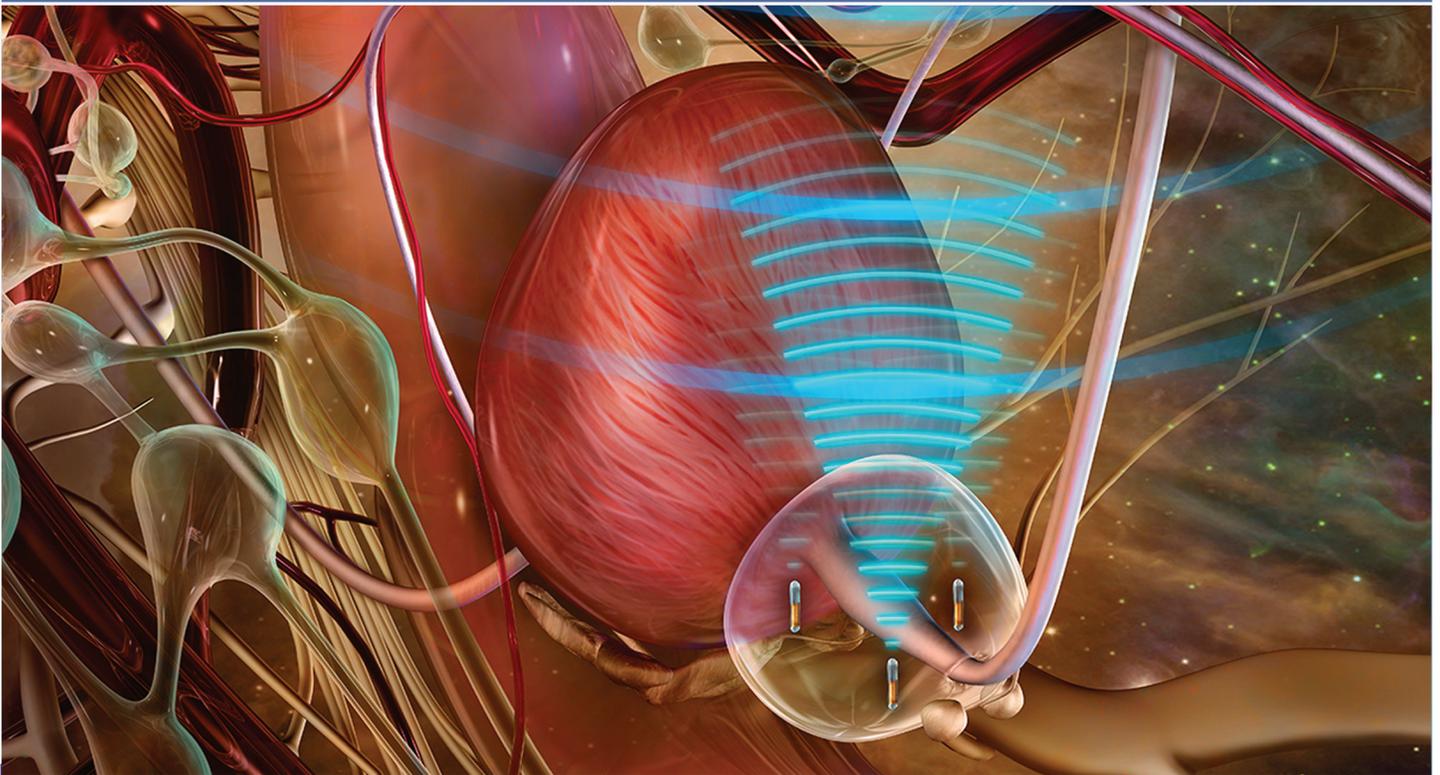


# Assessing the Impact of Margin Reduction (AIM) STUDY



Reduction in Patient-Reported Acute Morbidity in Prostate Cancer Patients Treated with an Increased Radiation Dose Using Reduced PTV Margins and Electromagnetic Tracking

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# OBJECTIVE

The primary objective of the AIM Study was to measure the effect of reduced planning target volume (PTV) margins in prostate cancer patients undergoing high dose intensity-modulated radiotherapy (IMRT) using real-time tumor tracking, measured by patient-reported quality of life (QOL) outcomes.

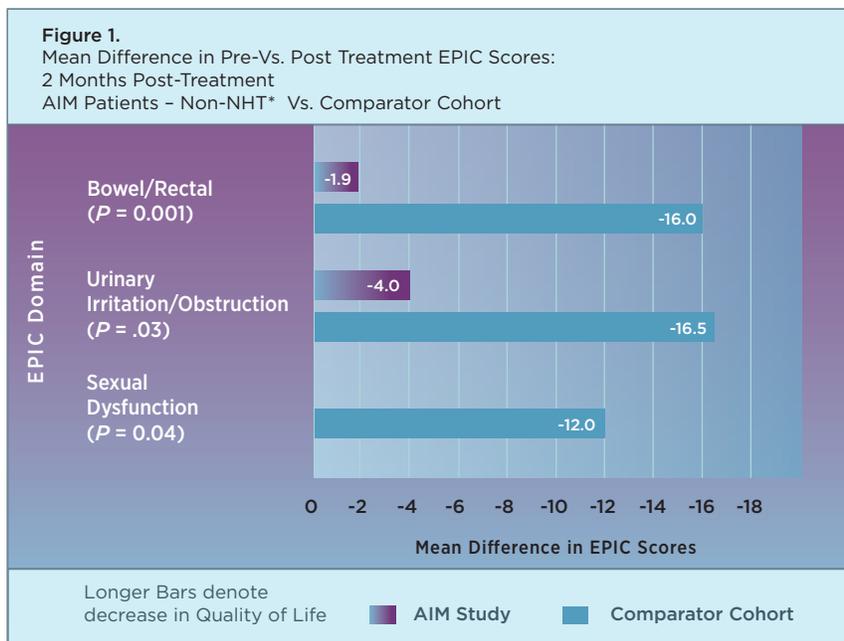
Data from the study were used to determine the effect on workflow when treating to tight PTV margins using patient realignment thresholds managed with electromagnetic real-time tracking.

# STUDY DESCRIPTION

- The primary objective was to measure the effect of reduced PTV margins in prostate cancer patients undergoing high dose intensity-modulated radiotherapy (IMRT) as measured by patient-reported outcomes.
- Sixty four patients with localized prostate cancer were enrolled in an institutional review board-approved multi-institutional prospective study.
- These 64 patients underwent primary intensity-modulated radiotherapy (IMRT) and were treated to a dose of 81 Gy in 1.8 Gy fractions to the prostate and proximal seminal vesicles, with a nominal PTV margin of 3-mm.
- Real-time tracking using the Calypso® System and a nominal 2-mm intervention threshold were utilized for repositioning the patient.
- The study used the Expanded Prostate Cancer Index Composite (EPIC) quality of life (QOL) index for the assessment tool.
- The EPIC QOL questionnaire was completed by AIM study subjects before and after IMRT and resulting scores were compared with published EPIC data for a comparator cohort of 153 patients undergoing IMRT.<sup>1</sup>
- The comparator cohort was comprised of men with previously untreated stage T1 to T2 prostate cancer who had elected prostatectomy, brachytherapy, or external-beam radiotherapy as primary treatment.

# RESULTS

While AIM patients had generally less favorable characteristics than the comparator group, they experienced fewer acute GI, acute sexual and some acute GU side effects than those patients in the comparator study\*, despite a high dose of 81 Gy (Figure 1).



\* Non-NHT: Non-Neoadjuvant Hormonal Therapy (n=43)

The AIM study results suggest that Varian Calypso real time tracking reduces sexual dysfunction at two months. The study authors explain that: "Sexual interest may be better maintained in the absence of bowel and urinary toxicity."

As expected, there was no statically significant change in Urinary Incontinence among the AIM study patients.

Overall bowel problems were fewer among AIM patients than in comparator patients as evidenced in Figure 2.

Percentages for men experiencing rectal/bowel symptoms (urgency, frequency, incontinence, bloody stools and/or rectal pain) in the AIM study cohort was clinically stable while the percentage of comparator patients with bowel problems increased from 4% to 20%.

**Figure 2.**  
Percentages of Patients Reporting Bowel/Rectal Symptoms  
2 Months Post-Treatment  
AIM Study Vs. Comparator Cohort

EPIC Domain	AIM Study		Co-Hort	
	Pre-Treatment	Post-Treatment	Pre-Treatment	Post-Treatment
Overall Bowel Function	9%	6%	4%	20%

## KEY FINDINGS

- Real-time target tracking and objective patient setup with the Calypso System enabled planning target volume (PTV) margin reduction.
- Use of the Calypso system resulted in a reduction in the majority of self-reported side effects compared to patients who were not treated with Calypso. This led to improved quality of life outcomes for patients.
- Clinically significant reductions in the patient-reported side effects were reported even with a dose of 81 Gy.

## FURTHER ANALYSIS

Further analysis of the AIM study data showed the efficiency of delivering increased dose with narrow margins was determined to be compatible with standard treatment time slots when using real-time localization and tracking.

Real-time tracking used for procedure setup and interventions was performed within standard 15-minute treatment slots. 57% of fractions required realignment to avoid dosing healthy tissue and increasing the incidence of acute side effects (Figure 3).

**Figure 3.**  
Percentages of Patient Repositioning Interventions During AIM Study<sup>3</sup>

Intervention Performed	Number of Interventions	Fractions Requiring Interventions (%)	Intervention vs. No Intervention (%)
Radiation beam held, spontaneous target realignment	60	2%	59%
Treatment couch realigned	1,618	57%	
No intervention	1,161	41%	41%

(n= 2,839 fractions, 64 patients)

# CONCLUSIONS

The Calypso System provides the accuracy, precision, and efficiency necessary to confidently manage interfraction and intrafraction prostate motion.

Continuous management of intrafraction motion may be critical when reducing PTV margins.

Reduced PTV margins, even with an 81 Gy dose, can result in decreased treatment-related side effects when prostate motion is carefully managed.

# REFERENCES

- <sup>1</sup> Sanda, Martin G., et al. "Quality of Life and Satisfaction With Outcome Among Prostate-cancer Survivors." *New England Journal of Medicine* 358 no. 12, (2008): 1250–61.
- <sup>2</sup> Sandler, Howard, et al. "Reduction in Patient-reported Acute Morbidity in Prostate Cancer Patients Treated With 81 Gy Intensity-modulated Radiotherapy Using Reduced Planning Target Volume Margins and Electromagnetic Tracking: Assessing the Impact of Margin Reduction Study." *Urology* 75 no. 5, (2010): 1004–1008.
- <sup>3</sup> Tropper, Scott, et al. "Efficiency and Clinical Workflow of Delivering IMRT to the Prostate Within 2-mm Tolerances." *International Journal of Radiation Oncology Biology Physics* 75 no. 3 Supplement, (2009): S580. Abstract no. 2889.

# RADIATION SAFETY

All radiotherapy may cause side effects, varying with the area of the body being treated. Systemic side effects can include fatigue, nausea, or low blood counts. Localized side effects can include skin erythema, hair loss, mucositis, shortness of breath, irritation of bowel and bladder function, or diminished sexual function. Radiation treatment is not appropriate for all cancers. Treatment sessions may vary in complexity and time.

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