



· 论 著 ·

放射治疗肿瘤协作组规范下的加速器 质量保证经验

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[摘要] **背景与目的:** 放射治疗的质量保证在精准实施肿瘤放射治疗中起着关键作用。本研究旨在探讨加入放射治疗肿瘤协作组 (Radiation Therapy Oncology Group, RTOG) 成员达到放射治疗质量保证标准的经验。**方法:** 加入RTOG的前期准备是制定本单位加速器设备质量保证方案, 包括表格和质控报告。质控项目如日检、月检、年检项目需参照美国物理学家协会 (American Association of Physicists in Medicine, AAPM)TG40和AAPM TG142报告所描述的内容进行实施。实施中由一位资深物理师全权负责1~2台加速器。日检由物理师在早晨实施, 月检和年检由物理师周末安排实施。日检、月检和年检的结果以电子表格存档。**结果:** 制定并严格执行规范化的设备质量保证方案。放射治疗质量保证结果的文档数字化能直接客观地显示加速器质控情况和存在问题。**结论:** 制定加速器质控方案并执行规范化的放疗质控规范在临床上值得推广。

[关键词] 放射治疗肿瘤协作组; 放射物理中心; 美国物理学家协会; 放射治疗; 质控

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[Abstract] **Background and purpose:** The quality assurance (QA) of radiation therapy plays an important role in the precise tumor radiotherapy. This study was to report the accelerator QA experience of joining the Radiation Therapy Oncology Group (RTOG). **Methods:** The QA protocols and the report forms were customized by following the RTOG requirements. The daily, monthly and annual quality assurance items were created according to the American Association of Physicists in Medicine (AAPM) TG40 and AAPM TG142. Each senior physicist was response for the QA of two accelerators due to the limited physicists. The daily QA was carried out by the physicists and therapists in the morning, and the monthly QA and annual QA were performed at weekends. The results of daily, monthly and annual QAs were filled in the electronic form. **Results:** The standardized QA protocols were established and strictly followed. The QA results of radiotherapy were digitized, which directly showed the accelerator QA status. **Conclusion:** The standardized radiotherapy QA protocols should be established and implemented, and it is worth spreading widely in clinics.

[Key words] Radiation Therapy Oncology Group; Radiological Physics Center; American Association of Physicists in Medicine; Radiotherapy; Quality assurance

放射治疗肿瘤协作组 (Radiation Therapy Oncology Group, RTOG) 是目前肿瘤放射治疗领域多中心研究的领导者, 是美国放射学院

(American College of Radiology, ACR) 的重要临床研究成员。自成立以来, RTOG已经发起了460个研究方案, 积累了约9 000例患者的临床资

料,发表了约800篇研究论文。

为了保证多中心研究的一致性,使研究结果更具可信度,RTOG将对成员的放射治疗设备的控制进行审核。目前的研究也证明,放射治疗的质量能够直接影响到患者的生存率^[1-4]。因此,RTOG对放射治疗的质量保证有明确的标准,其手册中规定成员加入RTOG,需同意放射物理中心(Radiological Physics Center, RPC)进行访问和评估,并提供机器校准和检测报告的副本,用于验证照射剂量。RTOG成员还需参加RTOG的热释光剂量计(thermoluminescent dosimeter, TLD)项目,用于检测设备的机械精度以及剂量精度。参与某些特殊研究,还需获得RTOG下属的相关医学组织的认可,向相关组织提交所需信息。根据RTOG的要求,在提交RTOG成员申请时,需提交本单位设备质量保证的方案、表格和近期的质控报告,要求报告覆盖美国物理学家协会(American Association of Physicists in Medicine, AAPM) TG40报告所描述的物理质量保证项目^[5],根据RPC的最新通告,目前已采用AAPM TG142报告对成员进行评估^[6],同时RTOG还要求提供TLD项目所有的原始材料。

复旦大学附属肿瘤医院作为国内首家加入RTOG的单位,按照RTOG的要求实施加速器设备的质量保证已接近4年,结合国内的放射治疗现状,为后续的申请提供参考经验。

1 资料和方法

1.1 放射治疗质量保证的人员与时间安排

对于放射治疗的质量保证工作,国外的常规做法是在每日放射治疗结束以后,由物理师对加速器实施质控。对于临床任务繁重的国内放射治疗单位,使用加速器完成每日临床治疗时间一般较晚,无法由物理师实施质控。因此,参考国内部分中心的现状,可行的方案是在周末对加速器实施质控。质控工作分为两大类,即质控规范制度建立及日常实施。具体步骤包括:

(1) 成立一个科室质控小组,制定质控相关的规章制度,规章制度内容包括质控实施的检测项

目、检测频率和检测方法。

(2) 制定质控会议召开的频率。质控会议主要讨论质控规程中出现的问题,确定响应方案,纠正并规范科室流程。

(3) 确定质控实施者。日常实施是指每日的质量监测(日检),由物理师或技术员在早上实施。月度和年度的质控由物理师实施,由物理师自行安排时间完成所需测量项目。表1为本中心对每台加速器所实施的具体质控项目、所需时间和人员安排。

1.2 放射治疗质量保证的主要项目和报表

按照AAPM的TG142、TG40和TG53报告并结合单位的实际来制定放疗质控项目^[7]。我们并没有完全按照TG142制定质控流程,而是根据临床实际对其进行一定微调,使其更加适合实际情况。同时制定更加适合本单位的方式质量保证方案。具体的质控项目见表2。

1.3 放射治疗质量保证结果文档的信息化

由于放疗质控项目较多,本单位使用统一的Excel模板对质量保证结果进行书面记录,质量保证项目的各个基准数据的建立是根据加速器安装验收时获取的数据。书面记录完成后,进行汇总分析评估并且输入到自主研发的信息化系统中。基准数据来自年检的正确数据(表3~5)。

1.4 质控结果及响应

本单位由高年资的物理师对每月质量保证的报表进行回顾,对于质量保证不合格的项目,通常先分析其原因和趋势,再确定响应方案。同时,在每次机器维修以后,对受影响加速器的数据也会加以记录,生成报告。

2 结 果

按照本单位的时间安排,在物理师每周末工作1 d的情况下,可以完成每月的质控测量,考虑到加速器维修保养可能占据部分机器时间和调强计划验证,一般需要4 d完成所有项目。由于年检项目比较多,一般由物理师自行安排时间和项目的实施顺序,在物理师每周工作2 d的情况下可以在1个月内完成。同时由于质控项目和数据较多,需要额外的时间对数据进行整理和录入。

表 1 加速器所实施的具体质控项目、所需时间和人员安排

Tab. 1 Specific quality assurance, time required and staff arrangements implemented by the accelerator

Frequency	Procedure	Time required	Staff
Daily	Dosimetry	10 min	Physicist/therapist(1)
	Mechanical and safety		
Monthly	Mechanical	0.5 d	Senior physicist (1) /junior physicist (1)
	Dosimetry	1.0 d	
	MLC	0.5 d	
	IGRT	0.5 d	
	VMAT	0.5 d	
	Total	3.0 d	
Annual	Mechanical	1.0 d	Senior physicist (1) /junior physicist (1)
	Dosimetry (absolute dose)	0.5 d	
	Dosimetry (3D water tank)	2.0 d	
	Dosimetry (other)	1.0 d	
	MLC	0.5 d	
	IGRT	0.5 d	
	VMAT	0.5 d	
	Total	6.0 d	

MLC: Multi-leaf collimator; IGRT: Image-guided radiation therapy; VMAT: Volumetric modulated arc therapy

表 2 质控项目

Tab. 2 Quality assurance project

Frequency	Procedure	Tolerance	Description	Instrument type
Daily	Dosimetry output	3%	Measurement before the beginning of the daily treatment	Morning check equipment
	Safety interlock	Functional	Follow manufacturer's test procedures	
Monthly	Rotation isocenter	2 mm	Including collimator, gantry and couch	Coordinate paper
	Collimator angle indicator	1°	Check the deviation of digital reading from actual angle	Spirit level
	Gantry angle indicator	1°	Check the deviation of digital reading from actual angle	Spirit level
	Couch angle indicator	1°	Check the deviation of digital reading from actual angle	
	Treatment couch position indicators	0.2 cm	Difference between moving distances measured with digital indicators and ruler	Ruler
	Localizing lasers	1 mm	Check the positional accuracy of lasers	Coordinate paper

续表2

Frequency	Procedure	Tolerance	Description	Instrument type
	Optical distance indicators	2 mm	Check the accuracy of reading from ODI	Front pointer
	Field size indicators (symmetric and asymmetric)	2 mm	Check the difference between digital readings and actual field size	Coordinate paper
	Light/radiation field coincidence	2 mm	Check the coincidence of light/radiation field	Film
	Dosimetry output coincidence	2%	Check measured output against baseline value	Ionchamber, dosimeter, phantom
	Beam profile constancy	1%	Check flatness and symmetry against baselines	2D diode array
	Beam quality constancy	2%	Check beam energy against baseline	Ionchamber, dosimeter, phantom
	Output linearity	2%	Check the output linearity of Linac	Ionchamber, dosimeter, phantom
	MLC	1 mm	Check the positional accuracy of MLC	Film
	IGRT		Check the image quality of IGRT devices	CAT phantom
	VMAT		Check the dose delivery accuracy of VMAT	EPID
	Collimator rotation isocenter	1 mm	Check the maximum deviation of isocenter during rotation	A4 paper
	Gantry rotation isocenter	1 mm	Check the maximum deviation of isocenter during rotation	Front pointer
	Couch rotation isocenter	1mm	Check the maximum deviation of isocenter during rotation	A4 paper
	Coincidence of light/radiation field isocenter	2 mm	Check the coincidence of light/radiation field isocenters	Film
	Electron applicator interlock	Functional	Follow manufacturer's test procedures	
	Table top sag	2 mm	Check table top sag under typical burden	Ruler, heavy item
	Couch angle indicator	1°	Check the deviation of digital reading from actual angle	
	Table travel maximum range			
Annual	2 mm	Check the maximum travel range of table in all directions	Ruler	
	Safety		Follow manufacturer's test procedures	
	Beam profiles	1%	Check flatness and symmetry against baselines (and spot-check point measurements)	3D water tank
	Output calibration	1%	Follow TRS277 and national standards	Water tank
	Photon beam output factors	2%/1%	Spot-check 2 or more field sizes	3D water tank
	Asymmetric field output factors	2%	Spot-check 2 or more field sizes	3D water tank

续表2

Frequency	Procedure	Tolerance	Description	Instrument type
	Electron beam output factors	2%	Spot-check of one size each year	3D water tank
	Beam quality and energy	1%	PDD10 for photon beams and R50 for electron beams	3D water tank
	Wedge factor	2%	The ratio of a certain dose rate on the center axis of radiation field for adding or without wedge	3D water tank
	Output linearity	2%	Check the output linearity of linac	Ionchamber, dosimeter, phantom
	Output constancy vs gantry angle	2%	Check the output constancy at different gantry angles	2D diode array
	Off-axis factor constancy vs gantry angle	1%	Check the off-axis factor at different gantry angles	2D diode array
	MLC	1 mm	Check the positional accuracy of MLC	Film
	MLC leakage	0.50%	Measure MLC transmission, check against baseline	Ionchamber, dosimeter, phantom
	IGRT		Check the spatial accuracy and image quality of IGRT devices	CAT phantom
	VMAT		Check the dose delivery accuracy of VMAT	EPID

表 3 本单位的放疗月检质控报表 (I)

Tab. 3 The radiotherapy monthly quality assurance report of our department (I)

Energy	Buildup1 //cm	Rdg1	Rdg2	Average	Reference	Tolerance	Pass/fail
6X	5.2	91.2	91.0	91.1	90.75	±2%	Pass
6e	1.2	111.5	111.3	111.4	111.8	±2%	Pass
8e	1.2	109.8	109.8	109.8	110.6	±2%	Pass
10e	2.2	113.1	113.1	113.1	113.8	±2%	Pass
12e	2.2	115.4	115.4	115.4	115.5	±2%	Pass

Dosimetry output consistency; SSD=100 cm, Field size:10 cm×10 cm, MU=100

表 4 本单位的放疗月检质控报表 (II)

Tab. 4 The radiotherapy monthly quality assurance report of our department (II)

Energy	Buildup2 //cm	Rdg1	Rdg2	Average	Ratio	Reference	Tolerance	Pass/fail
Photon								
6X	10.2	69.4	69.4	69.4	0.762	0.763	±2%	Pass
Electron								
6e	2.2	66.8	66.7	66.7	0.599	0.615	±2%	Pass
8e	3.2	38.9	39.9	39.4	0.359	0.355	±2%	Pass
10e	3.2	89.0	89.0	89.0	0.787	0.811	±2%	Pass
12e	5.2	15.9	16.0	15.9	0.138	0.14	±2%	Pass

Baseline: Commission data; Energy was constant; Ratio: Rdg (Bulidup 2)/Rdg (Bulidup 1)

表5 本单位的放疗月检质控报表(Ⅲ)

Tab. 5 The radiotherapy monthly quality assurance report of our department (Ⅲ)

Energy	Flatness		Symmetry		Tolerance	Pass/fail
	X	Y	X	Y		
6X						
Reference	1.5%	1.6%	0.9%	1.1%	3%	Pass
Rdg	1.2%	0.9%	0.6%	0.3%		
6e						
Reference	2.0%	2.3%	1.2%	1.5%	3%	Pass
Rdg	2.4%	1.9%	1.2%	0.6%		
8e						
Reference	3.2%	3.0%	2.6%	1.8%	3%	Pass
Rdg	3.0%	2.9%	0.8%	0.5%		
10e						
Reference	2.1%	3.7%	1.5%	1.4%	3%	Pass
Rdg	1.9%	1.7%	0.2%	0.5%		
12e						
Reference	3.1%	4.0%	0.8%	2.2%	3%	Pass
Rdg	2.8%	2.1%	1.8%	0.3%		

SSD=100 cm, Photon: 20 cm×20 cm, with 3 cm solid water buildup. Electron:20 cm×20 cm, with 1 cm solid water buildup

3 讨 论

RTOG旨在引导放射治疗的研究和临床合作并提供多中心国际临床合作。加入RTOG成为其成员可以参加和发起RTOG多中心临床试验,促进肿瘤放射治疗的研究。正式成为RTOG的成员,标志着物理质控及临床相关工作已达到了发达国家的水平。

肿瘤放疗的治疗原则是肿瘤区域得到足够的治疗剂量,正常组织和危及器官少受或者免受不必要的照射,以提高肿瘤的局控率,降低正常组织的并发症发生率。放疗的整个流程需要质控,质控的实施与保证是实现临床治疗理想目标的有力保障。

ASTRO发布了5项质控的白皮书,涉及影像引导放射治疗(image-guided radiotherapy,

IGRT)、调强放射治疗(intensity-modulated radiation therapy, IMRT)、正立体定向放射外科(stereotactic radiosurgery, SRS)、体部立体定向放射治疗(stereotactic body radiotherapy, SBRT)、Peer Review和高剂量率近程放疗(high-dose-rate brachytherapy, HDR)的详细质控项目,在临床实际运用中具有重要的指导作用。但是由于各个国家或地区的经济条件等情况不同,故临床背景、设备情况、医务人员配比情况不一样,具体的质控流程、细节也不尽一样。复旦大学附属肿瘤医院放射治疗中心目前拥有7台加速器,质控物理师和剂量师共20人,每年治疗患者约7 000例,是国内乃至全世界治疗患者较多的肿瘤放疗中心之一,在如此繁忙的临床工作和资源有限的情况下,医疗质量安全尤为重要。本中心实行定人定机器的策略,每台加速器配备1~2位资深物理师,星期一至星期五满足临床治疗患者

的需求,不占用机器来做质控,物理师每周末工作1~2 d,可以完成定期的质控测量,考虑到加速器维修保养可能占据部分机器时间和调强计划验证,通常需要4 d完成所有项目。年检由物理师自行安排时间来实施。

本中心所采用的质控项目和质控流程与目前国际上流行的测试项目基本一致。由于放射治疗技术发展很快,目前国内的标准GB/T 15213-1994和GB/T19046-2013^[8-9]并不能涵盖比较新的项目,特别是IMRT、容积调强放射治疗技术(volumetric modulated arc therapy, VMAT)及SBRT,对此类放射治疗技术质控要求极高,机械精度不够会影响治疗疗效并给患者带来一系列不良反应。Weber等^[4]从前瞻性和回顾性研究中得出的质控数据证实,不严格遵守放射治疗协议会导致患者的生存率降低,局控率降低,正常组织的潜在不良反应增加。谢耕等^[10]报道了复旦大学附属肿瘤医院放射治疗中心的放疗全程管理及质控的初步应用经验,规范化的放疗全程管理及质控制度可将治疗差错率由1.7%降低至0.9%。

目前,我们已经实现放射治疗质量保证体系的电子化,建立了数据库,且正在多中心运用。使用统一的数据库对数据进行采集,将有助于后续的数据分析。

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