2158 POSTER

A New Modified Autofluorescence Pleuroscopy in the Undiagnosed Lung Cancer With Pleural Effusion

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Background: Autofluorescence bronchoscopy (AFB) was developed to enhance the detection of lung cancer in the airway. The value of AFB in detecting early lung cancer or carcinoma has been evaluated in many research settings. However, its role in the work up of pleural space has not been evaluated. So We used a flexible bronchoscope (SAFE 3000, Pentax, Tokyo) to entry a pleural space with undiagnosed lung cancer with pleural effusion.
Materials and Methods: We used chest sonography to locate the entry. Then the endoscopy went through a tocar 5.5 mm under local anesthesia; We used a flexible bronchoscope (SAFE 3000, Pentax, Tokyo) to entry a wound which was less than 1 cm. A 16 Fr pig pig-tailed catheter inserted after the procedure. All abnormal lesions detected by white light bronchoschopy (WLB) or AFB were biopsy for histological examination Then the clinical data retrospectively studied. The whole procedures were done either in the bedside or endoscopic room.
Results: 22 patients were recruited. There were 6 patients with cytology negative and normal finding in WLB or AFB but 2 of them were found to have lung cancer. Among the 16 patients with atypia or suspicious cells had abnormal finding in the WLB or AFB, 15 patients of them had finally diagnosis of lung cancer. Lung cancer were more commonly found in those cytology with suspicious cells. AFB was also more sensitive than WLB (93% versus 53%) at detecting the abnormal lesion in pleural space.
Conclusions: This is a new modified pleuroscopy used for detecting the undiagnosed lung cancer with pleural effusion; especially for those cytology with suspicious cells. This is a daily practice not only performed in the endoscopic room but also in the bedside.

2159 POSTER

A Novel Biodegradable Balloon (BioProtect SpaceGuard™) Reduces Inter-fraction Prostate Motion and Provides Reproducible Geometry in Patients Receiving IMRT for Prostate Cancer

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Background: To assess intra-fraction prostate motion and positioning during radiation therapy in patients undergoing placement of BioProtect SpaceGuard™ biodegradable balloon in the rectal-prostate interface.
Methods: 23 prostate cancer patients from 5 institutions underwent transperineal insertion of a biodegradable balloon under TRUS guidance as part of a phase I study.
CT scans were performed prior to, after implant and during follow up. For 2 patients, during treatment, CT scans were acquired weekly. Contours of the organs and balloon for all scans were drawn by the same MD. Geometric analysis (positioning, volumes, displacement, and deformation) of the organs and balloon was carried out relative to bony landmarks. Patients were all planned to 75.6 Gy and DVH analysis performed. In addition, 18 of these 23 patients underwent measurements of balloon, prostate-rectal distance and balloon non dislocation by independent imaging specialist.
Results: The balloon displaced both the prostate posterior wall (11 mm; range: 5−18 mm) and anterior rectal wall (10 mm; range: 6−16 mm) along the interface while the anterior surface of the prostate and posterior surface of the rectum were displaced less (5 mm; range: 0−12 mm). The gap introduced by the balloon was 24.7±4.7 mm, 24.1±4.3 mm, and 15.9±0.6 mm for post implantation, during XRT and at 3 months post implantation, respectively. This gap resulted in a mean V65 of 4.3% (range: 0%-11.7%) compared to 14.5% (range: 11.1%-20.5%) before implant. Similarly, mean V70 changed from 12.2% (range: 9.3%-17.1%) to 3% (range: 0%-9.7%).
There was minimal change in position of the prostate posterior wall (2.5 mm, Range: 0.7−4.3 mm) and rectal anterior wall (2.8 mm, 1.5−5.1 mm) during treatment.
Follow up scans showed degradation of the balloon 90 days post treatment.
Conclusions: Bioprotect creates uniform and stable space between prostate and anterior rectal wall therefore reducing rectal dose significantly. The balloon seemed to acts as buffer for prostate inter-fraction displacement from changes in rectal volume. In our study, the inter-fraction motion of prostate was significantly less than reported in the literature. Larger study is planned to assess inter and intra-fraction prostate motion using BioProtect SpaceGaurd®.

2160 POSTER

Coping With the Data Deluge: the Quartz Software Platform for the Management, Visualisation and Analysis of Large Scale, Multimodal Genomic and Bioimage Data

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Background: Recent advances in genomic and bio-imaging technologies will only prove useful to the extent that the data they produce can be adequately visualized, analysed and interpreted. Indeed hardware improvements whether in resolution, speed, cost or novel imaging modality, present the oncology community with new challenges: the acquired data are increasingly bigger (e.g., SNP arrays now feature millions of probes, high-resolution histo-pathology images are often larger than a gigabyte), online databases accumulate ever more entries, multimodal studies comprise all sorts of data: clinical, imaging, genomic, etc. In these respects the realization of the immense potential of advanced hardware technologies is conditional upon the development of equally sophisticated software approaches capable of handling the size, number and heterogeneity challenges of this data deluge.
Methods: Ilixa's Quartz is a software platform capable of managing, visualizing and analysing heterogeneous datasets of arbitrarily large size. It was designed from the ground up for high-throughput applications requiring flexible, fast and scalable handling of data. The platform makes it possible for programmers to focus on the actual application features, rather than worry about memory, speed or visualization. In essence, it offers a high-performance, integrated environment to facilitate the design, rapid-prototyping and development of advanced, bespoke, user-friendly oncology tools.
Results: Taking advantage of the capabilities offered by the platform, we have developed for our research and clinical collaborators a number of genomic and bioimaging applications. In particular, we have to date delivered analysis software packages for (1) high-throughput microarray technology with the ability to handle thousands of samples from a variety of platforms and technologies (SNP arrays, aCGH, expression and methylation data, etc.); (2) visualization and analysis of karyotypes and (3) multimodal visualization and image analysis for MRI and histology/ immunohistochemistry, later adapted for the reconstruction of 3-D histological volumes.
Conclusion: In view of the daunting challenges facing genome and biomedical informatics, Ilixa believes that the Quartz platform can play a key role in catalysing the delivery of innovative solutions by streamlining the translation of ideas and concepts into efficient tools.

2161 POSTER

INTEGRATE: Driving Excellence in Integrative Cancer Research Through Innovative Biomedical Infrastructures

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Background: While the healthcare industry continues to improve its capabilities for electronic data capture, a gap remains in the ability of IT systems to deliver knowledge back to the researchers and clinicians they are intended to support. The fragmentation of infrastructures and tools used in clinical research and care, together with the lack of common methodologies and of sufficient high quality data, may make research a difficult task, especially in the case of high resolution genomic translational research projects in oncology.
Methods: We address the current low integration of information by focusing on main barriers such as the lack of interoperability and the low adoption of standards, and aim to build and provide access to large, high quality datasets (including data, annotated models, and metadata). We also develop a flexible infrastructure for information sharing in biomedical research, to bring together heterogeneous multi-scale biomedical data generated through standard and novel technologies within post-genomic clinical trials.
The environment will be designed and validated in the context of the Neo-BIG research programme of neoadjuvant trials of the Breast International Group (BIG), developed specifically to enhance and accelerate biomarker discovery and validation in early drug development in breast cancer.

Results: We adopt a standards-based approach in the development of our semantic interoperability layer. The semantics of the clinical terms will be captured by standard terminology systems such as SNOMED CT, ICD, LOINC, and scalability will be achieved by modularization, identifying a core dataset which covers the chosen clinical domain and our data. The core dataset will be validated by clinical and knowledge engineering experts to assure proper coverage and soundness.
Relevant clinical scenarios have been identified and formalized in technical use cases, and are used as basis for our requirements analysis. We have defined an open, service-oriented architecture which provides the technical blueprint for the implementation of the INTEGRATE framework (www.fp7-integrate.eu).
Conclusions: The huge potential of the current biomedical research in oncology cannot be fully exploited in the absence of a coordinated and systematic approach. Our infrastructure will enable the sharing within a large biomedical community of comprehensive datasets and knowledge generated by clinical trials. The project will support BIG in promoting in the clinical community new methodologies and standards concerning the collection, processing and sharing of data. This will improve the reproducibility of high resolution translational research embedded in clinical trials and facilitate future research.
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2162 POSTER

Implementation of an Open Source FDA and GCP Compliant Electronic Case Report Form (eCRF) System in an Oncology Department − an Option?

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Introduction: The data monitoring, regulatory procedures and data management in investigational trials are still having trouble to fulfill the national legislation. Investigators are forced to use inadequate tools in their trials − there is no audit trails in an excel worksheet.
Internet-based connectivity offer resources to improve the quality and efficiency of data management operations.
At Herlev University Hospital and Rigshospitalet, Departments of Oncology, we have implemented an Open Source FDA and GCP compliant Electronic Case Report Form (eCRF) system − OpenClinica. The system covers all the data management processes.
Materials and Methods: Several both commercial and Open Source eCFR systems were investigated to ensure if they fulfilled governmental legislation and GCP demands. Secondly a set of minimum requirements were established concerning system functionality and security. It was decided to implement OpenClinica based on above considerations and the following criteria: economy, department policy, resources, IT infrastructure and availability.
An implementation plan was created including (main tasks only): Testing as part of FDA and GCP compliance
- IQ − Installation Qualification
- OQ − Operational Qualification
- PQ − Performance Qualification
- Site Standard Operational Procedure (SSOP), not yet finished.

Results: At the Departments of oncology, three studies have been up using OpenClinica, as summarized below.
- Project I. Enrolled 51/51 finished (Normal complexity)
- Project II. Enrolled 589/800 (Complex)
- Project III. Enrolled 2/500 (Very complex)

The complexity refers to treatment schedule and amount of different eCRFs. The final aim is to use OpenClinica for all investigator initiated studies in the department.
Discussion: At a time when clinical resources and financial budgets are tight, we have to find new ways to solve problems with inadequate data management tools. One option might be to turn to the many Open Source programs available today.
To succeed in implementing an Open Source FDA and GCP compliant eCRF system one needs:
- Allocation of adequate resources in the form of skilled dedicated staff covering the whole data management process including research nurses, physicians, secretaries and IT personnel.
- Funding − The system is free BUT the implementation is NOT.
- A well defined time implementation plan.
- Preferably some person(s) with experience from similar projects

2163 POSTER

Integrating Web-based Real-time Analysis System With Clinical Research Database Facilitates Interim Analysis

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Background: Interim analysis is usually used for assessing patients' performance on clinical trials and modification or early termination of the trial if there is large difference between treatment groups. However, performing interim analysis requires separate data collection and processing at certain predetermined points. The study aim was to decrease time and effort needed for collecting, validating, cleaning and analysing data.
Materials and Methods: In our novel technique, we have developed a clinical research system that entitles performing real-time data collection for our patients and feeding the database with updates at each visit. Data were validated automatically at data-entry step and challenged against different algorithms. Real-time statistical analysis results including survival analysis are updated in numerical and graphical presentations without the need for stopping the trial or data collection. The whole trial results are updated collectively based on each individual visit. This instant statistics interface is made available for independent researchers and auditors.
Results: With automated web-based solution, data-entry validation, cleaning and simultaneous analysis time and effort decreased significantly. Moreover, interim analysis became available at any point in the trial so allowed the researcher to examine the trial concurrently. This can help the researchers to modify the trial at any time earlier or later than a predetermined point. Its web-based property made the results available remotely for central reviewing and auditing.
Conclusion: Integrating online statistical analysis with clinical research systems improved data-entry process, and study monitoring, hence it improved the interim analysis and decision making.

2164 POSTER

Central Multi-disciplinary Consultation and Decision Making on Treatment of Patients With Complex Tumours

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Objective: Centralization of the decision making on treatment of patients with complex tumours in order to achieve proper treatment and care for every oncological patient in north east region of The Netherlands, by multi site and multi-disciplinary oncology meetings with expert consultants.
Background: The comprehensive cancer of The Netherlands (CCCN) aims to achieve proper treatment and care for every oncology patient within the country. To reach this aim, the CCCN can call upon the consulting services of 400 medical experts from university medical centers. One of the tasks of these experts is advising medical specialists in general hospitals, thus ensuring the availability of high-quality specialised cancer care throughout the Netherlands.
Methods: Through expert consultation and centralised decision making in tumour boards, patients can rely on being treated at the highest quality level, according to the latest findings, regardless of the hospital. In recent years the CCCN initiated general tumour boards to be replaced by tumour-specific multi site and multi disciplinary meetings. Sometimes with 4 to 6 hospitals simultaneously, accompanied by one or more consultants from the expert center. To enable these meetings video conference is used.
Video conferencing involves specific demands on the organization of oncology meetings. The CCCN supports hospitals in buying, installing and using the hardware. The CCCN supports secured webbased patient information sharing among participants. The CCCN provides virtual meeting rooms, using videoconferencing standards and internet, in which all kinds of diagnostic images can be presented in real to all participating locations. Hospitals are provided with training of members and chairmen. A guideline is developed for the organisation of multi site oncology meetings per videoconferencing, including a format for patient presentation.
Results: All hospitals in the CCCN-region have facilities for video conferencing. In addition, all radiotherapy centers and pathology laboratories use video conferencing to participate in the tumour boards, which easily and secure take place in a virtual meeting room. It's possible to share data during videoconferencing: on one screen the participants of the other locations are projected, on the other screen the patient presentation and images such as CT scans. Even tele-pathology through high definition coupe scanners can be used in tumour boards. Several multi site tumour specific tumour boards are implemented. For instance for ovarian cancer and urologic tumours on a weekly basis, so that all patients are being discussed with experts before the start of their treatment.