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Background

- The outcome for a breast cancer patient depends significantly on the diagnostic skills of the multidisciplinary team. Recently, much criticism of breast cancer care is related to so called over-detection, over-diagnosis and "unnecessary" treatment. The fear is that we perform too many biopsies of lesions that turn out to be benign or would not have become significant during lifetime and therefore biopsy could have been avoided if we had known in advance.
- We believe with continuous imaging, pathology, and statistical outcome feedback with the help of the Living Atlas system we will potentiate gain in knowledge and make more efficient the workflow and treatment path at Northwestern. The continuous feedback of all these parameters aims to improve physicians' decision-making confidence in recommending biopsies to evaluate breast lesions. This eventually will improve accuracy of future decisions.

Research Objectives

- The goal of the Living Atlas (LA) is to improve patient care by reducing the benign to malignant ratio (BMR) and to gain knowledge more rapidly in the diagnosis and treatment of breast lesions by using a novel real time methodology in one digital medical information system.
- We acquired an IRB (Project Number: STU00032148) with the title: Living Atlas: A Real Time Clinical Evaluation System for Imaging-Guided Percutaneous Biopsies. During this process we generated a patient consent form for all patients of interventional procedures performed at the breast imaging section NMH. We will follow patients diagnostic and treatment path over time to evaluate pathologic results related to imaging and biopsy recommendations. This sequential analysis of a patient's care is crucial to the success of LA in bringing about improvement in outcome.

Methods

- To reach our goal we will use a novel digital system - the Living Atlas - developed and advanced in our section over a period of 4 years (see figure 1). The system is based on the precursor system (4DMAM) that Dr. Karst began to develop in 2003 at a German site, Charité University Hospital in Berlin. Analysis of the precursor system's data suggests ability of the system to effect changes in management of high risk lesions, for example flat epithelial atypia, as well as to allow new knowledge of upgrade rates to determine diagnostic and treatment strategies (see table 1). The precursor system has established the practicality of this real time feedback system.
- LA comprises a client/server system, in a 4D (4th dimension)-developed database system with user-friendly graphical interfaces, in 4D-programmed user functions, an integrated DICOM server, an integrated statistical program and digital datasheets for data entering (see figure 2). An easy-to-use method for entering data was uniquely developed for the LA-system (see figure 3). Different from other databases, such as the EDW all data are structured and enterable as discrete information with predefined values e.g. the pathology diagnosis, technique used etc. This is avoiding statistical errors that can otherwise occur e.g. by slightly different spelled medical terms or by synonyms of the same entity. All information stored in LA is valuable and statistically countable within the system with preconfigured statistical display formats for easy review in an instant. As a result all entered information is scientifically analyzable accurate data. To protect the data the server was implemented in the NMFF datacenter. Comprehensive data protection mechanisms were integrated into the system as defined in and approved by the IRB such as client-server data encryption, secure access of only IRB enabled personal, etc. I developed a smooth integration into the departmental environment and put a lot of effort into slimming down the entry process and time for entering cases. Images can be sent directly from PACS to LA. The images are processed automatically by the server. As much information as possible is retrieved from the DICOM headers and is translated into data in LA including complete creation of cases with lesions, studies, and images as well as the associated data. A complete workflow was designed to make the entry of information as easy and rapid as possible. As a result, cases can be usually entered in less than a minute. This allows integration of use of LA during routine clinical work and entry of all interventional cases during a day.
- The LA system will provide real time feedback of all significant information of image guided breast interventions. The system is designed to contain all relevant information about the diagnostic imaging study, the biopsy, and pathology results. It includes data about the history, the lesion, the imaging studies, the significant images, the technique used, the pathology diagnosis, treatment recommendation and if applicable, diagnosis post surgery. With the LA integrated conference tool, interesting cases and outcome data such as upgrade rates will be presented and discussed at weekly tumor boards and multidisciplinary conferences.

Table 1. Results from 4DMAM:

Entity	Number of Biopsies	With Excision	Upgrade to malignant in % (Number/of all)			
			All	off		
				Stereo	US	MRI
All	232	146	21% (30/146)	19% (16/84)	23% (14/59)	0% (0/3)
FEA	73	54	15% (8/54)	15% (8/52)	0% (0/1)	0% (0/1)
ADH	27	20	45% (9/20)	27% (4/15)	100% (5/5)	0% (0/0)
LIN	22	10	20% (2/10)	33% (1/3)	20% (1/5)	0% (0/2)
Papilloma	62	34	20% (7/34)	17% (1/6)	21% (6/28)	0% (0/0)

Figure 1. Mainpage Living Atlas

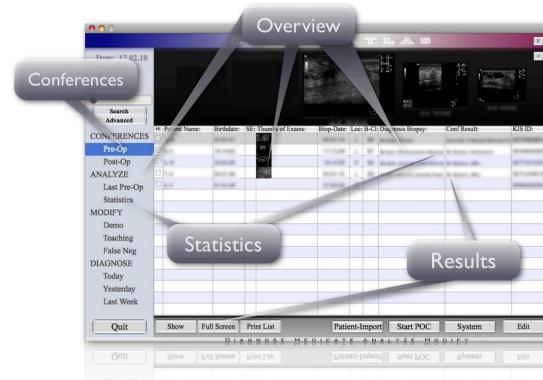


Figure 2. Structure Living Atlas

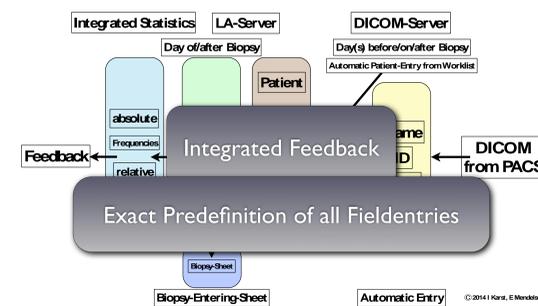


Figure 3. Data entry in LA



Results

- It is difficult to measure direct effect of a totally new information method, e.g. the gain of knowledge. To evaluate the effectiveness of the new tool at Northwestern we will enter all of approximately 3000 interventional breast imaging cases per year including all ultrasound, stereotactic, and MRI-guided biopsies at the breast imaging section NMH. By evaluating significant quality measures directly with the integrated statistical program within LA, e.g. positive predictive value (PPV), BMR, upgrade rates, we will measure the effect of the outcome by using the new LA-methodology. In addition a multi center comparison of results from Berlin, Germany and Chicago will give helpful insights into the effect of two different healthcare systems while using this new method.

Limitations

- In the future, given the effectiveness of LA, this method could be translated into other fields of cancer therapy e.g. thyroid, liver, lung. To make the method more widely available, we are considering cooperation/licensing with global players in healthcare IT such as GE and Siemens. The translation of the prototype into open source software and offering it as a service would broaden the availability in a different way. The long-term goal is the adoption and integration of the method into industry IT healthcare systems e.g. RIS, HIS, PACS etc.

Conclusions

- With the Living Atlas we hope to be able to show that with the development, introduction, and use of clinical real time feedback systems we can change the way of gaining knowledge in breast cancer treatment and medicine. After completion and installation, LA will remain to achieve its integrational role of quality management and research goals in Northwestern's breast imaging section. A rising list of faculty emphatic junior faculty and fellows is already being involved in this important clinical project directed at patient quality and safety of care as well as advancements of clinical knowledge.

References

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