UNIVERSITÀ DEGLI STUDI DI MILANO
DIPARTIMENTO DI FISICA

Rischio clinico in SBRT

Ivan Veronese

Outline

- Introduzione (rischio clinico vs SBRT)
- Strumenti di analisi del rischio
  - Strumenti prospettici (FMEA)
- Esempi in letteratura su FMEA in SRT/SBRT
- Applicazione FMEA a SBRT con Cyberknife
- Conclusioni

Rischio clinico vs. SRBT

Rischio clinico:

possibilità che un paziente subisca un "danno o disagio involontario, imputabile, alle cure sanitarie, che causa un prolungamento del periodo di degenza, un peggioramento delle condizioni di salute o la morte".

- Complessità tecnologica e procedurale
- Poche frazioni / alta dose per frazione
- Piccoli volumi bersaglio, spesso prossimi a OARs

Margine di errore significativamente più piccolo rispetto alla RT convenzionale

- Errori di localizzazione/set up → severi sottodosaggi al target e sovradosaggi degli OARs
- Errori di calibrazione in dose → dose per frazione significativamente diversa da quella pianificata

Incidenti *dichiarati* in SRS/SRBT

- **Errori di calibrazione (linac)**

Tolosa, 2006-2007

Le Monde

Accidents de radiothérapie : 145 patients sur-irradiés à l'hôpital de Toulouse

Le Monde | 23.05.2007 à 09h11 • Mis à jour le 28.03.2008 à 03h38 |
Par avec "Le Parisien"

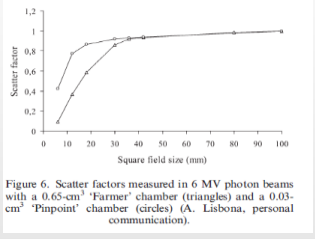


Figure 6. Scatter factors measured in 6 MV photon beams with a 0.65-cm³ 'Farmer' chamber (triangles) and a 0.03-cm³ 'Pinpoint' chamber (circles) (A. Lisbona, personal communication).

Derreumaux, RPD 2008

Missouri, 2004-2009

The New York Times

Radiation Errors Reported in Missouri

By WALT BOGDANICH and REBECCA R. RUIZ
Published: February 24, 2010

Incidenti simili:

- commissioning unità SRS
- uso di un dosimetro inadeguato
- sottostima degli OF → sovradosaggio
- oltre 200 pazienti in totale coinvolti

Incidenti *dichiarati* in SRS/SRBT

- **Errori di settaggio dei jaws**

Francia, 2004

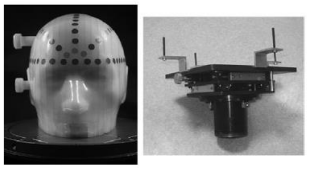


Figure 2. Stereotactic radiotherapy treatment delivery with successive beam entrance positions as a function of accelerator and table rotation angles (left). The plate used in the centre (Case 2) to hold the cylindrical additional collimator (right).

Derreumaux, RPD 2008

Illinois, 2009


The New York Times
THE RADIATION BOOM
A Pinpoint Beam Strays Invisibly, Harming Instead of Healing
By WALT BOGDANICH and KRISTINA REBELO
Published: December 28, 2010

Incidenti simili:

- campo troppo esteso rispetto al collimatore stereotassico usato

→ Sovradosaggio di un volume esteso al di fuori del target

- 3 pazienti in totale coinvolti (gravi conseguenze)

Strumenti di analisi del rischio

Analisi retrospettive: 1. Incident reporting

- Sistemi locali di segnalazione di eventi avversi
  - Non specifici per la RT
  - Mancanza di diffusione delle informazioni all'esterno
- Piattaforme web
  - ROSIS
  - SAFRON (IAEA)
  - NEW RO-ILS (ASTRO-AAPM)

ROSIS Radiation Oncology Safety Information System

SAFRON

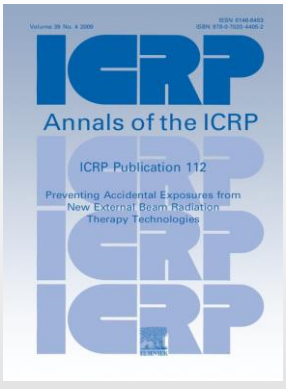
RO-ILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM Sponsored by ASTRO and AAPM

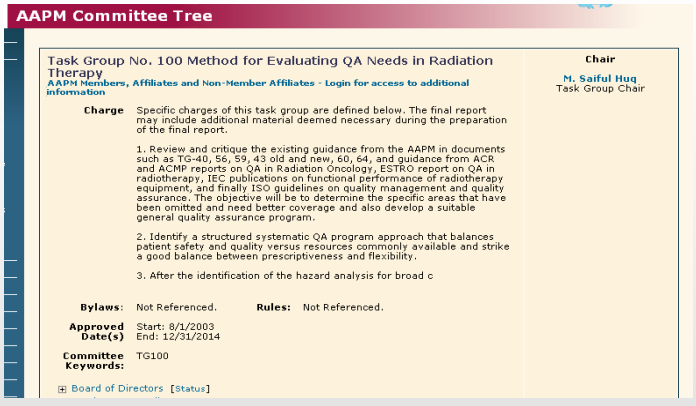
Analisi retrospettive: 2. Analisi (RCA)

Strumenti di analisi del rischio

Analisi prospettiche

- Fino a 6-7 anni fa non contemplate come strumenti di analisi del rischio in RT
- Oggi strumenti noti, riconosciuti e letteratura sempre più ampia
- Fattori propulsivi:

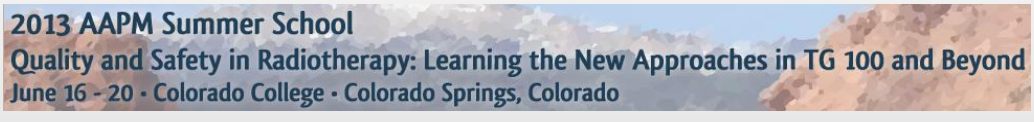




Strumenti di analisi del rischio

Analisi prospettiche (USA)

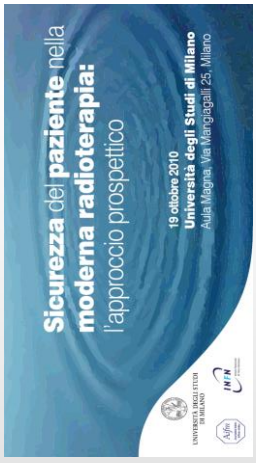
- In attesa del report del TG-100 (AAPM)



Strumenti di analisi del rischio

Analisi prospettiche (Italia)

- Iniziative AIFM-AIRO



Strumenti di analisi del rischio

Failure Mode and Effects Analysis (FMEA)

1. Scelta del processo da studiare e costituzione del gruppo di lavoro
2. Modellizzazione del processo per individuare le varie azioni e sottoprocessi
3. Identificazione dei possibili failure modes di ciascun sottoprocesso, unitamente alle cause ed effetti potenziali
4. Assegnazione di tre indici di rischio ad indicare la probabilità di accadimento del failure (O), la severità delle conseguenze (S), e la rivelabilità (D) e calcolo del Risk Priority Number RPN=OxSxD

Aspetti critici: - mancanza di dati storici
- esistenza di diverse scale

Strumenti di analisi del rischio

Ford et al, IJROBP 2009

Table 1. Example scoring system of severity, frequency of occurrence, and detectability for input into failure mode and effects analysis

Score	Severity	Occurrence	Detectability
1	No effect	Less than every 5 years	
2	Dose Δ5%	Every 2–5 years	Very easy to detect
3		Once a year	
4	Minimal delay in care	Several times a year	Easy to detect
5		Once a month	
6	Allergic reaction; moderate delay in care	Several times a month	Mildly difficult to detect
7		Once a week	
8	Dose Δ20%, reportable	Several times a week	
9		Once a day	
10	Patient dies	Several times a day	Impossible to detect

Hug, Annual Meeting AAPM 2012

Rank	Occurrence		Severity		Detectability
	Qualitative	Frequency	Qualitative	Categorization	Estimated Probability of going undetected in %
1	Failure unlikely	1/10,000	No effect		0.01
2		2/10,000	Inconvenience	Inconvenience	0.2
3	Relatively few failures	5/10,000			0.5
4		1/1,000	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2%	Limited toxicity or under-dose	Wrong dose, dose distribution, location or volume	2.0
6	Occasional failures	<0.5%			5.0
7		<1%	Potentially serious toxicity or under-dose		10
8	Repeated failures	<2%			15
9		<5%	Possible very serious toxicity	Very wrong dose, dose distribution, location or volume	20
10	Failures inevitable	>5%	Catastrophic		>20

Perks et al, IJROBP 2012

Table 1 Description of 10-point scales used to derive values of probability, severity, and detectability for each failure mode

	Probability of failure mode	Severity	Ability of the team to detect mode
1–2	Very low; affecting 1% of patients or less	No dosimetric effect, may cause patient discomfort or distress	Very easy to detect; QA checks already in place
3–4	Low; affecting approximately 5% of patients	Up to 5% dose difference, no radiation out of intended location	Easy to detect, could be missed without double check, human error (*e.g.*, mismarking patient or transcription)
5	Moderate	10% dose difference, dose delivery to site with insufficient accuracy	Moderate, a "lucky catch"
6–8	Medium; will occur once per day or week	Reportable event, 20% dose difference, wrong site irradiation	Very difficult to detect because of either subtle difference in setup or highly unusual situation
9–10	High; will occur on almost every patient	Reportable event, patient injury or death	Almost impossible to detect; no QA in place

Abbreviations: QA = quality assurance; SBRT = sterotactic body radiation therapy.
This follows the method of Ford *et al.* (12) with SBRT-specific adjustment to our clinical background.

Strumenti di analisi del rischio

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Aspetti critici:
- mancanza di dati storici
- esistenza di diverse scale

Soluzioni:
- giudizio degli esperti
- soggettività «mediata» nel GlD
- ciò che importa è il ranking relativo, non i valori assoluti

Strumenti di analisi del rischio

Analisi prospettiche in SRS/SBRT: cosa c'è in letteratura

International Journal of Radiation Oncology biology • physics
www.redjournal.org

Physics Contribution

Failure Mode and Effect Analysis for Delivery of Lung Stereotactic Body Radiation Therapy

Julian R. Perks, Ph.D., Sinisa Stanic, M.D., Robin L. Stern, Ph.D., Barbara Henk, R.N., M.S.N., Marsha S. Nelson, R.N., M.B.A., Rick D. Harse, R.T.T., Mathew Mathai, B.S., C.M.D., James A. Purdy, Ph.D., Richard K. Valicenti, M.D., M.A., Allan D. Siefkin, M.D., and Allen M. Chen, M.D.

University of California Davis Medical Center, Sacramento, CA

Received Mar 22, 2011, and in revised form Aug 29, 2011. Accepted for publication Sep 12, 2011

- Delivey a lesioni al polmone
- Linac convenzionale (Elekta) con CBCT
- Compressione addonimale

Strumenti di analisi del rischio

Analisi prospettiche in SRS/SBRT: cosa c'è in letteratura

Table 2 Risk factors associated with particular treatment steps

Step in process	Failure mode	Likelihood of occurrence	Likelihood of detection	Severity	Risk priority number
Improper laser marking of patient	Patient alignment checked to ceiling laser when couch rotated	2	4	10	80
Automatic setup failure	Incorrect calibration of couch motors	1	7	10	70
CBCT scan isocenter misaligned	Difference with beam isocenter	1	6	10	60
Documentation of couch coordinates	Transcription error	2	2	10	40
Machine faults leading to interlocks	Loss of beam	5	1	8	40
Overly large CBCT shifts	Shifts should all be less than 1 cm	4	1	10	40
SBRT frame at isocenter	Transcription error in coordinates	2	1	10	20
Improper laser marking of patient, reassessed values after procedural changes	Patient alignment checked to ceiling laser when couch rotated	1	2	10	20
Incorrect CT data	If patient rescanned because of clinical change	2	1	10	20
Patient moves during treatment	Repositioning of patient	2	1	10	20

Abbreviations: CT = computed tomography; CBCT = cone-beam computed tomography.

Errori strumentali →QA

Strumenti di analisi del rischio

Analisi prospettiche in SRS/SBRT: cosa c'è in letteratura

1328 Perks et al. International Journal of Radiation Oncology • Biology • Physics

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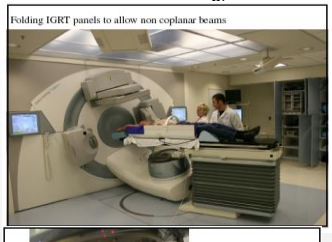
Errori procedurali → modifica del processo

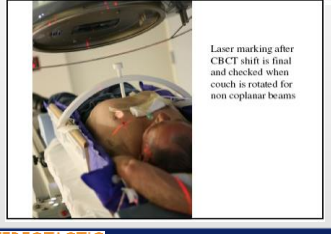
Strumenti di analisi del rischio

Analisi prospettiche in SRS/SBRT: cosa c'è in letteratura

Errori procedurali → modifica del processo

2012 AAPM Annual Meeting, J. Perks





Prima dell'FMEA:

1. Imaging con CBCT
2. Marcatura del torace in corrispondenza dei laser
3. Trascrizione della posizione del lettino
4. Traslazione del lettino per riavvolgere I pannelli del rivelatore
5. Riposizionamento all'isocentro di trattamento

Dopo l'FMEA:

Pianificazione del piano in modo che I rivelatori possano non essere ripiegati durante l'intera frazione, o solo quando il lettino è ruotato (paziente non traslato rispetto all'isocentro)

Strumenti di analisi del rischio

Analisi prospettiche in SRS/SBRT: cosa c'è in letteratura

practical radiation oncology
pro
www.practicalradonc.org

Application of failure mode and effects analysis to intracranial stereotactic radiation surgery by linear accelerator

Laura Masini MD [a], Laura Donis MD [a], Gianfranco Loi PhD [b], Eleonora Mones PhD [b], Elisa Molina RT [a], Cesare Bolchini RT [a], Marco Krengli MD [a, c,*]

[a] *Department of Radiotherapy, University Hospital Maggiore della Carità, Novara, Italy*
[b] *Department of Medical Physics, University Hospital Maggiore della Carità, Novara, Italy*
[c] *Department of Translational Medicine, University of Piemonte Orientale, Novara, Italy*

Received 22 November 2013; revised 27 January 2014; accepted 29 January 2014

- Intero flusso di processo
- Linac convenzionale (Clinac 600 DBX Varian) con head frame

Strumenti di analisi del rischio

Analisi prospettiche in SRS/SBRT: cosa c'è in letteratura

Table 2 Failure modes with the highest risk probability number (RPN) for which corrective measures were adopted

Step	Failure mode	Effect	S	O	D	RPN	Corrective measure
Preparation of the treatment room	Choice wrong collimator	Treatment of smaller or larger volume	9	4	5	180	Second check by a physician, a physicist, and a radiation therapist.
Localization with LTLF device with patient in treatment position	Wrong coordinates on LTLF device	Treatment of wrong location	9	3	5	135	Exportation isocenter data to the localization independent system: Vision RT
Contouring GTV and OARs	Wrong volume	GTV underdosage or OARs over dosage	7	2	5	70	Contours review
Clinical and radiologic documentation assessment	Exchange of clinical documentation and/or images	Wrong prescription	7	3	3	63	Cross-checks physician-nurse

D, detectability; GTV, gross tumor volume; LTLF, laser target localizer frame; O, occurrence; OARs, organs at risk; RPN, risk probability number; RT, radiation therapy, S, severity.

- 116 failure modes identificati nell'intero flusso di processo
- 2 failure con RPN>125 → azioni correttive prevedono sistemi di verifica indipendenti (bar code collimatori, vision RT per isocentro)
- 2 failure «outlier» nella distribuzione dei failure del sottoprocesso

Applicazione FMEA: SBRT con Cyberknife

- Macchina dedicata ai trattamenti stereotassici
- Sistemi di posizionamento e tracking del target durante il trattamento

Applicazione FMEA: SBRT con Cyberknife

FONDAZIONE I.R.C.C.S. ISTITUTO NEUROLOGICO CARLO BESTA

- 1 Cyberknife
- 1 Elekta Synergy linac

Staff del Dipartimento di RT:
- 4 radio-oncologi,
- 3 fisici medici
- 5 tecnici di radioterapia,
- 2 segretarie

~ 700 pazienti/anno
(SRT con Cyberknife ~ 380)

CENTRODIAGNOSTICOITALIANO CDI

- 2 Cyberknife

Staff dell'Unità Cyberknife:
- 2 radio-oncologi,
- 3 fisici medici
- 4 tecnici di radioterapia,
- 2 segretarie

~ 800 pazienti/anno

SCENARIO

Applicazione FMEA: SBRT con Cyberknife

FONDAZIONE I.R.C.C.S. ISTITUTO NEUROLOGICO CARLO BESTA

Lesioni alla colonna

Xsight® Spine Tracking System (XSTS)

- Identifica dei punti di riferimento anatomici per localizzare e tracciare il target durante il trattamento
- Non necessita di impianto di fiducials, ed è idoneo alla quasi totalità dei trattamenti alla colonna

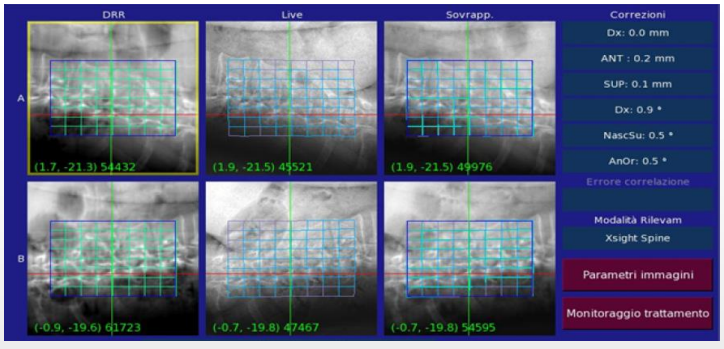
Applicazione FMEA: SBRT con Cyberknife

FONDAZIONE I.R.C.C.S. ISTITUTO NEUROLOGICO CARLO BESTA

Lesioni alla colonna

Xsight® Spine Tracking System (XSTS)

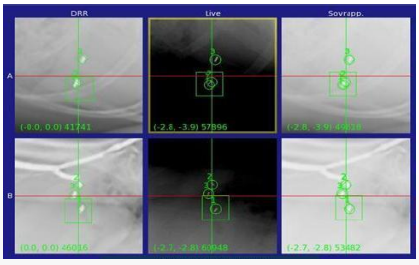
- Definizione di ROI contenente una griglia con 81 nodi durante la pianificazione.

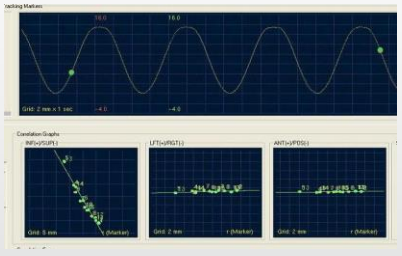


- Durante il delivery XSTS calcola e compensa gli spostamenti del target monitorando gli spostamenti dei nodi della ROI nelle immagini live rispetto alle DRR

STEREOTACTIC BODY RADIATION THERAPY
UNIVERSITÀ DEGLI STUDI DI MILANO
24/25 OTTOBRE 2014

Applicazione FMEA: SBRT con Cyberknife





CENTRODIAGNOSTICOITALIANO
CDI

Lesioni epatiche

Synchrony® Respiratory Tracking System (SRTS)

- Impianto preliminare di fiducials
- Sincronizza il fascio con il movimento del target costruendo un modello che correla la posizione del target (fiducials) con il respiro

Applicazione FMEA: SBRT con Cyberknife

PROCESSI

1) **Planning** (comune ai due centri)

2A) **Delivery a lesioni alla colonna** mediante Xsight® Spine Tracking System → Besta

2B) **Delivery a lesioni al fegato** mediante Synchrony® Respiratory Tracking System → CDI

Ipotesi di scenario:
- almeno 3 fiducials correttamente impiantati,
- presenza di lesioni multiple (max.3) trattate con frazioni multiple e con piani di trattamento distinti

Applicazione FMEA: SBRT con Cyberknife

GdL: Ivan Veronese, Elena De Martin, Anna Stefania Martinotti , Maria Luisa Fumagalli , Cristina Vite, Irene Redaelli, Tiziana Malatesta, Pietro Mancosu, Giancarlo Beltramo, Laura Fariselli, Marie Claire Cantone

RISULTATI

Planning : 48 sottoprocessi

Delivery (colonna): 30 sottoprocessi

Delivery (fegato): 42 sottoprocessi

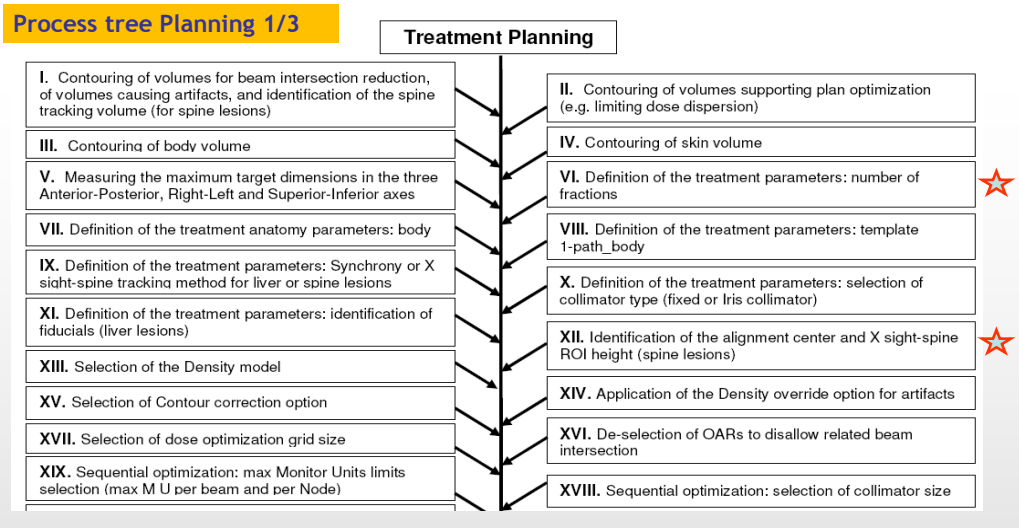
Tutti potenzialmente soggetti ad uno o più failure modes

19 Failures con S e/o RPN elevato:
- 5 planning
- 9 delivery colonna
- 5 delivery fegato

- Generici
- SBRT specifici
- Cyberknife specifici

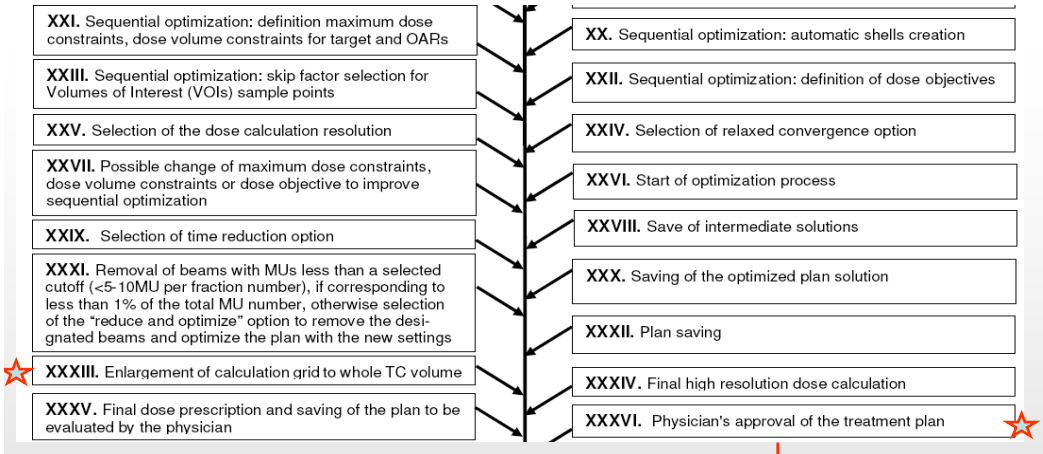
Applicazione FMEA: SBRT con Cyberknife

Process tree Planning 1/3



Applicazione FMEA: SBRT con Cyberknife

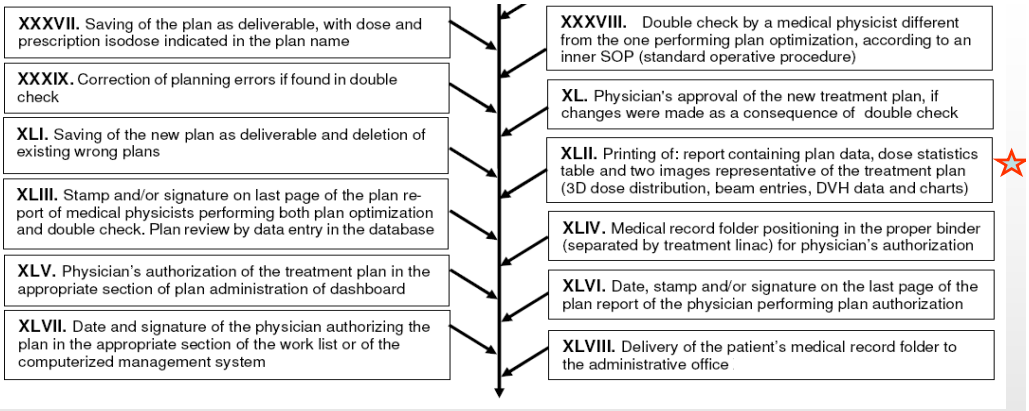
Process tree Planning 2/3



con eventuale riprescrizione di dose o N frazioni

Applicazione FMEA: SBRT con Cyberknife

Process tree Planning 3/3



Applicazione FMEA: SBRT con Cyberknife

Planning: failure con RPN ≥ 80 o S ≥ 9

Sub-process	N	Potential Failure Mode	Potential Causes of Failure	Potential effects of Failure	S	O	D	RPN
VI. Definition of the treatment parameters: number of fractions	1	Typing of a wrong number of fractions	Erroneous identification of the fractions number on the patient's record, wrong patient's record (coincidence of names), wrong typing	Wrong fraction dose administration	10	2	3	60
XII. Identification of the align center and X sight-spine ROI height (in the case of spinal lesions)	2	Wrong positioning of the align center and ROI height	Inexperience, presence of multiple lesions, damaged vertebrae	Tracking non-representative of the lesion's movement (underdosage of the PTV, overdosage of the OAR)	7	2	7	98
XXXIII. Enlargement of the calculation grid to all the TC volume in the three views	3	Missed enlargement of the calculation grid to all the TC volume	Inexperience, distraction, haste, activity interruption	Missed visualization of the hot spots in areas far from target and OARs, partial evaluation of the DVH	9	2	3	54
XXXVI. Physician's approval of the treatment plan, with eventual re-prescription of dose and number of fractions	4	Missed or wrong re-prescription of dose or number of fractions	Inexperience, distraction, haste, activity interruption, high workload, missed communication between physicist and physician	Erroneous dose delivery	10	2	4	80
XLII. Print of the report containing plan data, of the dose statistics table and of two images representative of the treatment plan (3D dose distribution, beams entry, DVH data and charts)	5	Missed or wrong printing of the plan report, of the table and images, printing of report, table and images not concerning the approved plan	Inexperience, distraction, haste, activity interruption, high workload, printing performed not contextually with the plan approval, missed communication among physicists	Missed check of the treatment plan, delivery of a sub-optimal plan or erroneous dose (in case there are other deliverable plans present)	10	1	4	40

Applicazione FMEA: SBRT con Cyberknife

Planning: failure con RPN ≥ 80 o S ≥ 9

Sub-process	N	Potential Failure Mode	Potential Causes of Failure	Potential effects of Failure	S	O	D	RPN
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XXXIII. Enlargement of the calculation grid to all the TC volume in the three views	3	Missed enlargement of the calculation grid to all the TC volume	Inexperience, distraction, haste, activity interruption	Missed visualization of the hot spots in areas far from target and OARs, partial evaluation of the DVH	9	2	3	54
XXXVI. Physician's approval of the treatment plan, with eventual re-prescription of dose and number of fractions	4	Missed or wrong re-prescription of dose or number of fractions	Inexperience, distraction, haste, activity interruption, high workload, missed communication between physicist and physician	Erroneous dose delivery	10	2	4	80
XLII. Print of the report containing plan data, of the dose statistics table and of two images representative of the treatment plan (3D dose distribution, beams entry, DVH data and charts)	5	Missed or wrong printing of the plan report, of the table and images, printing of report, table and images not concerning the approved plan	Inexperience, distraction, haste, activity interruption, high workload, printing performed not contextually with the plan approval, missed communication among physicists	Missed check of the treatment plan, delivery of a sub-optimal plan or erroneous dose (in case there are other deliverable plans present)	10	1	4	40

Fallimenti *non* SBRT specifici, può esserlo la severità degli effetti

Comunicazione e tracciabilità di cambiamenti in corso d'opera

STEREOTACTIC BODY RADIATION THERAPY
UNIVERSITÀ DEGLI STUDI DI MILANO
24/25 OTTOBRE 2014

Applicazione FMEA: SBRT con Cyberknife

Planning: failure con RPN ≥ 80 o S ≥ 9

Sub-process	N	Potential Failure Mode	Potential Causes of Failure	Potential effects of Failure	S	O	D	RPN
VI. Definition of the treatment parameters: number of fractions	1	Typing of a wrong number of fractions	Erroneous identification of the fractions number on the patient's record, wrong patient's record (coincidence of names), wrong typing	Wrong fraction dose administration	10	2	3	60
XII. Identification of the align center and X sight-spine ROI height (in the case of spinal lesions)	2	Wrong positioning of the align center and ROI height	Inexperience, presence of multiple lesions, damaged vertebrae	Tracking non-representative of the lesion's movement (underdosage of the PTV, overdosage of the OAR)	7	2	7	98
XXXIII. Enlargement of the calculation grid to all the TC volume in the three views	3	Missed enlargement of the calculation grid to all the TC volume	Inexperience, distraction, haste, activity interruption	Missed visualization of the hot spots in areas far from target and OARs, partial evaluation of the DVH	9	2	3	54
XXXVI. Physician's approval of the treatment plan, with eventual re-prescription of dose and number of fractions	4	Missed or wrong re-prescription of dose or number of fractions	Inexperience, distraction, haste, activity interruption, high workload, missed communication between physicist and physician	Erroneous dose delivery	10	2	4	80
XLII. Print of the report containing plan data, of the dose statistics table and of two images representative of the treatment plan (3D dose distribution, beams entry, DVH data and charts)	5	Missed or wrong printing of the plan report, of the table and images, printing of report, table and images not concerning the approved plan	Inexperience, distraction, haste, activity interruption, high workload, printing performed not contextually with the plan approval, missed communication among physicists	Missed check of the treatment plan, delivery of a sub-optimal plan or erroneous dose (in case there are other deliverable plans present)	10	1	4	40

Gestione dei piani multipli → SBRT

Applicazione FMEA: SBRT con Cyberknife

Planning: failure con RPN ≥ 80 o S ≥ 9

Sub-process	N	Potential Failure Mode	Potential Causes of Failure	Potential effects of Failure	S	O	D	RPN
VI. Definition of the treatment parameters: number of fractions	1	Typing of a wrong number of fractions	Erroneous identification of the fractions number on the patient's record, wrong patient's record (coincidence of names), wrong typing	Wrong fraction dose administration	10	2	3	60
XII. Identification of the align center and X sight-spine ROI height (in the case of spinal lesions)	2	Wrong positioning of the align center and ROI height	Inexperience, presence of multiple lesions, damaged vertebrae	Tracking non-representative of the lesion's movement (underdosage of the PTV, overdosage of the OAR)	7	2	7	98
XXXIII. Enlargement of the calculation grid to all the TC volume in the three views	3	Missed enlargement of the calculation grid to all the TC volume	Inexperience, distraction, haste, activity interruption	Missed visualization of the hot spots in areas far from target and OARs, partial evaluation of the DVH	9	2	3	54
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XLII. Print of the report containing plan data, of the dose statistics table and of two images representative of the treatment plan (3D dose distribution, beams entry, DVH data and charts)	5	Missed or wrong printing of the plan report, of the table and images, printing of report, table and images not concerning the approved plan	Inexperience, distraction, haste, activity interruption, high workload, printing performed not contextually with the plan approval, missed communication among physicists	Missed check of the treatment plan, delivery of a sub-optimal plan or erroneous dose (in case there are other deliverable plans present)	10	1	4	40

***Hot spots* nei trattamenti con Cyberknife**

STEREOTACTIC BODY RADIATION THERAPY
UNIVERSITÀ DEGLI STUDI DI MILANO
24/25 OTTOBRE 2014

Applicazione FMEA: SBRT con Cyberknife

Curēus

Robotic Radiosurgery and the "Fingers of Death"

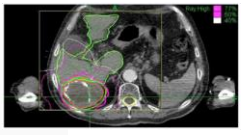
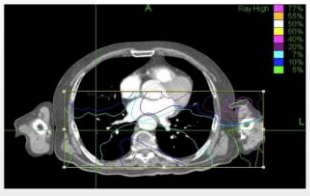


Figure 1A

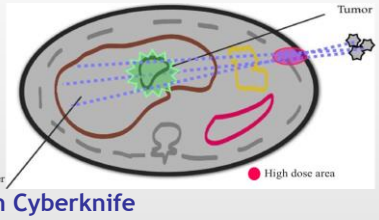


David M. Berlach , Dominic Beliveau-Nadeau, David Roberge

Corresponding author: David M. Berlach

1. Department of Radiation Oncology, Montreal General Hospital 2. Department of Medical Physics, Notre Dame Hospital 3. Department of Radiation Oncology, Centre hospitalier de l'université de Montréal (CHUM)

Figure 1B



Hot spots nei trattamenti con Cyberknife

Applicazione FMEA: SBRT con Cyberknife

Planning: failure con RPN ≥ 80 o S ≥ 9

Sub-process	N	Potential Failure Mode	Potential Causes of Failure	Potential effects of Failure	S	O	D	RPN
VI. Definition of the treatment parameters: number of fractions	1	Typing of a wrong number of fractions	Erroneous identification of the fractions number on the patient's record, wrong patient's record (coincidence of name?), wrong typing	Wrong fraction dose administration	10	2	3	60
XII. Identification of the align center and X sight-spine ROI height (in the case of spinal lesions)	2	Wrong positioning of the align center and ROI height	Inexperience, presence of multiple lesions, damaged vertebrae	Tracking non-representative of the lesion's movement (underdosage of the PTV, overdosage of the OAR)	7	2	7	98
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Parametri per Tracking→ Cyberknife

Applicazione FMEA: SBRT con Cyberknife

Planning: ulteriori misure di sicurezza

- Evitare la presenza simultanea di più piani di trattamento *erogabili*
- Doppio check dell'unicità del piano erogabile

- Conferma della prescrizione finale (dose, N frazione) da parte del medico in fase di valutazione del piano insieme al fisico, e *firma contestuale* in una apposita sezione della cartella clinica

- Doppio check del centro di allineamento (XSTS) inizialmente non previsto

Applicazione FMEA: SBRT con Cyberknife

Delivery colonna (1/2): failure con RPN ≥ 80 o S ≥ 9

Sub-process	N	Potential Failure Mode	Potential Causes of Failure	Potential effects of Failure	S	O	D	RPN
I. Call of the patient in the waiting room	1	The patient is called but a different one answers/ The patient is not called	Identification does not include patient's name, surname, date of birth, photo-Patient was not informed of modifications regarding the time of the appointment, patient is late	Delivery of the treatment to the wrong patient -the radiotherapy treatment is not delivered or is administered late	10	1	2	20
II. Verification of the patient's identity at the treatment's room entry by asking personal data confirmation	2	Patient's identity verification by checking all the personal data not performed	Only patient's surname check	Possibility of mistaking patients and therefore treatments	10	2	3	60
X. Check of the correct view of the patient from the treatment workspace using adjustable video cameras	3	Patient is not monitored during treatment	Video cameras are not correctly oriented or functioning	Cyberknife may hit the patient without the operator noticing it. Patient may be in need and not been seen.	9	2	2	36
XII. Patient selection using personal data (Name and surname)	4	Wrong patient's name-Personal data check is not performed	Patient is called without checking patients' list-Lapse of memory	Delivery of the treatment to the wrong patient-possibility of mistaking patients and therefore treatments	10	2	5	100

Applicazione FMEA: SBRT con Cyberknife

Delivery colonna (2/2): failure con RPN ≥ 80 o S ≥ 9

XIII. Check of the correct treatment plan and of the number of fractions as described on the report print	5	Delivery to the patient of a wrong plan-plan check not performed	Personal data and patient ID on the printed plan not checked-lapse of memory	Patient receives wrong irradiation-possibility of mistaking patients and therefore treatments	10	2	3	60
XV. Check of patient's name, surname and medical ID by flagging the appropriate box for acceptance	6	Patient's personal data not checked	Automatic action-Lapse of memory	Wrong patient or treatment-possibility of mistaking patients and therefore treatments	10	2	7	140
XVI. Check of: plan name, tracking method (XSight spine), path, number of fraction, collimator type and aperture-flag of the appropriate box for acceptance	7	Data check is wrong or not performed	High workload-lapse of memory	Wrong patient or treatment-possibility of mistaking patients and therefore treatments	10	2	7	140
XVII. Accurate alignment of the patient by comparing DRR and live images: adjustment of the values and tolerance levels defined in the image parameters window-adjustment of the X Sight Spine ROI dimensions	8	Wrong alignment-Threshold levels of the different parameters not modified when necessary	Difficulty to visually identify spine tract in the live images-Lapse of memory, insufficient experience of the operator with the treatment system	Treatment not properly delivered-longer time to start treatment	10	1	4	40
XIX. Setting of the most appropriate patient size	9	Appropriate patient size not set	Lapse of memory, insufficient experience of the operator with the delivery system	Possible collisions or errors of the PDP system slowing down treatment	9	2	5	90

Applicazione FMEA: SBRT con Cyberknife

Delivery colonna (1/2): failure con RPN ≥ 80 o S ≥ 9

Sub-process	N	Potential Failure Mode	Potential Causes of Failure	Potential effects of Failure	S	O	D	RPN
I. Call of the patient in the waiting room	1	The patient is called but a different one answers/ The patient is not called	Identification does not include patient's name, surname, date of birth, photo-Patient was not informed of modifications regarding the time of the appointment, patient is late	Delivery of the treatment to the wrong patient -the radiotherapy treatment is not delivered or is administered late	10	1	2	20
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Collisioni tra il robot e il paziente

Applicazione FMEA: SBRT con Cyberknife

Delivery colonna (2/2): failure con RPN ≥ 80 o S ≥ 9

XIII. Check of the correct treatment plan and of the number of fractions as described on the report print	5	Delivery to the patient of a wrong plan-plan check not performed	Personal data and patient ID on the printed plan not checked-lapse of memory	Patient receives wrong irradiation-possibility of mistaking patients and therefore treatments	10	2	3	60
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Collisioni tra il robot e il paziente

Applicazione FMEA: SBRT con Cyberknife

Delivery colonna (1/2): failure con RPN ≥ 80 o S ≥ 9

Sub-process	N	Potential Failure Mode	Potential Causes of Failure	Potential effects of Failure	S	O	D	RPN
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XII. Patient selection using personal data (Name and surname)	4	Wrong patient's name-Personal data check is not performed	Patient is called without checking patients' list-Lapse of memory	Delivery of the treatment to the wrong patient-possibility of mistaking patients and therefore treatments	10	2	5	100

Scambio pazienti

STEREOTACTIC BODY RADIATION THERAPY
UNIVERSITÀ DEGLI STUDI DI MILANO
24/25 OTTOBRE 2014

Applicazione FMEA: SBRT con Cyberknife

Delivery colonna (1/2): failure con RPN ≥ 80 o S ≥ 9

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Selezione e verifica dei vari parametri del piano di trattamento

Applicazione FMEA: SBRT con Cyberknife

Delivery colonna (2/2): failure con RPN ≥ 80 o S ≥ 9

XIII. Check of the correct treatment plan and of the number of fractions as described on the report print	5	Delivery to the patient of a wrong plan-plan check not performed	Personal data and patient ID on the printed plan not checked-lapse of memory	Patient receives wrong irradiation-possibility of mistaking patients and therefore treatments	10	2	3	60
XV. Check of patient's name, surname and medical ID by flagging the appropriate box for acceptance	6	Patient's personal data not checked	Automatic action-Lapse of memory	Wrong patient or treatment-possibility of mistaking patients and therefore treatments	10	2	7	140
XVI. Check of: plan name, tracking method (XSight spine), path, number of fraction, collimator type and aperture-flag of the appropriate box for acceptance	7	Data check is wrong or not performed	High workload-lapse of memory	Wrong patient or treatment-possibility of mistaking patients and therefore treatments	10	2	7	140
XVII. Accurate alignment of the patient by comparing DRR and live images: adjustment of the values and tolerance levels defined in the image parameters window-adjustment of the X Sight Spine ROI dimensions	8	Wrong alignment-Threshold levels of the different parameters not modified when necessary	Difficulty to visually identify spine tract in the live images-Lapse of memory, insufficient experience of the operator with the treatment system	Treatment not properly delivered-longer time to start treatment	10	1	4	40
XIX. Setting of the most appropriate patient size	9	Appropriate patient size not set	Lapse of memory, insufficient experience of the operator with the delivery system	Possible collisions or errors of the PDP system slowing down treatment	9	2	5	90

Selezione e verifica dei vari parametri del piano di trattamento

Applicazione FMEA: SBRT con Cyberknife

Delivery colonna (2/2): failure con RPN ≥ 80 o S ≥ 9

XIII. Check of the correct treatment plan and of the number of fractions as described on the report print	5	Delivery to the patient of a wrong plan-plan check not performed	Personal data and patient ID on the printed plan not checked-lapse of memory	Patient receives wrong irradiation-possibility of mistaking patients and therefore treatments	10	2	3	60
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XIX. Setting of the most appropriate patient size	9	Appropriate patient size not set	Lapse of memory, insufficient experience of the operator with the delivery system	Possible collisions or errors of the PDP system slowing down treatment	9	2	5	90

Allineamento del paziente mediante confronto DRR e immagini live

Applicazione FMEA: SBRT con Cyberknife

Delivery fegato (1/2): failure con RPN ≥ 80 o S ≥ 9

Sub-process	N	Potential Failure Mode	Potential Causes of Failure	Potential effects of Failure	S	O	D	RPN
IX. Patient's instruction on how to request the intervention of the technician in case of need (voice call via intercom and/or lifting a hand)	1	Absent or insufficient patient's information on the request for help in case of need	Negligence, difficult communication with the patient, inattention, haste *(intensive scheduling)*	Lack of assistance in case of need, discomfort to the patient	10	1	3	30
XVI. Verifying the right vision of the patient from the control room with swiveling cameras	2	Failure to verify the vision of the patient from the cameras, suboptimal patient's vision	Negligence, inattention, haste *(intensive scheduling)*, superficiality, cameras not working, presence of objects in the treatment room that limit the vision of the patient	Lack of monitoring (i) possible collisions between the treatment manipulator and the patient; (ii) the patient's welfare; (iii) possible collisions between the treatment manipulator and any object present in the treatment room. Lack of action in anomalous situations; treatment not in accordance with the planned one; postponement of the treatment session	10	1	3	30

Collisioni tra il robot e il paziente

Applicazione FMEA: SBRT con Cyberknife

Delivery fegato (2/2): failure con RPN ≥ 80 o S ≥ 9

XVIII. Checking the correctness of patient and treatment plan data, check that the Synchrony field displays "Yes"	3	Failure to verify the patient and treatment data correctness, failure to verify that the Synchrony field is active	Negligence, inattention, haste *(intensive scheduling)*, interruption of the activity, patient clinical record not present at the time of treatment	Wrong dose delivery (in case of wrong prescription of dose or number of fractions in the planning stage), elongation of the work time, unnecessary live X-ray images acquisition, postponement of the treatment session	**10**	**2**	**8**	**160**
XXX. Selection of the appropriate size of the safety zone (small/medium/large), based on the patient's size	4	Not appropriate selection of the size of the safety zone	Negligence, superficiality, inattention, haste *(intensive scheduling)*, wrong estimate of the actual size of the patient	Risk of collision between the treatment manipulator and the patient (if PDP alerts are ignored), elongation of the treatment time (for PDP alerts)	**10**	**2**	**2**	**40**
XXXVIII. At the end of each session, compilation of the specific section in the worklist by the technician who delivered the treatment	5	Missed/wrong/partial/not clear compilation of the worklist at the end of each session	Negligence, inexperience, inattention, haste *(intensive scheduling)*, interruption of the activity, patient clinical records not present at the end of the treatment, shift of technicians during the treatment (high workload)	Incorrect delivery of treatment plans (wrong plan, wrong day,…) if multiple lesions (plans) are present, incomplete patient clinical records, slowdown of the workflow.	**8**	**2**	**5**	**80**

Collisioni tra il robot e il paziente

Applicazione FMEA: SBRT con Cyberknife

Delivery fegato (2/2): failure con RPN ≥ 80 o S ≥ 9

XVIII. Checking the correctness of patient and treatment plan data, check that the Synchrony field displays "Yes"	3	Failure to verify the patient and treatment data correctness, failure to verify that the Synchrony field is active	Negligence, inattention, haste *(intensive scheduling)*, interruption of the activity, patient clinical record not present at the time of treatment	Wrong dose delivery (in case of wrong prescription of dose or number of fractions in the planning stage), elongation of the work time, unnecessary live X-ray images acquisition, postponement of the treatment session	**10**	**2**	**8**	**160**
XXX. Selection of the appropriate size of the safety zone (small/medium/large), based on the patient's size	4	Not appropriate selection of the size of the safety zone	Negligence, superficiality, inattention, haste *(intensive scheduling)*, wrong estimate of the actual size of the patient	Risk of collision between the treatment manipulator and the patient (if PDP alerts are ignored), elongation of the treatment time (for PDP alerts)	**10**	**2**	**2**	**40**
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Verifica dei dati del piano di trattamento

Applicazione FMEA: SBRT con Cyberknife

Delivery fegato (2/2): failure con RPN ≥ 80 o S ≥ 9

XVIII. Checking the correctness of patient and treatment plan data, check that the Synchrony field displays "Yes"	3	Failure to verify the patient and treatment data correctness, failure to verify that the Synchrony field is active	Negligence, inattention, haste *(intensive scheduling)*, interruption of the activity, patient clinical record not present at the time of treatment	Wrong dose delivery (in case of wrong prescription of dose or number of fractions in the planning stage), elongation of the work time, unnecessary live X-ray images acquisition, postponement of the treatment session	**10**	**2**	**8**	**160**
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XXXVIII. At the end of each session, compilation of the specific section in the worklist by the technician who delivered the treatment	5	Missed/wrong/partial/not clear compilation of the worklist at the end of each session	Negligence, inexperience, inattention, haste *(intensive scheduling)*, interruption of the activity, patient clinical records not present at the end of the treatment, shift of technicians during the treatment (high workload)	Incorrect delivery of treatment plans (wrong plan, wrong day,…) if multiple lesions (plans) are present, incomplete patient clinical records, slowdown of the workflow.	**8**	**2**	**5**	**80**

Gestione dei piani multipli

Applicazione FMEA: SBRT con Cyberknife

Delivery fegato : Syncrony Respiratory Tracking System: Failure mode?

- Sistema complesso e laborioso che influenza la qualità complessiva del trattamento.
- Prevede sottoprocessi critici : rivelazione del forma d'onda del respiro, identificazione dei fiducials, verifica dell'accuratezza del modello Syncrony di correlazione in fase di set up e di trattamento.

I vari parametri e incertezze del sistema (radial correlation error, rigid body error...) sono continuamente visualizzabili dall'operatore e caratterizzati da una soglia massima che non può essere superata.

I failure modes ricadono in una regione intermedia di rischio (S≤8, D≤4, RPN ≤80)

Applicazione FMEA: SBRT con Cyberknife

Delivery: ulteriori misure di sicurezza

- Presenza di due operatori, di cui un senior all'inizio di ogni sessione
- Procedura operativa (check list) relativa al setting del trattamento
- Divieto di iniziare il trattamento se una copia stampata del piano non è disponibile per il doppio check
- Verifica delle informazioni del piano parlando a voce alta
- Notifica al fisico in caso di presenza di più piani erogabili

- Training iniziale e corsi di aggiornamento sull'uso dei tool e software relativi al delivery (potenzialità e limiti dei sitemi intrinseci di soglia e warning).

Applicazione FMEA: SBRT con Cyberknife

TRACCIABILITA' E RECORD KEEPING IN SBRT

- E' comune che un paziente riceva due o più trattamenti SBRT in un breve arco temporale (lesioni multiple, metastasi).
- Al fine di salvaguardare gli OARs definendo i giusti constrains è fondamentale tenere traccia dei trattamenti pregressi.

Ciascun Cyberknife è dotato di un Data Management System che però nella versione in uso non può essere considerato un vero e proprio sistema di R&V

- Non permette di inserire la strategia di trattamento da confrontare con quella inviata dal TPS per verifica indipendente
- Non permette lo storage e la condivisione dei parametri dosimetrici in caso di trattamenti con diversi linac

Conclusioni

- SBRT è una metodologia "intrinsicamente rischiosa"
- Esistono strumenti collaudati per l'analisi del rischio
- L'approccio prospettico FMEA può essere un valido strumento per anticipare possibili errori
- FMEA ha dei limiti, difficilmente catturerà tutti i possibili failure modes, ed è "time consuming"
- Una stretta sinergia tra approcci prospettici e retrospettici per l'analisi del rischio resta la chiave vincente, sempre se inserita in un discorso più generale di safety culture (education, training, carico di lavoro, ambiente di lavoro…)

Grazie per l'attenzione!

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FONDAZIONE I.R.C.C.S. ISTITUTO NEUROLOGICO CARLO BESTA

CENTRODIAGNOSTICOITALIANO CDI

SCENARIO

- CT (con e senza mdc, spessore fetta 1 mm, breath-hold per trattamenti al fegato, scansione 15 cm sopra e sotto la lesione)
- RMN (con e senza mdc, spessore fetta 1.5-2 mm).

- Pianificazione del trattamento (Multiplan® 4.6 TPS, Multiplan MD Suite administrative application) con singola frazione o frazioni multiple

1-5 frazioni, range di dose 12-25Gy

3 frazioni, 15Gy/frazione per lesioni epatiche

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