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Evaluation of the Adverse Events Reported on SpaceOAR from the MAUDE Database in 2021

Prostate cancer is anticipated to become the most prevalent non-cutaneous cancer among American males by 2023. Image-guided radiation therapy is a common treatment, with higher doses correlating with lower recurrence rates, especially in patients with higher PSA scores. However, increased radiation doses lead to higher rates of genitourinary and gastrointestinal toxicities, such as rectal bleeding, ulcers, fistula formations, and colorectal cancer, significantly impacting patients' quality of life. To mitigate these toxicities, various techniques have been explored, including the use of spacers to create a space between the prostate and surrounding tissue.

SpaceOAR, the earliest FDA-approved spacer product since 2015, is a polyethylene glycol gel inserted transperineally to create a 12.6mm buffer zone between the prostate and rectal wall. It has shown promising results in reducing grade 1 and 2 genitourinary and rectal toxicities, particularly at higher radiation doses. Cost-effectiveness analyses have indicated its viability for high-dose radiotherapy, despite marginal cost increases. SpaceOAR Vue, a radio-opaque version with iodine, aids in visualization.

Continuous monitoring of device safety is essential. Studies analyzing adverse events reported on the MAUDE Database since SpaceOAR's approval have shown a concerning increase over the years, with some cases resulting in significant harm or life-threatening situations. While the MAUDE Database has limitations, it remains a valuable resource for understanding the safety profile of SpaceOAR products. This study aims to provide insights into adverse event frequency, types, and severity to guide urologists in ensuring the safe and appropriate use of SpaceOAR and SpaceOAR Vue for their patients.