Adverse Events of After-loading High Dose Rate Brachytherapy Reported to the United States Food and Drug Administration (FDA)

Destie Provenzano MS 1,2, Kevin Rao BS3, Gizem Cifter PhD 1, Mehrdad Sarfaraz PhD 1, Hamid Aghdam MS 1, Martin Ojong MD 1, Murray H. Loew PhD 2, Sharad Goyal MD 1, Yuan James Rao MD 1,2

1. Division of Radiation Oncology, The George Washington University School of Medicine and Health Sciences, Washington, DC

2. Department of Biomedical Engineering, The George Washington University, Washington, DC

3 Department of Biomedical Engineering, Johns Hopkins University, Baltimore, MD

@gwbiomed

THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

PURPOSE/OBJECTIVE(S)

OpenFDA is an open access database maintained by the United States Food and Drug Administration (FDA) that provides information on adverse events related to medical devices, such as high dose rate after-loading brachytherapy (HDR-BT). We seek to report and categorize the adverse events related to HDR-BT.

MATERIAL & METHODS

The OpenFDA was queried for adverse events related to HDR-BT between 1993 and 2019. An academic brachytherapist reviewed all reports and categorized events based on disease site, type of applicator, manufacturer, event type, impact on radiation dosimetry, and patient outcomes. Important findings and observations are reported in quantitative and qualitative forms. As this study is observational, no attempt was made to statistically differentiate rates of events between disease sites, applicators, manufacturers, and outcomes.

RESULTS

Figure 1: Count of Adverse Events for JAQ related product failures between 1995 and August 2019.

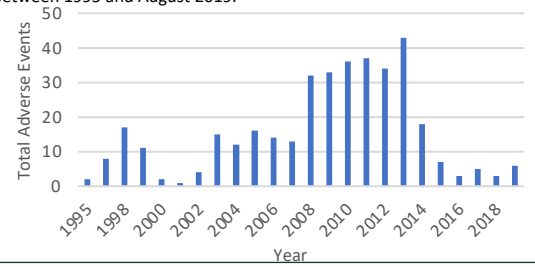

Figure 2: Breakdown of event type for total adverse events regarding the "JAQ" product code.

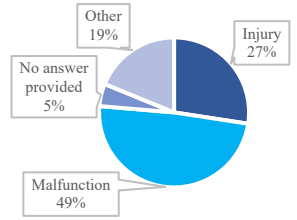

Figure 3: Breakdown of manufacturer for total adverse events regarding the "JAQ" product code.

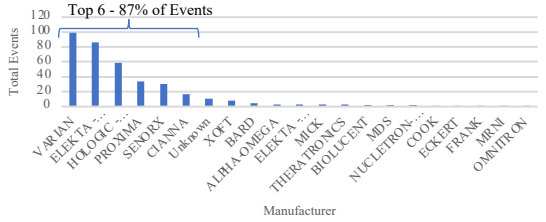

Table 1: Categorization of interesting or unique events

Summary

	Total	%
Major hardware failure	26	57%
Major patient complication	2	4%
Major software failure	13	28%
Major user error	5	11%
Total	46	

372 adverse events were reported between 1993 and 2019, with the number of events declining after 2014. 48.9% of events reported a device malfunction, while 27.4% of events reported an injury. Breast balloon implants were the most common applicator involved in events (38.7%). The most common disease site of reported events was Breast (49.2%), followed by Gyn (23.7%). Applicator breaks caused the majority events (64.2%), and user error contributed to only 16.7% of events. 24.7% of patients received an incorrect radiation dose as a result of the event, and 16.4% required additional procedures to rectify the adverse event. 11.0% of events required repair of the afterloader. 3.0% of events resulted in unintended radiation dose to staff. There were no reported staff injuries or patient deaths from an adverse event in this time period.

SUMMARY/CONCLUSION

The OpenFDA database shows a decreasing trend in adverse events of HDR-BT. Most adverse events are not caused by user error, and most events do not result in patient injury or incorrect radiation dose. These results support the continued use of HDR-BT as a safe treatment modality for cancer.

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