Advances and challenges in radiation protection of patients

Synthesis

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A FEW NUMBERS

- Total number of participants: 320
- Number of countries represented: 34
  - European countries: 12
  - Other countries : 22
- 12 sessions : 41 oral presentations
- 2 Poster sessions : 67 posters
- 2 Round tables

CONTENTS

- Benefits of radiotherapy
- Paradigms of external radiotherapy and brachytherapy
- Challenges in radiotherapy
  - Individual radiosensitivity
  - Risk/benefit issue
- Accidents
  - Lessons from the past
  - Events recording, reporting and evaluation
- Treatment of complications and late morbidity
- Equipment safety, staffing, education and training
- Controls, quality assurance and audits
- National strategies and regulations
- Patient information

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Benefits of radiotherapy (*Cosset*)

- Radiotherapy, one of the 3 major treatments of cancer
- Radiotherapy is chosen for cancer treatment in more than 50% of cancers by multidisciplinary committees
- 10 million people treated in the world
- Good results : 80 % healing
- 10 % of the whole cost of oncology
- Few accidents but unavoidable side effects for all anticancer therapies

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Paradigms of external radiotherapy and brachytherapy (1)

- **Advances in external radiotherapy *(Brada)***
  - Helical tomotherapy, robots,gating and imaging improves in theory 4D conformational radiotherapy :
    - Increase tumour dose by shaping radiation field
    - Dose modulation within the tumour
    - Limitation of dose to surrounding normal tissues
  - Introduction of new technology needs :
    - Only to demonstrate the safety of the new equipment = good
    - But not its real efficacy and benefits for patients
      - Tumour control without increased toxicity
      - Improved patient survival and quality of life
    - Clinical trials similar to drug testing needed for evidence based radiotherapy

Paradigms of external radiotherapy and brachytherapy (2)

- **Advances in brachytherapy *(Peiffert*)**
  - Brachytherapy delivers a fast, conformal, concentrated and hyperfractionated dose of radiations with an optimum therapeutic index
  - Innovations (3D imaging, new radioactives sources HDR, computer controlled projectors ...) allow intensity-modulated conformal radiotherapy in which the system delivering the dose is directly connected to the target volume
  - The latest brachytherapy techniques are of clinical benefit for the patients. Risks of point source or implant positioning errors are real, hard to detect and could have serious clinical consequences.

Paradigms of external radiotherapy and brachytherapy (3)

- **The impact of new technologies on the risk of accidents *(Amalberti*)**
  - Innovation is perceived as a tool to enable a potentially considerable breakthrough in the advancement of safety = Short cycle (2 years)
    - The former risk has disappeared = overall benefit
    - New errors and failures appear
  - Traditional "Quality and safety" methods always needed to optimise the available methodology by combating faults and failures related to practices = Long cycle (10 years = no time / innovation)
  - Gains related to innovation (100%) >> gains that the quality based approach (20%) can provide
  - But virtually no authorisation for innovation !!

Paradigms of external radiotherapy and brachytherapy (4)

- **The highlights of the IAEA-ICARO conference *(Chhem)***
  - International conference on advances in radiation oncology - Vienna April 2009
  - Shortage of qualified personels in radiotherapy
  - Increased demand of RTH worldwide (use of Co^{60} in developing countries)
  - Requirements to adopt advanced technologies in RTH:
    - Availability of adequate imaging services
    - Experience with 3D conformal RTH and advanced treatment planning
    - Clinical studies demonstrating benefit of advanced technology
    - Adequate training of staff in planning, implementation and quality assurance of advanced technology
    - Continuous medical education and self assessment programs

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Challenges in radiotherapy
Individual radiosensitivity (1)

- What is a side effect, a complication or an accident in radiotherapy ? *(Scalliet, Azria*)
  - Side effect : reversible, results from a transitory down regulation of normal tissue renewal
  - Complication : irreversible, results from permanent damage after irradiation. Risk to be weighted against the severity of the disease
  - Accident : not part of a normal treatment. Not related to the treatment objective
  - All effects graded for 1 to 5
  - Conformal therapy has decreased side effects

Challenges in radiotherapy
Individual radiosensitivity (2)

- The range of radiosensitivity in the normal population : Hyper / hyporadiosensitivity ? *(Bouffler)*
  - About 5% [1 – 10 %] of patients show severe normal tissue reactions in RTH (deterministic side effects & complications)
    - Extreme radiosensitivity (e.g., Ataxia telangectasia ...) due to abnormal genes or signalling pathways
    - Hypersensitivity in heterozygous carriers
  - Hypersensitivity to radiation carcinogenesis
  - Hyposensitivity exists but still to be further documented
  - Perspectives :
    - Large genome-wide association studies needed
    - Intrinsic radiosensitivity ot tumours / normal tissues
    - refinement of treatments to maximize rates of cure by RTH while minimizing severe normal tissue reactions

Challenges in radiotherapy Individual radiosensitivity (3)

- Radiation-induced sequelae : toward an individual profile ? *(Azria*)
  - Late radiation-induced lesions : direct stem cells destruction, fibrosis, necrosis, atrophy, vascular damage
  - Radiosensitivity factors related to treatment : total dose, fractionation and time gap between fractions, protraction,volume irradiated
  - Radiosensitivity factors related to the patient : genetic factors (abnormal repair of DNA lesions)and predisposing factors (chemotherapy, age, smoking, microvascular disorders [diabetes]...)
  - Predictive tests of radiation toxicity :
    - Low radiation induced CD8 lymphocyte apoptosis
    - Four or more single nucleotide polymorphism (SNP) alterations in ATM, SOD2, TGFB1, XRCC1, XRCC3 and RAD21
    - Combination of the 2 tests
    - Large studies needed + on whole genome

Challenges in radiotherapy Individual radiosensitivity (4)

- Human radiosensitivity : new concepts and new tools to predict over-acute reactions after radiotherapy *(Foray)*
  - Most animal models not appropriate because mutated proteins do not exist in humans
  - Requirements to link tissue reactions with molecular endpoints : human cells, wide range of dose, models and protocols as close as possible to clinical situations, clear definition of radiosensitivity
  - Assays based on gene expression : not convincing
  - Assays based on gene mutation (SNP alterations) : not sufficient
  - Combination of 2 assays based on DNA-DSB repair gene function from skin biopsies is predictive over the whole range of radiosensitivity and doses :
    - pH2AX immunofluorescence assay
    - MRE11 immunofluorescence assay

Challenges in radiotherapy Risk/benefit issue (1)

- Evaluation and management of secondary cancer risk in modern radiotherapy : elaboration of an ICRP /ICRU publication for 2010 *(Cosset*)
  - Previous publication n° 44 in 1985
  - New publication part 1 : analysis of clinical data (NIH 2006)
    - The majority of second induced cancers occur in or close to the high-dose treatment volume (*Hall*)
    - Children are much more sensitive to the carcinogenic effect of ionizing radiations than adults
  - New publication part 2 : physical distribution of doses
    - Increase of the volume of healthy tissues receiving low doses (< 1 Gy) in modern radiotherapy in comparison to standard RTH : increased risk ?
  - New publication part 3 : risk models and radiation biology
  - New publication part 4 : recommendations on risk acceptability for each new technique
  - No more cancer risk with IMRT than with conventional radiotherapy

Challenges in radiotherapy
Risk/benefit issue (2)

- Cardiovascular risk in radiotherapy *(Trott)*
  - Evidence in HN survivors (*Preston*)
  - Known for a long time for Hodgkin disease patients
  - 33% increase risk of late heart failure in women with left breast cancer and radiotherapy with an average dose of 5 Gy to the heart (*Darby*)
  - Current international research :
    - What is the nature of radiation-induced heart disease after radiotherapy ?
    - Is very late cardiovascular radiation damage caused to the coronary arteries or to the microvasculature ?
    - How should the heart dose be specified for treatment plan optimisation with modern equipements ?
    - How can the risk of very late heart failure be included in the definition of an acceptable risk, an overall index of harm ?

Challenges in radiotherapy Risk/benefit issue (3)

- Risk acceptability *(Mettler, Trott, Sia)*
  - A good radiotherapy is not the one which does not cause any serious side effects nor one which cures all patients
  - In between these 2 extremes, a good radiotherapy unfortunately causes an acceptable level of serious late morbidity
  - More patients die from failure of curing the first cancer than from treatment-induced second cancers (<1% in adults, much higher in children and young adults)
  - Large and long term epidemiological studies needed
  - The patient should be placed in the positions to understand the risk of RTH / other risks and to decide
  - European ALLEGRO project to measure latency, severity and impact of side effects on quality of life and to develop new criteria for treatment plan optimisation and patient information

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Accidents
Lessons from the past (1)

- Lessons learned from accidents in conventional external radiotherapy *(Holmberg*)
  - Analysis of the few available specific case histories, finding of causes, contributing factors, actual circumstances of discovery and methods of future prevention (IAEA report series n°17 & ICRP 86 publications)
  - Points to be adressed systematically :
    - Working with awareness and alertness
    - Need for comprehensive, properly documented and fully implemented procedures
    - Qualified and well trained staff with necessary educational background including safety and specialized training
    - Clarification of responsibilities : no gaps and ambiguities in the function of personel along the lines of authority and responsibility
    - Feedback, incident reporting, investigations and learning

Accidents
Lessons from the past (2)

- Lessons learned from accidents in modern external radiotherapy *(Ortiz-Lopez*)
  - Significant increase in workload and introduction of new techniques may lead to serious mistakes
  - Mistakes in beam calibration (small beams...) and commissioning of radiotherapy equipment
  - Improper use of treatment planning (TPS) & record and verify (RV)
  - Notification to physicist about any repair for control checks
  - Proper communication between operators
  - Misuse of conventional wedges instead of dynamic wedges
  - Loss of data integrity after a “computer frozen event”
  - Errors of coordinates and marks from medical imaging
- Lessons from accidental exposures to be incorporated into education and solid training curricula
- Recommendation on proactive training on ”what else could go wrong” or “which other potential hazards might be present” (e.g., software)
- ICRP 112 to come

Accidents
Lessons from the past (3)

- Lessons learned from accidents in brachytherapy *(Pinillos Ashton*)
  - Overexposure during packing, transport, exchange of sources and emergency action regarding the source
  - Mechanical problems related to control unit or computer, source cable or catheter or applicator : loss of source control
  - Human errors at all stages +++
  - Migration of small sources in the patients
  - Cremation of “radioactive patients” after delay
  - Surgery on implanted patients

Accidents
Lessons from the past (4)

- Lessons learned from French accidents *(Derreumaux)*
  - Human errors in a context of lack of organisation
    - Insufficient communication between operators
    - Confusions due to unfriendly & non-ergonomic software
    - Miscalculations in home-made softwares
    - Calibrations errors
    - Daily portal imaging
  - Four priorities for improvement
    - Better knowledge of the doses effectively delivered
    - Enhanced monitoring of practices
    - Better personel training
    - Development of a safety culture

Accidents

Events recording, reporting and evaluation (1)

- WHO risk profile *(Barton – www.who.int)*
  - The risk profile (literature review) quantifies the process of care in RTH and adresses the risks at each stage:
    - Accidents : 38 deaths (1%) due to overdose of radiations in RTH between 1976 and 2007
    - Incidents : planning stage 55%, introduction of new systems or equipments 25%, errors in treatment delivery 10%, information transfer 9%
    - Near miss : planning stage 9%, information transfer 38%, errors in treatment delivery 18%, combination 35%
  - Taxonomy issues still to be adressed : incident, event, accident, near miss, error, mistake, ...
  - Reduction of risks by planning protocol checklists, independent checking, competency certification, recording of risk factors... based on risk profile

Accidents

Events recording, reporting and evaluation (2)

- Methods of risk analysis *(Ramirez)*
  - Risk analysis tools contribute to identify vulnerable aspects of RTH and provide a fundament for decision making in chosing safety measures
  - Risk matrix method screens for discriminating lower-risk events from higher risk events
  - Probabilistic safety assessment method :
    - identifies initiating events that may trigger accident sequences (Failure mode and effects analysis FMEA method)
    - modelizes the sequence of events that can evolve to an accidental exposure if no obstacle stops this development
  - Both methods are complementary proactive methods to be used before anything goes wrong

Accidents

Events recording, reporting and evaluation (3)

- Radiation safety issues in RTH linked to the omnipresence of computers *(Rosenwald*)
  - Computer based radiotherapy is meant to improve treatment quality and safety
    - Treatment planning systems (TPS) choose the best beam setup allowing to achieve an optimal irradiation of the target volume while keeping the doses at the organs at risk below an acceptable threshold
    - Record and verify systems (RVS) check that accelerator parameters are consistent with the prescription and record all accessible technical data
    - Portal imaging provide 2D/3D images from the accelerator to be compared with images from TPS or any virtual simulation
    - Computers drive accelerator operations : gantry, multileaf collimation, beam control, external communication
  - Most accidents linked to TPS and to data transfer
  - Prevention through TPS and RVS acceptance, commissionning and QA
  - Major role of manufacturers (fully integrated systems, safety tools) and users who must understand how it works

Accidents

Events recording, reporting and evaluation (4)

- Recording of precursor events and feedback experience *(Lartigau)*
  - Quality and safety in RTH : risk similar to that of other therapeutic strategies (e.g.,chemotherapy...) and linked to human performance
  - Experience feedback committees (CREx):
    - Collect priority precursor events : a necessity
    - Analyse each month one event
    - Decide and follow up the corrective actions undertaken
  - Requires a dedicated management atmosphere : events to be considered as system failures and not individual faults (no punishment framework), a guarantee of trust, loyalty and active participation of the personel
  - Mutualisation of feedback experience with all the oncology centers in France

Accidents

Events recording, reporting and evaluation (5)

- Accident reporting system : the ROSIS experience *(Coffey/Cunningham)*
  - Establish in 2001 an international reporting system in radiation oncology for proactive safety
  - System to be used to reduce occurence of incidents by:
    - Enabling RTH departments to share reports on incidents
    - Collecting and analysing information on the occurrence, detection, severity and correction of incidents
    - Disseminating the results and generally promoting awareness of incidents and a safety culture
  - 120 clinics registered so far
  - Course in risk management in RTH based on ROSIS
  - Improvements on the way : a better classification system, prospective risk assessment component, languages other than English…

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Treatment of complications and late morbidity (1)

- General management (*Bourhis*)
  - Symptomatic treatments in most situations
  - Prevention
    - Control of dose :
      - Dose cannot be reduced
      - Action : increase safety, security of dose and use QA
    - Control of volume :
      - Action : control safety margins /tumours
      - Conformal RTH reduces adverse effects
    - Attention to be paid to combination of RTH and chemotherapy
    - Diagnosis of hyper-radiosensitivity
  - Managing side effects
    - Cytoprotection with molecules targeting different pathways
    - 5 posters on the subject

Treatment of complications and late morbidity (2)

- Cell therapy treatment for radiation induced cutaneous damage (*Lataillade*)
  - Mesenchymal stem cells have fancy properties : self renewal, high proliferation capacity and multipotency for cell differentiation, anti-inflammatory, antiseptic, immunomodulatory and trophic effects
  - MSC can be expanded in vitro in million copies
  - MSC have been successfully used in combination with skin grafting to heal severe skin lesions due to radiations
  - Hopefully, MSC can be & will be used to treat radiotherapy burns
  - Alternative way : use of growth factors

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Equipment safety, staffing, education and training (1)

- The equipment : safety, commissioning, re- commissioning – calibration. The medical physicist's point of view (*Lisbona*)
  - Equipment increasingly sophisticated, techniques and human skills closely interconnected through various machine -machine and human- machine interfaces
  - Commissioning and start-up procedures in the hands of physicists, but also manufacturers for the most recent sophisticated equipments
  - Commissioning and calibration are the first steps of the quality control program and guarantee reliability, consistent mechanical and dosimetric performance and technical safety throughout lifetime
  - Commissioning and calibration mistakes can be very costly
  - Innovation in RTH is growing faster than QA recommendations

Equipment safety, staffing, education and training (2)

- The equipment : safety, commissioning, re-commissioning – calibration. The equipment manufacturer point of view (*Lutz -Snitem*)
  - Regulated market must provide people with safe and efficient healthcare equipment
  - EC framework and normative standards
    - The manufacturer shall decide if the residual risk related to innovative equipment is acceptable
    - Controls to be adapted to the residual risk
    - Standardization of medical devices
    - Acceptable by stakeholders

Equipment safety, staffing, education and training (3)

- The radiation therapist profession : a challenge and an opportunity to improve the safety and the patient care in RTH (*Brusadin - EFRS*)
  - Radiation therapist (RT), one member of the team with the radiation oncologist and the medical physicist
  - RT detects the majority of events
  - Role and responsibility of RT variable depending on countries : harmonisation needed
  - Shortage of RT worldwide
  - Better definition of RT status, harmonisation of training, continuous education (new equipments) and career perspectives are keys for the future
  - IAEA TC series 25, ICRP 86, WHO RT risk profile

Equipment safety, staffing, education and training (4)

- EFOMP approach to reducing errors in radiotherapy (*Van Kefflens*)
  - Based on education and training of medical physicists, including a course in safety and risk analysis (Eindhoven school since 1990)
  - Harmonized qualification necessary for the recognition of professional qualifications (directive 2005/36/EC + Bologna declaration regarding the European Higher Education System) :
    - Qualified medical physicist (QMP) = master on medical physics or equivalent + 2 years of postgraduate training
    - Specialist medical physics (SMP) : 2 more years

Equipment safety, staffing, education and training (6)

- Education and training : The IAEA experience (*Czarwinski*)
  - Education, training and competence : requirements for key personels
  - Two weeks course on Radiation protection in RTH since 2005 (dedicated training package)
  - One week course on Prevention of accidental exposure in radiotherapy (IAEA & WHO) since 2008 (dedicated training package + practical exercises)
  - Other IAEA courses for RP professionals
  - IAEA fellowships (12 months)
  - Books, ppt, distance learning materials in different languages
  - http://rpop.iaea.org for RP of patients

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Controls, quality assurance and audits (1)

- The IAEA quality audits in radiotherapy *(Izewska)*
  - Independent peer review evaluation of practice
  - IAEA/WHO TLD postal dose audit (Co60) for 40 years: > 1650 hospitals in 121 countries
  - Dosimetry audit based on a semi-anthropomorphic phantom to assess external beam radiotherapy
  - Quality Assurance Team for Radiation Oncology (QUATRO) audits since 2005 check the adequacy of infrastructure, equipment, human resources and procedures. 5 days on site. Points for improvement are documented
  - IAEA audits have been proved useful and contribute to improvement of RTH dosimetry worldwide
  - TPS audit as new coming IAEA procedure

Controls, quality assurance and audits (2)

- EQUAL-ESTRO: a dosimetry laboratory keeping pace with modernisation in RTH *(Veres)*
  - EQUAL-ESTRO provides external independant quality control programme for quality assurance in RTH systems
    - Intercomparison with postal TLD method / reference dosimeter
    - Dose distribution tests using TLDs & Gafchromic films in dedicated phantoms (Easycube, anthropomorphic) to check treatment plan quality on IMRT machines
    - Dosimetric evaluation of small beams with dedicated TLDs and phantoms
    - Useful external audits since major dose deviations are decreasing

Controls, quality assurance and audits (3)

- The Norwegian program on quality assurance in RTH (KVIST) : organisation, benefits and experiences for stakeholders involvement *(Olerud)*
  - Successful program established by the Norvegian RP authority (NRPA – www.nrpa.org)
  - Multidisciplinary (oncologists, medical physicists, radiation technologists) = national consensus
  - Part time employees shared with RTH departments
  - Act as secretariat and coordinates WG for QA projects :
    - External dosimetry audits
    - Patterns of care data, available equipment, staff, QA routines
    - National system for incident handling and reporting
    - Comparison of treatment plans (e.g., target volumes)
    - Clinical guidelines and audits in radiotherapy

Controls, quality assurance and audits (4)

- Audits in radiotherapy in Switzerland *(Stuessi)*
  - Audits in low and high voltage radiotherapy
    - Low voltage : 31 units every 3 years
    - High voltage : 9 units every year
    - Check parameters, their tolerance and responsibilities
    - In fact OFSP inspections
  - Audits in megavoltage radiotherapy (57 units)
    - Audits + from 2010 : e.g., patient pathway
    - Real clinical audits starting in 2013

Controls, quality assurance and audits (5)

- Other national or local experiences and initiatives to improve patient safety
  - In Belgium (*Haest*)
  - In Estonia (*Gershkevitsh*)
  - In France (*Charrier*)
  - In Italy (*Caccia*)
  - In Japan (*Fukumura*)
  - In Nepal (*Subedj*)
  - In Russia (*Narkevich*)
  - In Spain (*Angulo Pain*)
  - In the UK (*O'Doherty, Fillingham*)
  - In the USA (*Flannery,*)

Controls, quality assurance and audits (5)

- Clinical audits : who should control what ? European guidelines *(Jarvinen)*
  - Requirement of Directive 97/43 Euratom (Art 6.4)
  - Multi-disciplinary, multi-professional expert assessment of RTH practices, procedures and results for the improvement of the safety and quality of practices.
  - Clinical audits are neither regulatory inspections nor other quality assessment or control but provide recommendations on good practices (structure, process, outcome)
  - Internal and external audits are different and complement each other
  - Guideline on clinical audit for medical radiological practices of the European Commission (RP 159) : http://europa.eu/energy/nuclear/radiation_protection/publications_en.htm

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National strategies and regulations (1)

- The ICRP take home message (*Ortiz-Lopez*)
  - « Purchasing new equipment without a concomitant effort on education and training and on a programme of quality assurance is dangerous (ICRP 86) »
  - Key issues :
    - Staff training, availability and dedication
    - Safety awareness of responsible persons of RTH department
    - Manufacturer responsibility for safe equipments
    - Large programmes of acceptance and commissioning
    - Protocols for treatment prescrition and dosimetry to be revised to accomodate new technologies
    - Prudent dose escalation
    - Safety-critical communication and notifications
    - Computer crash situations and data integrity
    - Updating quality control tests
    - Using lessons from experience
    - Overcoming the lack of experience when introducing new technologies

National strategies and regulations (2)

- The French action plan for radiotherapy (*Maraninchi*)
  - Overview of oncology and radiotherapy in France : 1st cancer plan
  - Plan of 33 measures established in 2007 by the minister of health after the Epinal and Toulouse accidents involves all actors
    - Quality and safety of practices (7)
    - Radiation protection monitoring (4)
    - Human resources and training (7)
    - Safety of systems (5)
    - Relations with patients and public (4)
    - Reinforcement of inspection (1)
    - Knowledge of the discipline (4)
  - National steering committee to coordinate the implementation
  - Transition period until the end 2010 (80% of measures completed) and the full development of 2nd national cancer plan

National strategies and regulations (3)

- National regulators experiences (*Flannery [USA], Griebel [D], O'Doherty [UK], Petrova [CZ], Godet [F]*)
  - Different regulatory/expertise organisations in each country / federal states
  - Share common objectives
    - Complexity of RTH is a challenging issue
    - Comprehensive regulation updated with new technologies
    - Control / inspect RTH departments with the aim to prevent radiological events
    - Provide publications, guides and recommendations for developing a safety culture and reporting events
    - Need or necessity of enforcement actions
    - Perform site visits and analysis of events
    - Establish a system for sharing experience on RTH events at national level with professional for future actions
    - Inform patients and public (classification of events)
    - Need for sharing experience at international level
    - Role in clinical audits ?

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