DICOM header of each sequence (when allowed); much of the detailed protocol information including image acquisition parameters are also stored. After the database population process is complete, the original data is automatically anonymized and prepared in an easy-to-use form for the processors, including sorting by protocol and additional time-consuming signal processing (detailed in *The processing* section). If data comes from an outside source with no direct collaboration with us, but still with external IRB approval, the data are immediately de-identified.

The interface

The database interface was designed with a focus on user-friendliness while maintaining a wide variety of tools. There are three categories of users with assigned permissions: administrators, processors, and clients. Additional groups can be implemented as required. Currently, the administrators can see all the records from the database and have access to different tools that are not available for the other two types of users. For example, the administrator can add and delete users, institutions, studies, patients, and modify data, etc. They can edit different fields from the interface such as the assigned processor, disease state, and notes. The processors can see only the cases assigned to them and have limited access to the tools and fields. The clients can see only their own data as well as reports created by the processors and it is presented in an ease to view format behind an encrypted layer for better manageability without security penalty. Sorting and filtering for each individual field is enabled by default for all types of users. Additional tools are available only to the administrators, like maintaining projects (organize data for different institutions), advanced searches (combining multiple fields), exporting physical data, exporting Comma-separated values (CSV) formats of the current/filtered view, and running custom queries. Some

functions are shared, for example, edit in-line, hide/display columns/fields, change column order, data export, paging support, bookmarkable searches, and save table state. Since administrators have unlimited access, they can assign cases to the processors who have restricted access to information identifying the study and any patient identifiers that may introduce bias under a research or reporting setting such as age, sex, and disease state. Thus, the interface has been effective in maintaining blindness when doing research and technical report writing. It has also proven useful when meeting with clients at their own site or even at professional meetings where they might meet with representatives of MR Innovations. Some other tools include: storage of processed data, technical report documentation based on the individual data set, sharing original and processed data between institutions that have been granted co-access and downloading data. A notification system will email users (that includes administrators and processors responsible for the data/results and the client) if there is new/modified data submitted. For each case, notifications will let administrators and processors know if a report was submitted in the initial states so they can go back and forth for further corrections. When the final report is uploaded, the client will receive notifications and instructions on how to download it.

The processing

In our post-processing pipeline, we are able to perform the following time-saving operations per individual case and in bulk (provided the images are present): anonymization, sort original data based on the protocols and sequences used, generate DTI maps, quantitative susceptibility maps, PWI maps such as cerebral blood volume, cerebral blood flow and mean transit time, brain extraction from FLAIR with white matter lesion count and volumes, maximum intensity projections, as well as image registration to reorientation to a reference image. To do all these, we use the command line option of our in-house developed software known as SPIN (signal processing in nuclear magnetic resonance). The advantage of pre-processing on the server saves the data processor from processing automatable tasks on his or her workstation, and helps give more time for analysis, especially in bulk processing tasks. Using some of the processing mentioned above, much of the data that has been sent to us for MS and TBI has been processed with SPIN and technical reports have been prepared for both researchers and radiologists (these reports are technical only and meant to provide the radiologist with quantitative information, they are in no way meant to serve as clinical interpretations of the data). Each report is linked to its corresponding entry in the database and as a whole these reports provide a source for data mining.

Sharing and maintenance

We are eager to collaborate, work, and share our data for all imaging related projects. In compliance with HIPAA, and under consent of the subject and institution based on a data use agreement, we can offer the use of our software and sharing of the data with prospective collaborators. In this process, we ask that the users reference their collaborations and when appropriate the use of our software. Some notable collaborations have included projects involving: cancer, MS, stroke, and TBI research. Another advantage of this type of sharing and collaboration is the future ability to cooperate on grant funding as a team of researchers. Given the importance of team science and data mining today, this makes a powerful combination of resources to encourage participation.

The long term plans for maintaining the resources will include hardware maintenance with scheduled upgrades to stay on top of the curve as new improved computer components are available from time to time. These plans include the implementation of redundant hardware to maximize availability (redundant power supply unit (PSU), redundant motherboard setups, multiple backups, battery backup for the RAID controllers, etc.), and the implementation of load balancing for an increased speed in accessing the database and faster uploads. In regards to the database, keeping the database normalized and optimizing existing queries will minimize existing bottlenecks. Administering users and their assigned permissions keeps the database under strict surveillance. The interface will get updates on a regular basis as new vulnerabilities and bugs are found or new tools are developed.

Challenges

We encountered a few challenges developing the relational database and the hardware behind it. The large amount of data that is required to be stored, in the anonymized original and/or post-process format, is on the order of tens of terabytes. This required fast and high capacity storage, currently at ~50 Tb per server, using the safest redundant array of inexpensive disks (RAID) configuration without speed penalty. Due to this large amount of data that needs to be stored and accessed regularly, tape backup was out of the question, so backing up on another similar server (minus the computational power) was chosen as the best path. All our servers are hosted in a data center, where dedicated internet connections are provided; this is required for reliable, high speed uploads and downloads. Currently, we are not using any clusters for increased computational processing, due to the limited processing required at our end, but we plan to implement this in the future as more tools will require higher processing power and will make it possible to maximize our resources.

From vision to reality

While it was a vision back a few years ago, now it has become a full time job involving numerous staff and collaboration sites. The datasets from previous collected protocols using conventional imaging and SWI have sparked interest in the private sector as well. Recently, a pharmaceutical company teamed up with MR Innovations to establish operational guidelines/criteria for detecting cerebral microbleeds (CMBs) from cerebral T2*, SWI and QSM images (Haacke et al., 2015). The objective was to determine bleed incidence, volume, and iron content in a large cohort of MS patients, a database which we have at hand already. The partnership proved mutually beneficial and the pharmaceutical company had the added benefit that it did not have to incur costs recruiting and waiting for new subjects to be scanned, administrative costs or maintenance costs that an imaging center would have generated (Poline et al., 2012). Similar projects for detecting microbleeds may have major applications in dementia, stroke and traumatic brain injury as well.

Conclusions and future directions

Many of the previous collaborations are still intact today; these joint studies keep the database growing. In the meantime, we continue to manage and optimize the MR imaging protocols to ensure premium data quality. Currently, the original and processed datasets do not come with citable digital object identifiers (doi) or uniform resource identifiers (uri),

however, this is something that we will implement in the future. What was once a dream for many researchers has now become a reality, the ability to acquire, store, access and data mine images with the hope of not just improving diagnosis but giving radiology the tools to help discover the etiology of disease. Establishing standard protocols and adhering to common data formats have eased our efforts of data sharing (Poldrack et al., 2013), software and command-line processing, and publication. Thanks to this database, we have discovered a new vascular anomaly in Parkinson's disease. Recent results in our collaborative stroke study in Asia may open the door to better initial treatment and follow-up treatment for patients. And our discovery of venous anomalies in mild TBI (mTBI) patients, even though it is only at the 10% level, could affect hundreds of thousands of patients affected by mTBI every year. The role of biomarkers even in mTBI has been useful in stratifying the severity of the injury (Tosetti et al., 2013). The access to this data has also forced us to develop new software to deal with processing the data and to look for more methods of automating such software. If this direction is successful, it will give us the opportunity to provide radiologists better tools for diagnosing their patients. This database concept has been an impetus for many collaborations and has led to numerous publications, giving further credibility to the utility of such databases now and even more so in the future.

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Fig. 1.
Process scheme for MR Innovations.

Table 1

Sites that have collaborated with us with the number of scans per disease or condition type, and scanning protocol name. Each site is listed as a number.

Site no.	Disease	Country	Manufacturer	Bo (Tesla)	Model	Protocol	Count
1	MS	USA	SIEMENS	3	TrioTim	VENOUS	434
2	TBI	USA	SIEMENS	3	Verio	TBI	248
	MS	USA	SIEMENS	3	Verio	VENOUS	88
	Lyme's	USA	SIEMENS	3	Verio	VENOUS	54
	Parkinson's	USA	SIEMENS	3	Verio	VENOUS	11
3*	Cancer	USA	SIEMENS	3	Verio	TBI	21
	Normals	USA	SIEMENS	3	Verio	TBI	16
4	TBI	USA	SIEMENS	3	TrioTim	VENOUS	13
5*	MS	Canada	GE	3	Signa HDxt	VENOUS	424
	VS	Canada	GE	3	Signa HDxt	VENOUS	102
6*	MS	Germany	SIEMENS	3	TrioTim	VENOUS	10
7*	MS	Canada	SIEMENS	3	Verio	VENOUS	24
8*	TBI	USA	SIEMENS	3	Verio	TBI	72
9*	MS	USA	SIEMENS	3	Verio	VENOUS	28
10	MS	USA	GE	1.5	Signa HDxt	VENOUS	711
11*	MS	USA	SIEMENS	1.5	Espre	VENOUS	26
12	MS	USA	SIEMENS	3	TrioTim	VENOUS	255
	Normals	USA	SIEMENS	3	TrioTim	VENOUS	34
	TBI	USA	SIEMENS	3	TrioTim	VENOUS	12
13	Stroke	China	SIEMENS	1.5	Avanto	STROKE	68
14	Heart	USA	SIEMENS	3	Verio	VENOUS	230
	Normals	USA	SIEMENS	3	Verio	VENOUS	141
	TBI	USA	SIEMENS	3	Verio	VENOUS	100
	MS	USA	SIEMENS	3	Verio	VENOUS	70
15*	MS	USA	SIEMENS	3	Verio	VENOUS	21
16	Normals	China	SIEMENS	3	TrioTim	VENOUS	24
TOTAL							3237

A standard research contract was obtained from this site for internal data usage rather than our current global data usage agreement document.

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