



DEVELOPMENT OF CLINICAL AUDITS
FOR MEDICAL USE OF RADIATION

**International Workshop on Practical Implementation of
Clinical Audit for Medical Exposure to Ionizing Radiation**



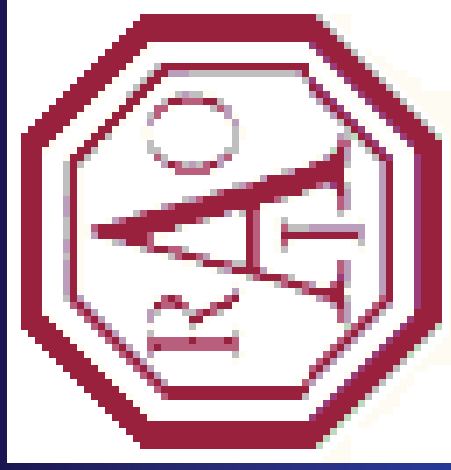
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STUDY GROUP ON QUALITY INDICATORS FOR CANCERS

Head and neck Tumors Self Evaluation Indicators



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Aim

The self-evaluation indicators represent useful tools to monitor the services, the performances and other peculiar features of a health structure in the frame of a programme of continuous quality improvement, for projects of certification or clinical audits.

In 2002 a booklet was published by the Istituto Superiore di Sanità (ISS), Rapporto Istituzionale 02/2, on general evaluation indicators to be used as measurement tools in radiotherapy centers. Those indicators were elaborated by a Working Group (including radiation oncologists, radiotherapists, physicists) altogether with physicists and biologists from the Technology and Health Department of the ISS.

After that, a project of ISS, supported by a grant of the National Health Service Ministry, was approved in 2002 and finished in 2005: it was devoted to the development and application of evaluation indicators for different diseases, among which the head and neck (H&N) tumors.

The H&N indicators Working Group decided to choose common indicators for the different subsites of this anatomy district, selecting features fitting to the quality of radiotherapy treatment. After the elaboration, the indicators have been validated by 8 radiotherapy centers to verify their applicability.

Material and Methods

The proposed indicators for H&N tumors are 7, concerning the following issues:

H&N 01- waiting time for post-operative radiation therapy

From the literature data it is well known that an interval longer than 45 days can compromise the benefit achievable with post-op RT planned for patients at high-risk of relapse. According to recent criteria, a period of 100 days from the operation day and the end of RT may be considered as the ideal interval time.

H&N 02 – waiting time for exclusive RT with curative intent

A waiting time no longer than 30 days is the time, in which the disease and symptoms tend to be stable.

H&N 03 –CT planning

The CT images are used to define the treatment volumes according to a standard nomenclature (GTV, CTV, PTV and OAR) with slice spacing of 3 to 5 mm. The CT-based treatment planning is mandatory for modern techniques as 3D-CRT (3-Dimensional Conformal Radiation Therapy) and IMRT (Intensity Modulated Radiation Therapy), and it is also useful for 2-D techniques.

H&N 04, 05 – multimodality approaches and written guidelines

The multidisciplinary approach with collegial decision-making, written and shared guidelines can assure the best treatment for the patient.

H&N 06 – Staging MR/CT

The clinical stage assessment employs information from physical examination, imaging, endoscopy and biopsy. A modern diagnostic imaging is essential for treatment planning also in cases previously operated on, who undergo RT for high-risk factors of relapse, in order to outline the CTV.

H&N 07 – interruptions caused by acute toxicities

In the H&N radiotherapy treatment the interruptions are generally caused by intense mucositis; prolonged interruptions can compromise the outcome measured as loco-regional control. No interruptions even in presence of grade 3 and 4 mucositis, are indicative of an adequate supportive therapy and can assure the best results.

Conclusions

The outcome of the audit has been judged positively, the records resulted appropriate and understandable: furthermore, they resulted very suitable for the aims.

Head & Neck	H&N 01-PORT
Name	POSTOPERATIVE RADIATION THERAPY
Topic	Overall treatment time (from the time of surgery to completion of radiotherapy)
Rationale	The optimal overall time in order to have best results is maximum 100 days
Type	Process
Numerator	Number of patients treated in 100 days
Denominator	Number of patients who underwent PORT
Threshold/Conformity	To be defined/ trend towards 1
Definition	PORT is a radiotherapy treatment to reduce the potential relapse in presence of risk factors at operation/histology (see figures below)
Survey Responsible	Chief or other appointed individual
Analysis and interpretation responsible	Chief or person designate
Survey extension	On population
Analysis periodicity	By choice
Remarks	In case of inconformities, it is suggested to explore the interval between: Surgery and radiotherapy examination Radiotherapy examination and treatment planning Radiotherapy treatment duration

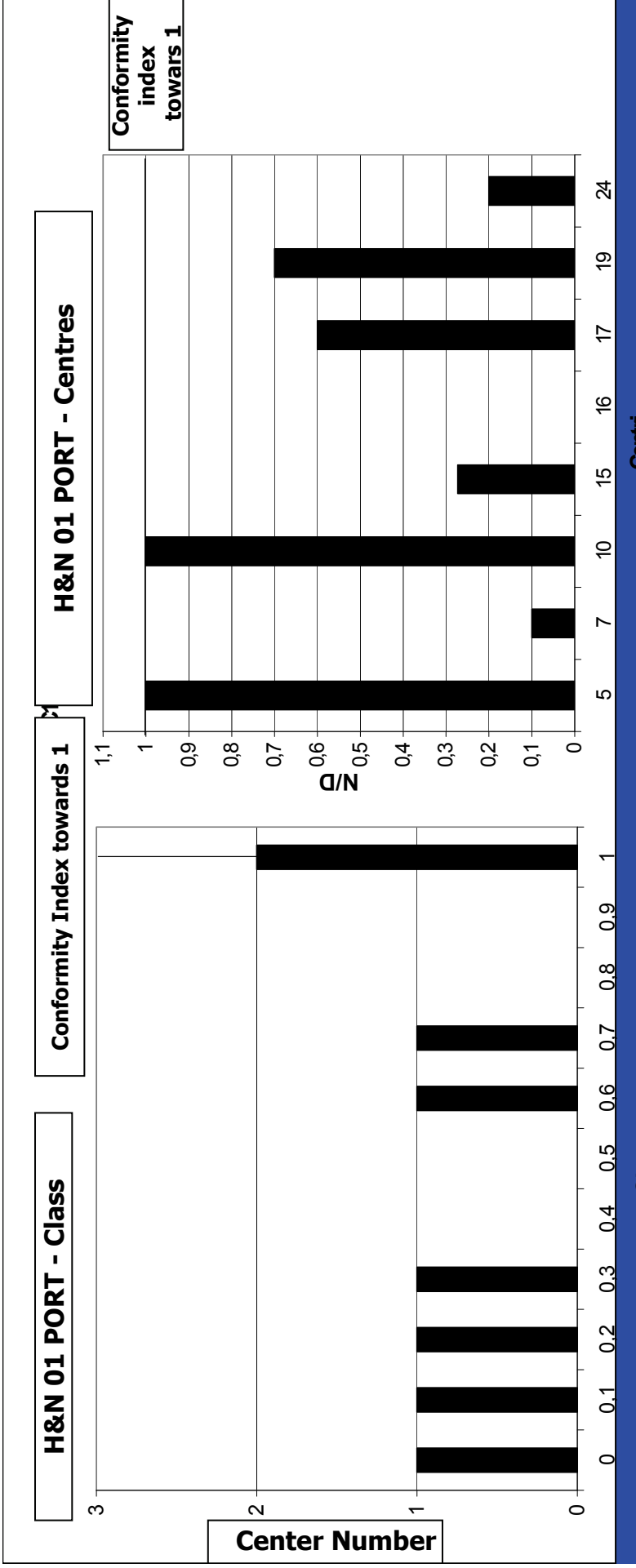


Fig.1a

Centers distribution according to proportion of patients selected for PORT in whom 100 days between surgery and the end of RT have been respected

Fig.1b

Proportion of patients selected for RT who respected an overall treatment time of 100 days

Each center is identify by a code number

Literature Data for clinical relevance

Ang et
al: IJROBP 2002, 51, 574

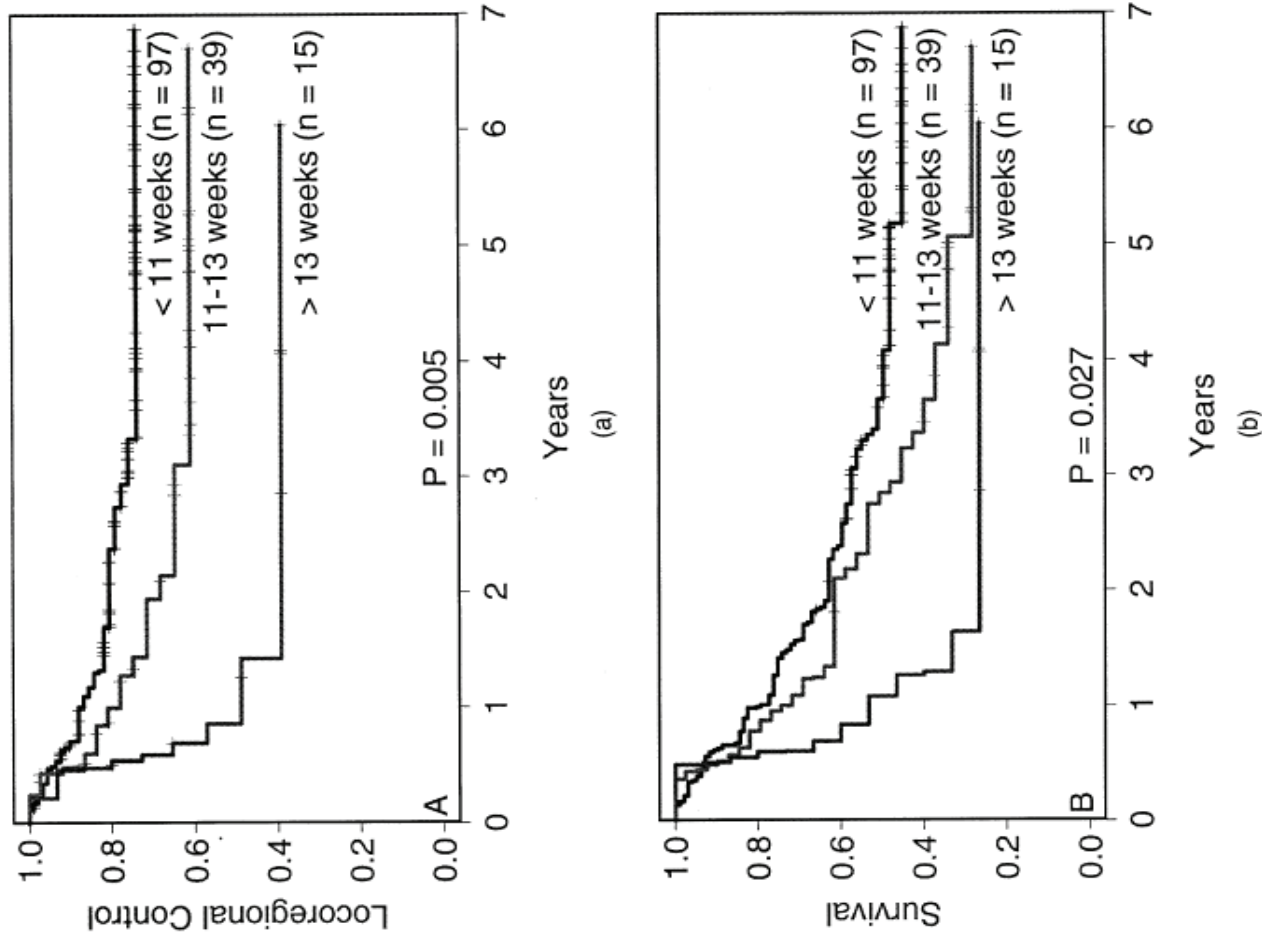


Fig. 5. Actuarial (A) LRC and (B) survival in high-risk patients as a function of the duration of the overall treatment “package” (i.e., from the day of surgery to PORT completion).

Head & Neck	H&N 02 - WT
Name	WAITING TIME FOR RT WITH CURATIVE INTENT
Topic	Waiting Time from RT booking (or from the last chemotherapy cycle) and to RT start in the exclusive curative treatments (± chemotherapy)
Rationale	The tumor is present and radiotherapy must be started within a maximum time span of 30 days, in order to achieve the optimal disease cure
Type	Process
Numerator	Number of patients treated within a time span ≤ 30 days
Denominator	Total number of patients treated with curative intent in the same period
Threshold/Conformity	Trend towards 1
Definition	Curative treatment with RT is the treatment aimed to locoregional control, specific survival and overall survival
Survey Responsible	Chief or other appointed individual
Analysis and interpretation responsible	Chief or other appointed individual
Survey extension	On population
Analysis periodicity	By choice
Remarks	---

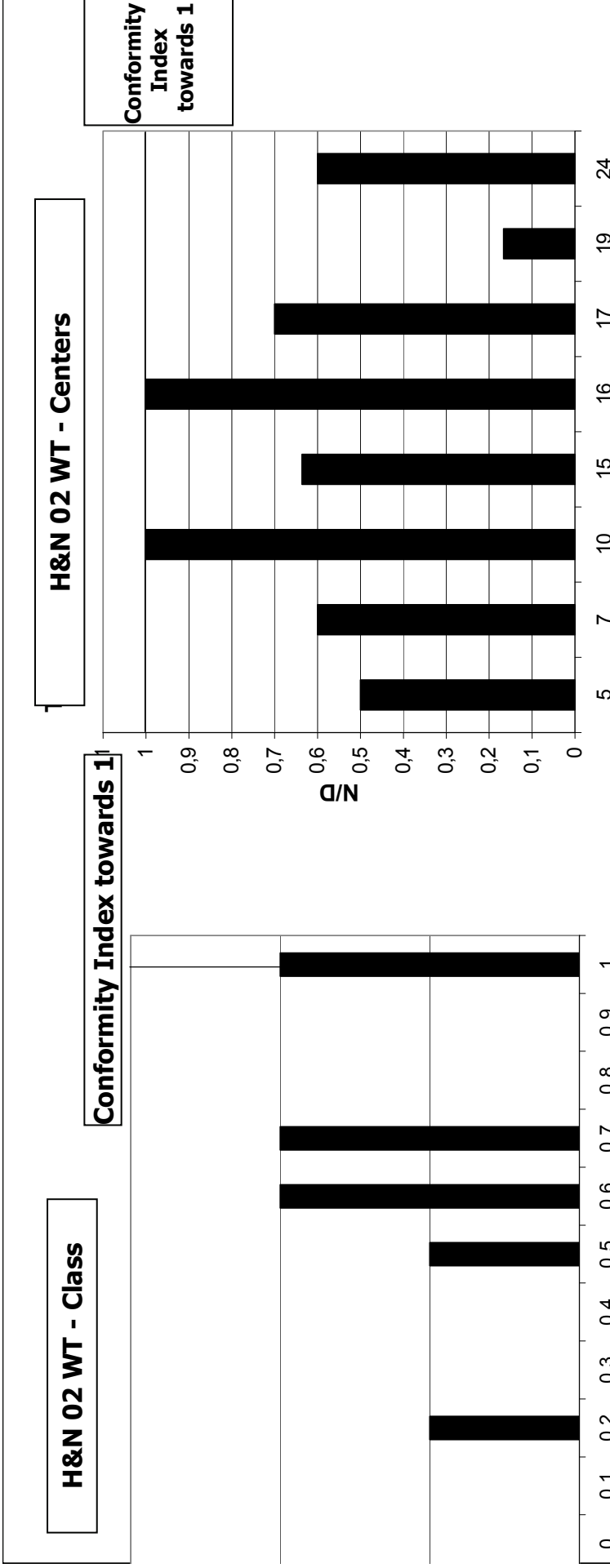


Fig.2a

Center distribution according to proportion of patients treated with RT within 30 days from RT booking or from the last chemotherapy cycle

Fig.1b

Proportion of patients treated with RT within 30 days from RT booking or from the last chemotherapy cycle

Each center is identify by a code number

Head & Neck	H&N - CTP
Name	CT PLANNING
Topic	CT planning to define the Volumes of Interest (VOI)
Rationale	The optimal CT slice thickness is ≤ 5 mm; according to the VOI the best quality can be assured with 2 and 3 mm thickness
Type	Process
Numerator	Number of patients planned with CT 2-3 mm slice thickness
Denominator	Number of patients treated with 3D conformal radiationtherapy and IMRT
Threshold/Conformity	To be defined/ trend towards 1
Definition	---
Survey Responsible	Chief or other appointed individual
Analysis and interpretation responsible	Chief or other appointed individual
Survey extension	On population
Analysis periodicity	By choice
Remarks	---

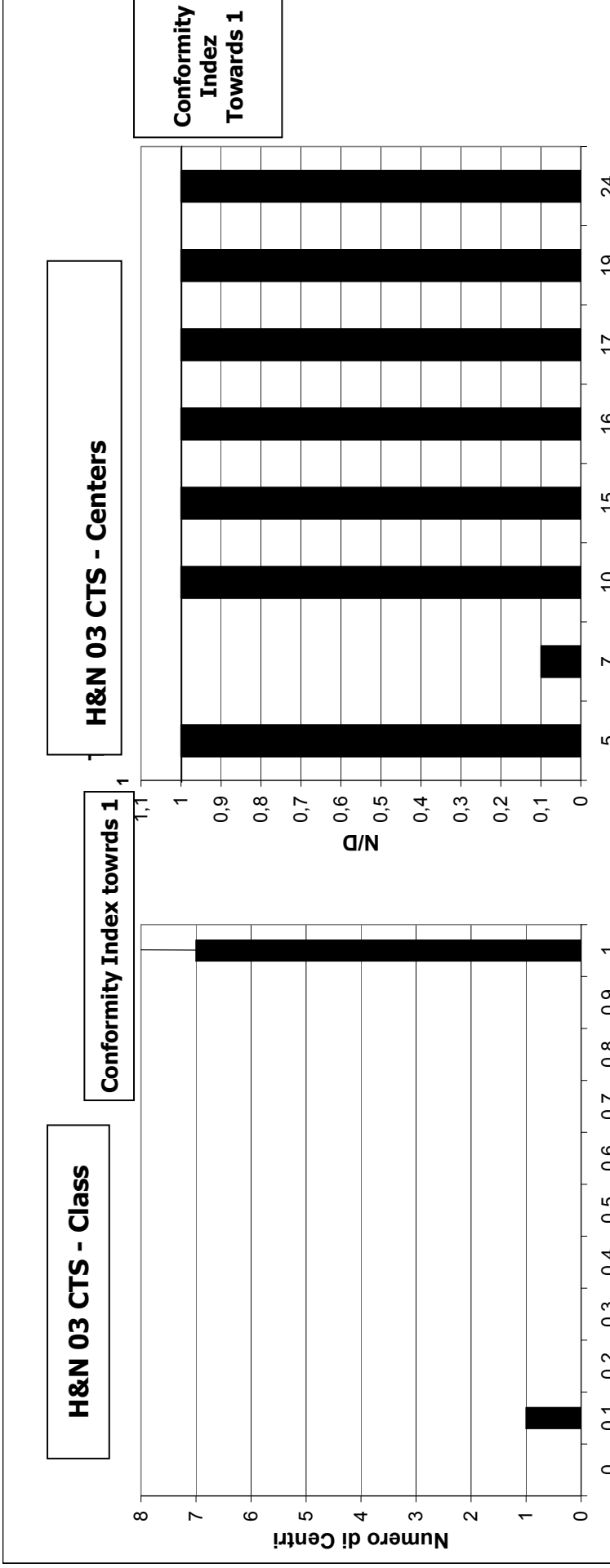


FIG.3a

Center distribution according to proportion of patients treated with Rt Plan studied with CT slice thickness ≤ 5 mm

FIG.3b

Proportion of patients treated with RT plan studied with CT slice thickness ≤ 5 mm

Each center is identify by a code number

OAR

structures to be considered constraints for acute and late toxicities

Pass of 2-3 mm
permitts
optimal
structures
contouring

Chiasma
Optical Nerves
Brain Stem
Eyeballs
Lens
Temporal Lobes
Coclea
Spinal Cord
Parotids
Masseters
PTV external mucosae
Temporo-mandibular Joints
Mandible
Sovraglottic, Glottic larynx
Pharynx constrictor muscles
Thyroid
Brachial plexus

Dose Constraints at OaR:

Chiasma	D1% ≤ 55 Gy
Optical nerves	D1% ≤ 55 Gy
Brain Stem	D1% ≤ 55 Gy
Eyeboll	Dm ≤ 35 Gy
Lens	D1 ≤ 6 Gy
Temporal lobe	D1% ≤ 60 Gy
Coclea	Dm ≤ 45 Gy; D1 < 55Gy
Spinal cord	D1% ≤ 45 Gy
Parotid	Dm ≤ 26 Gy o V30Gy ≤ 50%
Masseter	Dm ≤ 50 Gy
PTV External mucosae	Dm ≤ 35-40G
Mandible	D1% ≤ 70Gy; Dm ≤ 60-65 Gy
Soglottic, Glottic larynx	V60Gy < 50%
Pharynx constrictopr muscles	V60Gy < 50%
Temporomandibular joint	D1% ≤ 70Gy; Dm ≤ 60-65 Gy
Thyroid	V30Gy < 50%
Brachial Plexus	D1% ≤ 60-63 Gy

D1% = dose comprehensive of percent of volume ≤ 1% (dose max);

Dm = mean dose;

V30Gy ≤ 50% = organo volume which receives a dose ≥ 30 Gy must be ≤ 50% of global volume

Head & Neck	H&N 04 - MA
Name	MULTIDISCIPLINARY APPROACH
Topic	Frequency of the therapeutic strategy agreed by the specialist physicians
Rationale	The collegial decision making is a critical element to: Guarantee treatment quality Reduce lack of information Optimize the waiting time for the different type of therapy
Type	Process
Numerator	Number of new patients to whom the multidisciplinary approach has been applied
Denominator	Total number of new visited patients affected by H&N tumor
Threshold	To be defined
Definition	Multidisciplinary approach is: A decision shared by various specialists after a collegial discussion and reported in clinical record The enrolment of the patients into pre-established protocols and agreed by various specialists. The protocols should be available in written form The enrolment in clinical study according to international study rules
Survey Responsible	Chief or other appointed individual
Analysis and interpretation responsible	Chief or other appointed individual
Survey extension	On population
Analysis periodicity	By choice

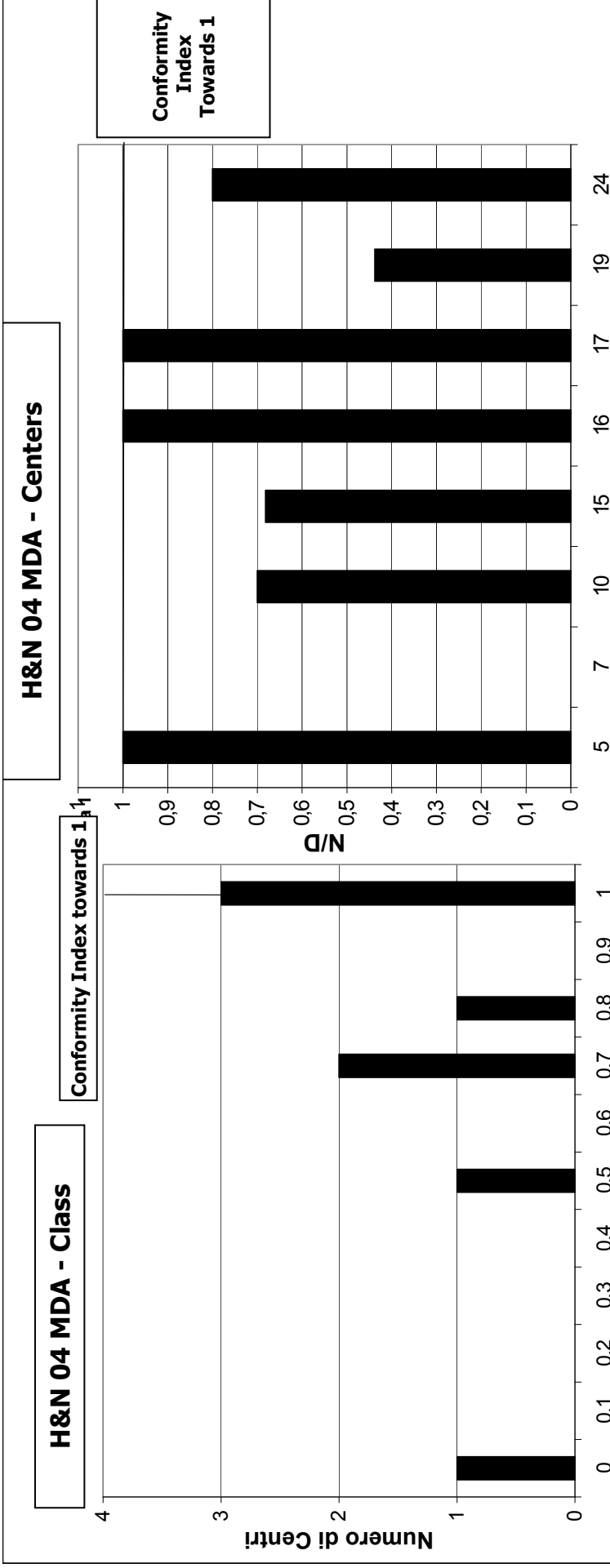


Fig.4a
 Center distribution according to
 proportion of patients selected for RT
 jointly discussed

Fig.4b
 Proportion
 of patients selected
 for RT jointly discussed

Each center is identify by a code number

Head & Neck	H&N 05 - MGL
Name	MULTIDISCIPLINARY GUIDELINES
Topic	Existence of clinical guidelines shared among radiotherapists, surgeons, medical oncologists
Rationale	Written shared clinical guidelines assure quality and uniformity of the clinical decision
Type	Process
Numerator	Number of written guidelines for head and neck tumors
Denominator	Site of origine and stage of head and neck tumors according to TNM System 2002
Threshold	To be defined/ Trend towards 1
Definition	The guideline can be defined as complete when for each site it includes subsite and differnt stages according to the most recent TNM system (2002). The guidelines must be related to 7 sites of origine of H&N cancers: oral cavity, naso-oro-hypopharynx,larynx, nasalfossa and paranasal sinuses, salivar glands
Survey Responsible	Chief or other appointed individual
Analysis and interpretation responsible	Chief or other appointed individual
Survey extension	On population
Analysis periodicity	By choice

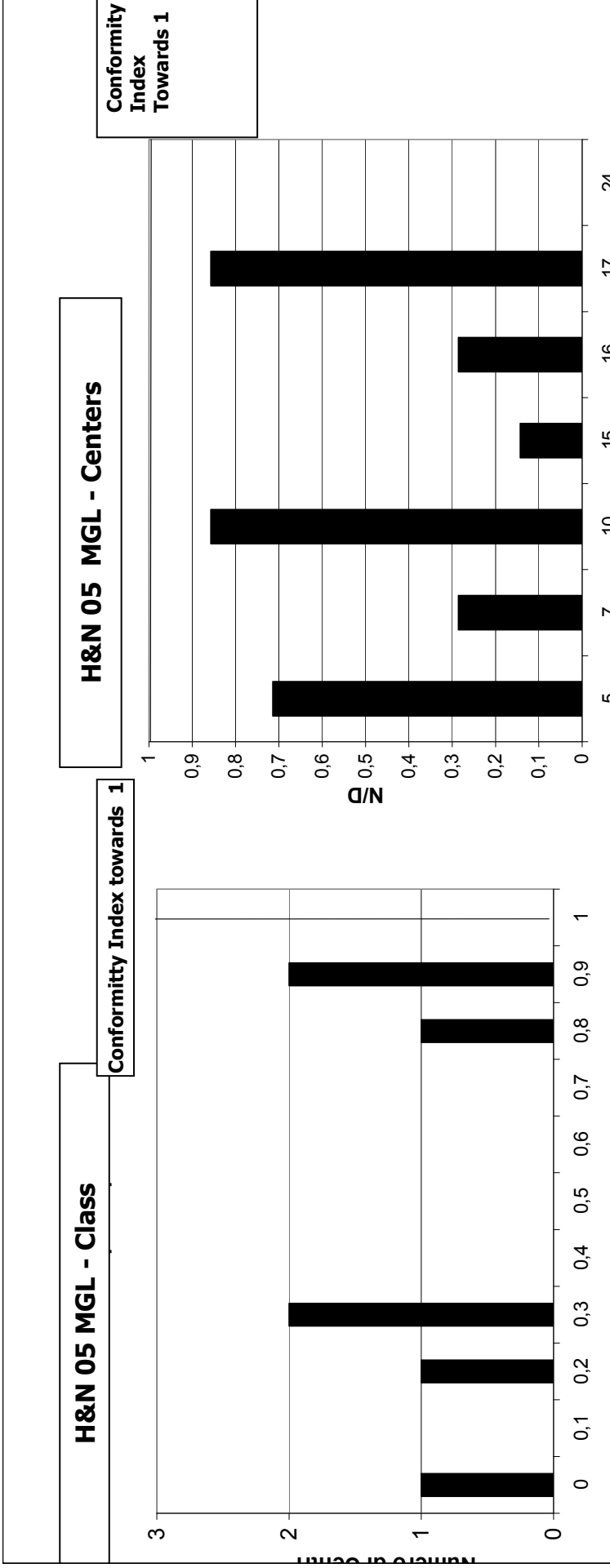


Fig.5a

Center distribution according to proportion of written guidelines of H&N tumors and site of origin

Fig.5b

Proportion of written guidelines of H&N tumors and site of origin

Each center is identify by a code number

Head & Neck	H&N 06- STAG
Name	Staging
Topic	Staging with radiologic imaging (RM or CT, PET, US) in patients with H&N cancer to be cured with RT (except glottic cancer T1N0)
Rationale	Staging with radiologic imaging allows a better definition of tumor extension and consequently a better staging
Type	Process
Numerator	Number of H&N cancer patients cancer staged with radiologic imaging
Denominator	Number of H&N cancer patients treated with RT
Threshold/Conformity	To be defined/ trend towards 1
Definition	---
Survey Responsible	Chief or other appointed individual
Analysis and interpretation responsible	Chief or other appointed individual
Survey extension	On population
Analysis periodicity	By choice
Remarks	---

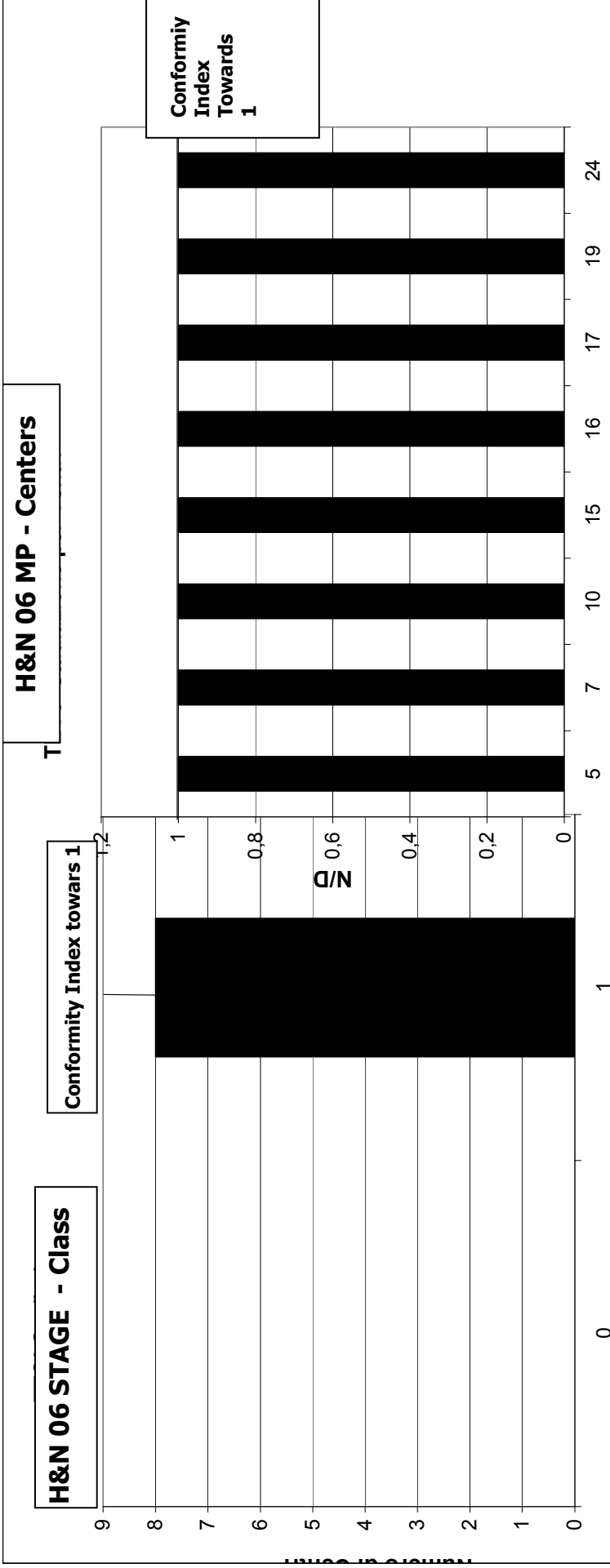


Fig.6a

Center distribution according to proportion of patients staged with radiologic imaging

Fig.6b

Proportion of patients staged with radiologic imaging

Each center is identify by a code number

Head & Neck	H&N 07 - BAT
Name	RT WITHDRAWAL FOR ACUTE TOXICITY (G3,G4)
Topic	RT withdrawal due to acute toxicity G3,G4
Rationale	A RT withdrawal can reduce the probability of locoregional control and it can possibly affect the overall and specific survival.
Type	Process
Numerator	Number of patients who experienced RT withdrawal due to acute toxicity (G3,G4)
Denominator	Number of patients treated with RT (\pm CT) with a curative intent
Threshold/Conformity	To be defined/ trend towards 1
Stratification	RT with curative intent, alone with standard fractionation RT with curative intent with standard fractionation and with CT
Survey Responsible	Chief or other appointed individual
Analysis and interpretation responsible	Chief or other appointed individual
Survey extension	On population
Analysis periodicity	By choice
Remarks	---

**H&N 07 BAT – Class
Conformity Index towards 1**

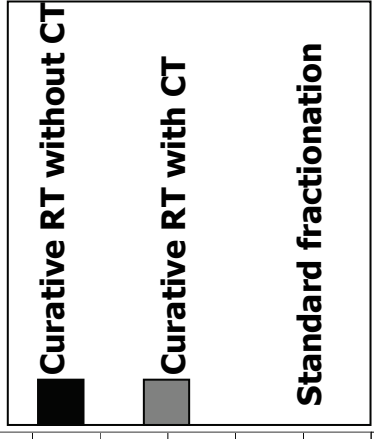
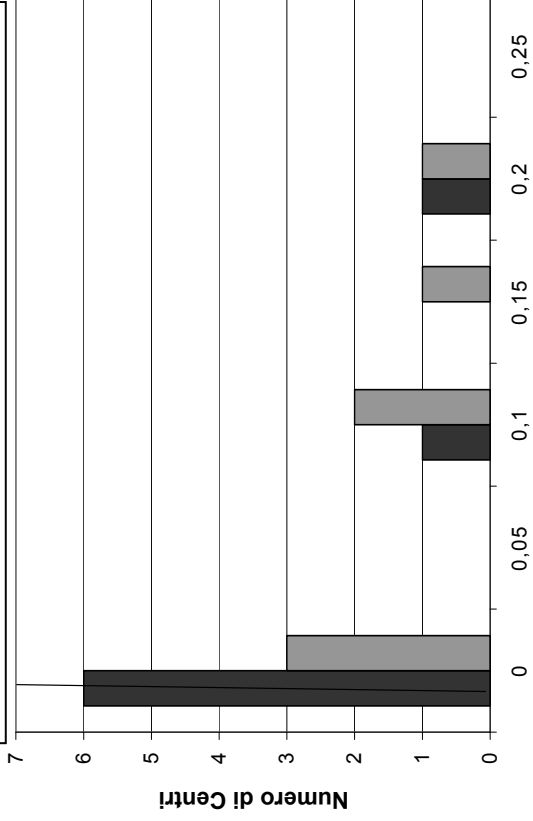


Fig.7a
Center distribution according to proportion of patients cured with radical intent with or without CT, who experienced RT withdrawal due to acute toxicity G3,G4

H&N BAT - Centers

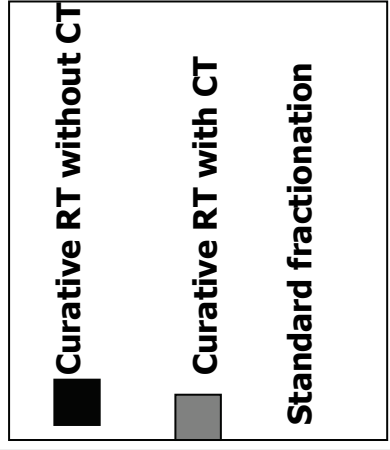
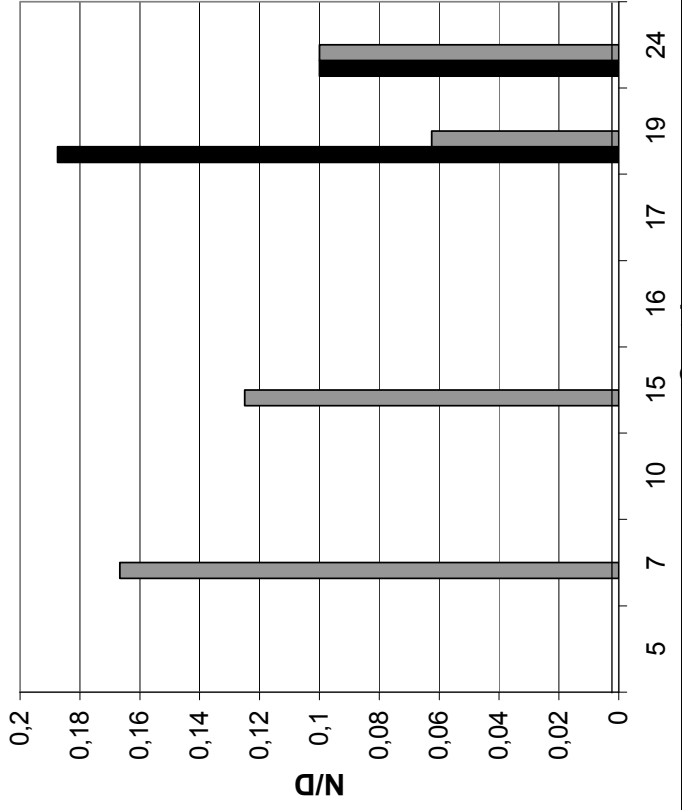


Fig.7b
Proportion of patients cured with radical intent with or without CT who experienced RT withdrawal due to acute toxicity G3,G4

Each center is identify by a code number

Acute local toxicity is a crucial issue in the management of head and neck cancer (HNC) with radiotherapy (RT) (1–4). Radiotherapy alone, given with standard fractionation (daily fractions of 1.8–2 Gy) is usually associated with acceptable and manageable acute toxicity, but treatment intensification with acceleration and/or concomitant chemotherapy (CHT) clearly produces a significant increase in the frequency and severity of adverse effects. The occurrence of an excessive amount of adverse effects during treatment can have several unfavorable consequences: it can reduce treatment efficacy, adversely affect patients' quality of life during treatment, and add significantly to overall treatment costs.

**Palazzi et al:
IJROBP 2008, 70 N.2,330**

Table 2. Acute toxicity data from selected clinical trials of concurrent CHT and RT

Institution	Scoring system	Treatment	Mucositis	Toxicity (%)				
				Dysphagia	Pain	Skin	Salivary glands	
RTOG (25)	CTC v2.0	AF-RT + CHT	G2, NR G3, 50 G4, 3	G2, NR G3, 58 G4, 4	G2, NR G3, 7 G4, 0	G2, NR G3, 4 G4, 1	NR	
MSK-CC (26)	RTOG	IMRT + CHT (86%)	G2, 54 G3, 38 G4, 0	G2, 62 G3, 16 G4, 0	NR	G2, 42 G3, 6 G4, 0	G1, 48 G2, 52 G3, NA	
UM (27)	RTOG	AF-RT + CHT	G2, 46 G3, 52 G4, 0	G2, 11 G3, 80 G4, 0	NR	G2, 46 G3, 13 G4, 0	NR	
TBCC (28)	RTOG/CTC v2.0	RT + CHT	G2, 41 G3, 29 G4, 2	G2, 39 G3, 36 G4, 0	G2, 52 G3, 7 G4, 0	G2, 43 G3, 29 G4, 2	G1, 52 G2, 43 G3, NA	
Present study	CTC v3.0	AF-RT (13%) + CHT (68%)	G2, 39 G3, 28 G4, 0	G2, 38 G3, 33 G4, 0	G2, 34 G3, 41 G4, 0	G2, 56 G3, 13 G4, 0	G1, 23 G2, 67 G3, 7	

Abbreviations: RTOG = Radiation Therapy Oncology Group; CTC v2.0 = Common Toxicity Criteria, version 2.0; AF = accelerated fractionation; RT = radiotherapy; CHT = chemotherapy; NR = not reported; MSK-CC = Memorial Sloan-Kettering Cancer Center, New York; IMRT = intensity-modulated RT; NA = not applicable; UM = University of Michigan, Ann Arbor; TBCC = Tom Baker Cancer Center, Calgary.

Summary

Indicators	Centers	Stratificat.	N. of conformal centers	Conformity value	% Conformity
H&N 01	8/8 (100%)	-	2/8	1	25
H&N 02	8/8 (100%)	-	2/8	1	25
H&N 03	8/8 (100%)	-	7/8	1	88
H&N 04	8/8 (100%)	-	3/8	1	38
H&N 05	7/8 (88%)	-	8/8	1	0
H&N 06	8/8 (100%)	-	8/8	1	100
H&N 07	8/8 (100%)	Curative RT alone Curative Rt + CT	8/8	0	75
				0	38

Summary

Number of centers which answered: 8 out 30

Survey simple to do

Items are relevant

Attached forms are adequate