

Research Letter

Testing the Feasibility of SentiMag/Sienna+ for Detecting Inguinal Sentinel Nodes in Penile Cancer (SentiPen): An eUROGEN and National Cancer Research Institute Trial

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Radioisotope-guided dynamic sentinel node biopsy (DSNB) is performed in patients with squamous cell carcinoma (SCC) of the penis who have disease stage greater than T1aG2 [1–3].

SentiMag is a new method involving subcutaneous injection of Sienna+ (a dark brown aqueous suspension of superparamagnetic iron oxide particles; Sysmex, Milton Keynes, UK) [4,5]. The magnetic signature is detected using a SentiMag probe (Endomag, Cambridge, UK). This technique reduces patient contact time, avoids exposure to radioactivity, the risk of blue dye tattooing, and anaphylaxis, and improves the patient experience.

Our primary objective was to assess the feasibility of SentiMag/Sienna+ for detection of inguinal sentinel nodes in patients with penile cancer in comparison to standard radioisotope-guided DSNB and to assess concordance using Cohen's κ with a threshold of at least 90%. The secondary objective was to assess complications.

All patients with intermediate- or high-risk cN0 SCC of the penis were recruited from a single centre. Ten of the 13 patients recruited were eligible for inclusion. The mean age was 67.6 yr (range 48–83). Staging was T1G3 in three, T2G2 in one, T2G3 in four, and T3G3 in two patients. All patients had undergone primary tumour surgery. Ten patients underwent ultrasonography, with fine needle aspiration (FNA) performed for potentially abnormal nodes. Two patients had FNA and both had negative cytology. Tc^{99m}-nanocolloid, Sienna+, and patent blue dye were administered at a mean time of 19.1, 13, and 0.22 h, respectively. The ten eligible patients received both a standard Tc^{99m}-nanocolloid injection and a Sienna injection. The mean time to nodal surgery was 20.2 h after radioisotope injection and 14.1 h after Sienna+ injection. The mean total surgery time was 84.4 min. One patient was excluded from the

analysis because of SentiMag mechanical failure. Among the remaining nine patients, one had no nodes detected with either Tc^{99m}-nanocolloid or Sienna+ in a unilateral inguinal region, leaving 17 inguinal regions identified via both techniques. Thirty-five nodes were excised using standard DSNB and 34 using Sienna+/SentiMag. Three positive nodes were detected in three patients with both techniques. The malignancy detection rate was 30% with both methods. Cohen's κ was calculated to assess whether Sienna+ was able to detect the node with the highest gamma count: 17 sentinel nodes were detected with the gamma probe and 16 of these were also detected with Sienna+ (Fig. 1). The standard unweighted Cohen's κ was 0.971 (standard error [SE] 0.028; 95% confidence interval [CI] 0.92–1.0), while the weighted Cohen's κ was 0.941 (SE 0.058; 95% CI 0.828–1.0), indicating very good concordance. Blue dye was detected in 31/38 (82%) nodes and brown coloration in 25/38 (66%). The median number of nodes excised per inguinal region was two for each technique. There were no significant adverse events or complications.

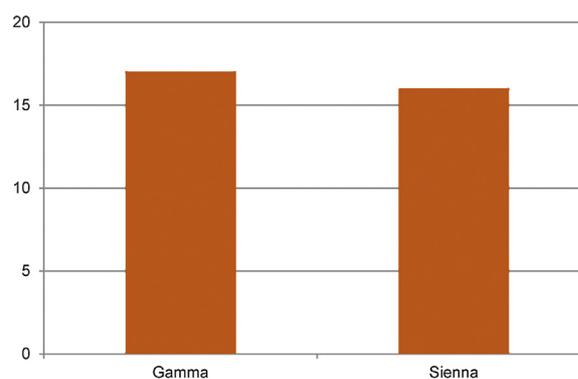


Fig. 1 – Number of sentinel nodes detected with each technique.

In conclusion, these results suggest very good concordance between standard radioisotope-guided DSNB and Sienna+/SentiMag. The Sienna+/SentiMag technique is a feasible and safe alternative in penile SCC. It removes the need for lymphoscintigraphy and can be administered up to 1 wk before surgery. Further studies to evaluate its true effectiveness are required and are in progress.

Conflicts of interest: The study received ethical approval (IRAS) and was listed as a National Cancer Research Institute and eUROGEN study. The study was sponsored by The Christie NHS Foundation Trust. Sysmex UK provided logistic support regarding SentiMag systems and the Sienna+ tracer, as well as technical services and training. There was no financial compensation for study subjects.

References

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