The Radiological Physics Center's Annual TLD Machine Calibration Audit and Its Impact on Clinical Trials

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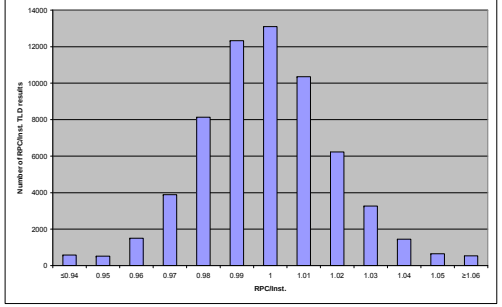
Introduction

The aim of the Radiological Physics Center, as funded by the NCI, is to assure NCI of the correctness and consistency of the physical data for radiotherapy patients entered onto clinical trials. The TLD audit of the machine output is the only QA process that reaches every participating institution on an annual basis and as such is the one audit tool that provides continued assurance that the basic output of each machine used to calculate the tumor dose for trial patients is accurate and consistent. The TLD audit also serves as a mechanism to gather demographic data from each of the participating institutions, i.e., personnel, linacs, treatment planning systems, etc. Another benefit of the TLD audit is to raise the awareness of the need for accuracy in machine calibration and as such attention is given to this need when the TLD are irradiated.

The RPC TLD audit program is the largest program of its kind and monitors all institutions (1647 institutions) that participate in NCI sponsored clinical trials, within the USA and internationally. The RPC initiated its TLD program for photon beams in 1977, in 1982 for electron beams and in 2007 for proton beams.

New megavoltage machines of the same make, model, and energy used to treat patients these days are similar in terms of their dosimetry properties; however, the one dosimetric quantity that is unique to each machine and dependent on personnel is the output calibration and as such is subject to human error. Figure 1 shows a histogram of the RPC TLD results since 2003. The mean RPC/Institution ratio is 0.999 with a standard deviation of 2.1%. Approximately 4-5% of the beams checked fall outside of the RPC's ±5% criterion on the first irradiation.

Figure 1. TLD results since 2003 for both photon and electron beams



Materials & Methods

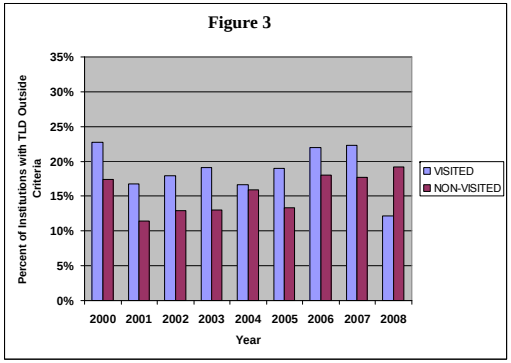
The RPC's TLD program uses TLD 100 (LiF powder) in small capsules that are placed in acrylic blocks that serve as mini-phantoms. These blocks are mailed to institutions where they are irradiated to 300 cGy (see figure 2) and returned to the RPC for analysis. The criterion used by the RPC is ±5%. The RPC sends repeat TLD to an institution after investigating the cause of the first TLD discrepancy.

Figure 2. Photon and electron TLD blocks and photon block irradiation set-up

Results

Over the past 8 years approximately 5% of the megavoltage beams audited with TLD have fallen outside of the RPC's ±5% dose criteria requiring some action and follow-up by the RPC staff. Today this would represent approximately ~140 photon and ~550 electron beams from nearly 3200 machines used to treat clinical trial patients. Of the approximately 770 institutions the RPC physicists have visited since its inception to conduct an on-site dosimetry review visit and who contribute ~85% of all clinical trial patients that receive radiotherapy, approximately 15 - 20% of these institutions per year (~150 institutions) (figure 3) have one or more photon or electron beams outside of the RPC's criteria requiring an investigation by the RPC.

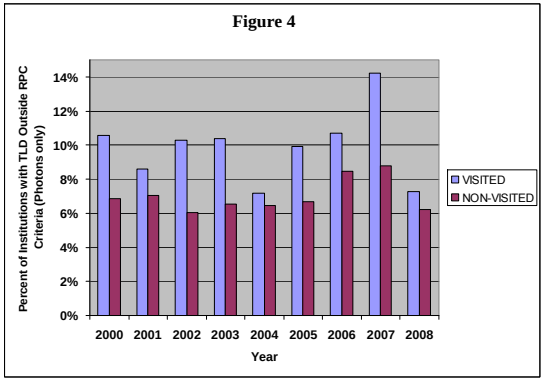
Figure 3



Because the majority of the NCI sponsored clinical trials use only photon beams, figure 4 illustrates the TLD results over the past 8 years for photons beams only, whereas figure 3 was for TLD results from both photon and electron beams. Figure 4 indicates that when only photon beams are considered, the percentage of institutions having a beam outside of the RPC's criteria is reduced from 15–20% to 6–14 %.

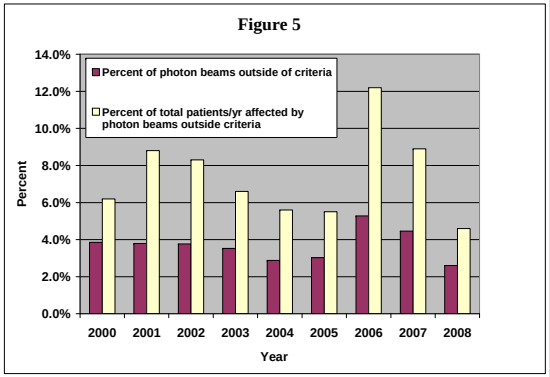
A further breakdown (figure 5) of these data in terms of photon beams only, and not institutions, show that the percent of photon beams that are outside of the RPC's 5% criterion range from 3 - 5%. Very few institutions (≤ 50 out of 150 per year) have unacceptable TLD results in two consecutive years. This is because the RPC investigates the discrepancies and follows up with the institution to make sure the errors have been resolved. Performing less frequent audits will result in more institutions with undiscovered calibration errors for longer periods of time.

Figure 4



If one takes a closer look at the TLD results for institutions in terms of their patient contributions and limiting the data to photon beams, the percent of total patients per year affected, on average, by the photon beams outside the RPC's TLD criterion ranges from 5 to 12% as seen in Figure 5. These data were derived from knowing the numbers of patients put onto clinical trials by each institution, the number of photon beams at each institution and the fraction of the photon beams outside of the RPC's 5% criterion for the TLD audit.

Figure 5



A statistical analysis would be needed to determine whether potentially 5 -12% of the patients having dosimetry errors would have an impact on a trial outcome. In addition it is not known how, reducing or increasing the frequency of the audit, would impact on the outcome of a trial due to the uncertainty in patient dosimetry. Published data by Bentzen et al[3] reviewing EORTC trial results indicate that, based on their TLD audit program, in cases where the beam calibration was low or high there were decreases in tumor control probability or increases in normal tissue morbidity, respectively, when looking at the clinical dose response data. The Bentsen article also indicated that sequential TLD audits improved the uniformity of the clinical outcome and that small deviations (2-3%) in beam output might lead to clinically important variations in outcome. These same conclusions were reached by Pettersen et al[4] when they discussed the impact of dosimetry quality assurance and its impact on sample size in randomized clinical trials as well as by Boyer and Schultheiss[5] who looked at the effect of dosimetry uncertainty on complication-free local tumor control.

Conclusions

1. The RPC's annual TLD audit detects and helps resolve numerous calibration problems each year.
2. These calibration errors may impact on the dosimetry for 5 – 12% of clinical trial patients.
3. Previously published work indicate that this error rate may have a significant impact on the outcome of clinical trials if dose errors are not corrected in a timely manner.
4. Further statistical analysis of the data is needed to determine any significance to the error rate observed by the RPC and frequency of the audit as it pertains to clinical trial outcomes.

References

1. Bentzen et al, Clinical impact of dosimetry quality assurance programmes assessed by radiobiological modeling of data from the thermoluminescent dosimetry study of the European Organization for Research and Treatment of Cancer., European J. Cancer (36), 615-620, 2000.
2. Pettersen et al, Quality assurance of dosimetry and the impact on sample size in randomized clinical trials., Radiotherapy and Oncology (86), 195-199, 2008.
3 Boyer, A. and Schultheiss, T., Effects of dosimetric and clinical uncertainty on complication-free local tumor control., Radiotherapy and Oncology (11), 65-71, 1988.

Support

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