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Surgery in Motion

Feasibility of Image-guided Navigation with Electromagnetic Tracking During Robot-assisted Sentinel Node Biopsy: A Prospective Study

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Abstract

Background and objective: Image-guided surgical navigation (IGSN) can enhance surgical precision and safety. The expansion of minimally invasive surgery has increased the demand for integration of these navigation systems into robot-assisted surgery. Our objective was to evaluate the integration of electromagnetic tracking with IGSN in robot-assisted sentinel lymph node biopsy (SLNB).
Methods: We conducted a prospective feasibility study to test the use of IGSN in SLNB. In total, 25 patients scheduled for SLNB at The Netherlands Cancer Institute were included (March 2022 to March 2023). SLNB using IGSN was performed using a standardised technique with a da Vinci robot (Intuitive Surgical, Sunnyvale, CA, USA) in four-arm configuration. Feasibility was determined as the percentage of sentinel nodes (SNs) successfully identified via IGSN. Successful SN resection was defined as SNs correctly localised via navigation and validated ex vivo with a gamma probe. Surgeon feedback on the robot-assisted IGSN workflow was evaluated using the System Usability Scale (SUS).
Key findings and limitations: In accordance with the protocol, the first five patients were used for workflow optimisation, and the subsequent 20 patients were included in the analysis. IGSN led to successful identification of 91% (50/55) of the SNs. There were no complications associated with navigation. The surgeon feedback (SUS) was 60.9, with lowest scores reported for the user interface and workflow integration.
Conclusions: IGSN during robot-assisted surgery was feasible and safe. The technique allowed identification and removal of predefined small pelvic lymph nodes.

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Patient summary: We carried out a study on the feasibility of imaging-guided navigation in robot-assisted prostate surgery. Our results show that this technique is feasible, safe, and effective.

ADVANCING PRACTICE

What does this study add?

This study demonstrated that integrating navigation during robotic abdominopelvic surgeries is feasible. Navigation helped to reach the target SNs effectively and safely. Participating surgeons are willing to use it in future procedures and are confident it will improve decisiveness.

Clinical Relevance

This study is important because it evaluated, and demonstrated, for the first time the feasibility of image-guided surgical navigation integrating an in-house built electromagnetic tracking system into the da Vinci robotic platform to perform pelvic sentinel lymph node biopsy in patients with prostate cancer undergoing radical prostatectomy. With this procedure a high success rate of 91% for the localization of sentinel lymph nodes could be achieved, which is critical for effective surgical guidance, particularly in complex anatomical locations within the pelvis. The era of minimally invasive surgery incorporating augmented reality and image-navigation has just begun, holding the promise to offer a personalized surgical procedure that ensures the highest diagnostic or therapeutical benefits, and reduces morbidity. However, future improvements in workflow integration and user interface design are necessary to optimize the usability of these navigation systems in clinical settings. Additionally, the reproducibility of these results in other clinical scenarios needs confirmation, as outcomes observed in a clinical trial might differ. Therefore, multicenter studies with larger patient cohorts will be essential to further validate these findings and expand the applicability of this innovative technology to other urological procedures.

Associate Editor: Gianluca Giannarini, M.D.

Patient summary

We carried out a study on the feasibility of imaging-guided navigation in robot-assisted prostate surgery. Our results show that this technique is feasible, safe, and effective.

1. Introduction

The presence of lymph node (LN) metastases is an important prognostic factor in prostate cancer (PCa), as these are associated with a higher likelihood of disease progression and dissemination. Extended pelvic LN dissection (ePLND) is the gold standard for nodal staging in clinically localised PCa [1]. However, ePLND is associated with significant morbidity and the template does not include aberrant lymphatic drainage sites from the prostate [2,3]. Improvements in preoperative and intraoperative techniques for localisation of aberrant LNs may result in a shift towards better treatment outcomes [4]. The ability to identify the location of nodal metastases according to lymphatic drainage from the primary tumour has led to exploration of sentinel LN biopsy (SLNB). In PCa surgery, SLNB-directed dissections have yielded a diagnostic accuracy comparable to that of ePLND, but with lower complication rates [5]. Critically, SLNB helps in identifying aberrant drainage outside the standard ePLND template, which occurs in up to one-third of prostatic sentinel nodes (SNs). Despite its experimental status in international guidelines, SLNB has potential because of its high sensitivity [6].

Navigation can significantly enhance the precision and safety of surgical procedures. A personalised anatomic roadmap that depicts tumour location in relation to delicate anatomic structures could allow significant improvements in outcomes. Such a roadmap could support surgical planning and provide real-time guidance during surgical excision. This can be achieved with image-guided surgical navigation (IGSN) with electromagnetic tracking (EMT), which has been well tested and is widely used in open surgeries [7–10]. IGSN can visually guide surgeons through the intervention. The rapid uptake of robot-assisted minimally invasive surgery has increased the need to integrate such navigation systems in robot-assisted surgery.

Owing to its high sensitivity, SLNB in PCa has become a well-established procedure at our hospital [11]. As IGSN shows high accuracy in localising SNs for SLNB, this setting offers an ideal framework for testing and validating the feasibility and safety of new image-guided technologies for surgery. SLNB provides an opportunity to test the feasibility

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of IGSN for localising small target lesions in general. Thus, we conducted a study to evaluate integration of EMT navigation is feasible in robot-assisted minimally invasive surgery for SLNB.

2. Patients and methods

2.1. *Study design*

We conducted a prospective feasibility study (March 2022 to March 2023) at The Netherlands Cancer Institute (NKI). The study protocol was approved by the institutional review board in August 2021 and was registered on ClinicalTrials.gov (NCT06091072). The study was conducted according to the principles of the Declaration of Helsinki and the Medical Research Involving Human Subjects Act. All participating patients gave written informed consent. Inclusion criteria were patients aged ≥18 yr scheduled for robot-assisted SLNB with target SNs fixed to retroperitoneal structures or major vessels. Exclusion criteria were a cardiac pacemaker, which could cause interference with the navigation system, and metal implants in the pelvic area, which could compromise the image quality of scans. After hands-on training using a phantom set-up, surgeons were ready to use IGSN.

2.2. *Navigation set-up*

2.2.1. *Preoperative procedures*

Approximately 5–6 hr before surgery, a hybrid indocyanine green-^{99m}Tc-nanocolloid agent was injected transrectally under ultrasonic guidance into the peripheral zone in the four quadrants of the prostate. After injection, early (15 min) and late (2 h) lymphoscintigrams were followed by a single-photon emission computed tomography (SPECT) scan and a low-dose CT scan. Three-dimensional (3D) SPECT/CT reconstruction facilitated preoperative anatomic localisation of SNs. An experienced nuclear medicine physician interpreted the images, which served as a roadmap for intraoperative SN localisation. Of the SNs indicated preoperatively, the surgeon selected target SNs that were surgically accessible for removal. The SLNB procedure has been described in detail by de Barros et al [12]. For the current study, critical anatomic structures (bones, arteries, veins, and ureters) were segmented on preoperative CT images using 3D Slicer (www.slicer.org) [13] to create a 3D model of the patient's anatomy(Fig. 1). The anatomic substrate for SNs was segmented manually by delineating them on CT. If an SN was not visible on CT, a threshold that yielded a 1-cm diameter was applied on SPECT for delineation.

2.2.2. *Intraoperative procedure*

The navigation set-up used in this study was based on a previously published technique [7–10] and adapted for robot-assisted surgery [14]. For real-time tracking of the patient position, three reference electromagnetic patient sensors (Philips Nederland B.V., Eindhoven, The Netherlands) were taped to the patient's back, on the skin near the pelvic bones. The patient sensors were tracked using an Aurora EMT system (Northern Digital Inc., Waterloo, Canada). The surgical table was adapted with a carbon fibre multipurpose plate (118044AC; Getinge AB, Göteborg, Sweden), with an Aurora tabletop field generator mounted below. An intraoperative cone-beam CT (CBCT) scan was performed using a Ziehm Vision RFD 3D system (Ziehm Imaging, Orlando, FL, USA) with the patient in the Trendelenburg position (20° for the first 14 patients and 25° for the remaining; Fig. 1). This CBCT scan allowed patient registration via alignment of the anatomy with the preoperative 3D model using a bone-to-bone approach.

2.2.3. *Navigation*

For IGSN, software that was developed in-house (SurgNav version 4.20; NKI, Amsterdam, The Netherlands) was used. During surgery, an electromagnetically tracked robotic pointer (with an Aurora sensor with 6 degrees of freedom) developed in-house was used. The surgeon could move the pointer within the patient in real time and see its corresponding position on the preoperative 3D model. All surgical procedures were performed using a da Vinci Xi robot (Intuitive Surgical, Sunnyvale, CA, USA) with an integrated Firefly fluorescence laparoscope. The navigation view (3D model and CT scans) was integrated via the da Vinci TilePro function. Using the tracked pointer, the surgeon was able to check the accuracy of the navigation system by pointing at anatomic landmarks and verify the location of the pointer within the 3D model (Fig. 1). If needed, recalibration of the registration was performed. Thereafter, the surgeon used the navigation to localise the target SN. In cases with unilateral negative SPECT results, template-based ePLND was performed; otherwise, only SNs were resected. When SNs were located in a region prone to surgical complications, it was left to the surgeon's discretion as to whether to proceed with the SLNB procedure or to leave these SNs in situ.

2.3. *Statistical analysis*

The main study parameter was the percentage of SNs successfully removed under IGSN. Success was defined as an SN correctly localised via navigation and validated ex vivo using a gamma probe to confirm tracer uptake. Success was assessed at the SN level using a mixed logistic regression model to account for SN dependence within patients. Since SNs were nested within patients, success was determined using an intercept-only logistic mixed regression model to account for correlation within patients. A success rate of 75% was assumed to consider the technique feasible. For sufficient power (>75%) to reject success probability of 50%, 20 patients with at least three target SNs were required.

Secondary outcomes were the System Usability Scale (SUS), SN size (largest diameter), and procedure times. SN size was retrieved from the delineation data. Different time parameters were analysed: total surgery time (from incision to closure), navigation preparation time (CBCT acquisition and patient positioning), and time for localisation. IGSN accuracy was assessed in terms of the distance between the pointer tip and the surface of the delineated SN. The video feed of the da Vinci camera was recorded. Additional outcomes were 90-d surgical complications, documented according to the Clavien-Dindo classification [15], and

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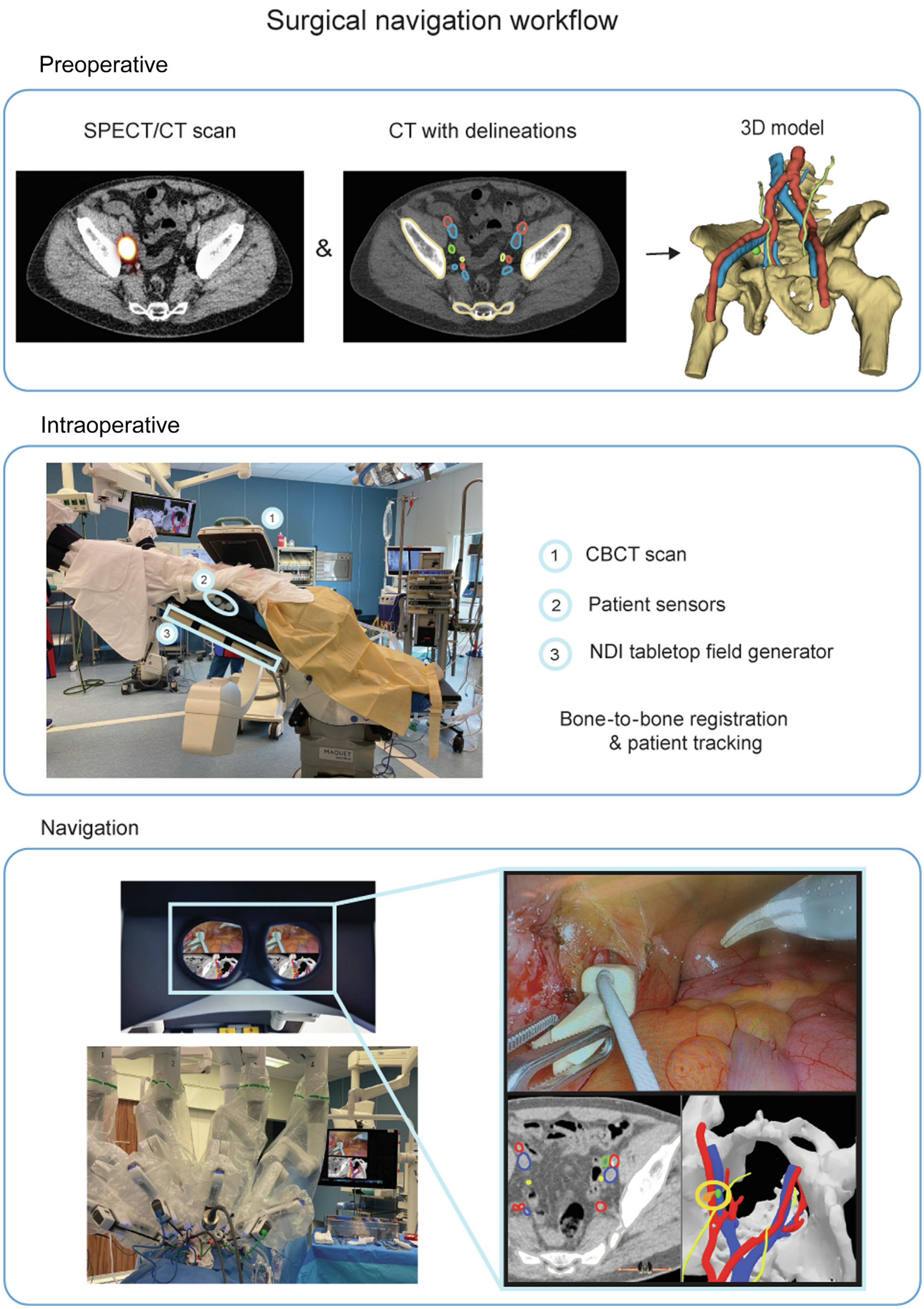

Fig. 1 – Workflow for surgical navigation using an electromagnetic system for real-time tracking of the patient and robotic pointer. Preoperative: relevant structures on CT are delineated with the sentinel nodes on SPECT to create a 3D model. Intraoperative: a CBCT scan is performed with the patient in the Trendelenburg surgical position. The electromagnetic tracking sensors placed before surgery are linked to the 3D model. This is done by registering the preoperative scan with the intraoperative scan. Navigation: an in vivo tracked electromagnetic pointer (orange ellipses) allows the surgeon to identify anatomic structures and target sentinel nodes in the 3D model, shown via the da Vinci TilePro feature. CT = computed tomography; SPECT = single-photon emission CT; 3D = three-dimensional; CBCT = cone-beam CT; NDI = Northern Digital Inc.

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prostate-specific antigen (PSA) levels, which were evaluated every 4 mo during the first 12 mo after radiotherapy. Biochemical recurrence (BCR) was defined as a PSA nadir plus 2 ng/ml, in accordance with the Phoenix definition.

After surgery, surgeons completed a questionnaire assessing the navigation system that comprised general questions about the navigation technique; evaluation of usability using SUS scores, and a comparison with the conventional approach. An SUS score ≥70 indicates above-average acceptance [16]. Comparison with the conventional approach was based on effectiveness, efficiency, and decisiveness items quantified on a 5-point Likert scale, with ≥3 points indicating added value in comparison to conventional techniques.

The Shapiro-Wilk test was applied to determine whether data were normally distributed. For normally distributed data ($p < 0.05$), results are reported as the mean and standard deviation (± SD); otherwise, the median and interquartile range (IQR) are reported.

3. Results

3.1. Patient and SN characteristics

In total, 25 male patients were included in the study. As predefined in the research protocol, the first five patients were used to optimise the new navigation set-up, and the next 20 for analysis. Twenty patients with a mean age of 65 ± 7 yr at surgery were analysed (Table 1). Before SLNB, four patients underwent an abdominopelvic procedure unrelated to PCa; no patient received radiotherapy related to PCa. Final treatment details for the patients after surgery are listed in Supplementary Table 1.

Of the 20 patients, one was excluded as the procedure was interrupted because the 20° Trendelenburg angle during CBCT acquisition was insufficient to complete the surgery. The Trendelenburg angle was modified to 30° and the procedure continued without navigation. For five patients (25%), unilateral visualisation was achieved on SPECT imaging; in these cases, ePLND was performed on the nonvisualised side. This resulted in 19 evaluable patients and a total of 64 SNs. Of these, nine SNs were intentionally not removed as they were not considered target nodes by the surgeon before the start of surgery because of an inaccessible anatomic location (five presacral, two mesorectal, and two pararectal LNs). Thus, navigation was performed for 55 SNs (Fig. 2).

3.2. Surgical navigation and outcome

IGSN was feasible for 50/55 SNs (91%; Fig. 3); five were considered failures. Three of the failures (5%) were related to technical issues because of operator error (wrong pointer calibration). In the other two cases (4%), the LNs removed after navigation identification were not radioactive. In these cases, the procedure continued without navigation and the SNs were located visually using the fluorescent camera and removed by the surgeon. No complications related to navigation occurred. Different positioning during the SPECT/CT and CBCT scans did not lead to any significant change in anatomic structures and landmarks. Overall, no patients (0%) experienced BCR within 1 yr after radiotherapy.

Some 85.4% of the SNs were identified via SPECT and delineated on CT, while 14.6% were delineated using a SPECT threshold. The median delineated SN size on CT imaging was 1.0 cm (IQR 0.9–1.2). Pathology results for the target SNs showed that 12.7% (seven of 55) were metastatic, all of which were successfully removed under navigation. The median localisation accuracy with the pointer was 0.4 cm (IQR 0.0–0.7). SNs were located around the iliac arteries and veins (external iliac, 25 SNs; internal iliac, ten SNs; common iliac, three SNs; obturator, 13 SNs; presacral, three SNs; and pararectal, one SN), as shown in Fig. 4.

The median total surgery time was 85 min (IQR 76–97) and the median navigation preparation time was 8 min (IQR 7–10). The median time for SN localisation via navigation was 6 min (IQR 3–9). Calibration refinement of the navigation set-up was required in nine of 19 procedures.

3.3. Surgeon satisfaction score and usability

In total, five different surgeons performed 20 surgeries with IGSN. In 18 cases the survey was completed (one patient was excluded and the form was not completed for another patient). Regarding general questions about the navigation technique, surgeons indicated that the navigation was of added value (78%) and helped with decisiveness (78%) and SN localisation (89%; Fig. 5). In these cases, real-time visualisation of the 3D model and CT scan was a great addition. The preoperative CBCT for navigation required additional time, but 78% of the surgeons reported that the value provided by the technology was worth this extra time. The median SUS score for the navigation technique was 60.9 (IQR 57.5–65). The lowest scores were reported for the user interface and usability, especially intuitiveness, visualisation, and workflow integration. The mean Likert score for IGSN in comparison to the traditional approach was 3.0 ± 0.3, indicating added value for IGSN.

4. Discussion

The aim of our study was to investigate the feasibility of IGSN with EMT during minimally invasive robot-assisted

Table 1 – Characteristics of the 20 patients who underwent sentinel lymph node biopsy

Variable	Result
Mean age at surgery, yr (SD)	65 (7)
Mean body mass index, kg/m^2 (SD)	25 (2)
Previous abdominal surgery, *n* (%)	4 (20)
Clinical stage, *n* (%)	
cT1	4 (20)
cT2	7 (35)
cT3	9 (45)
Biopsy Gleason sum score, *n* (%)	
7	13 (65)
9	5 (25)
10	2 (10)
Mean prostate volume, ml (SD)	35 (13)
Mean Briganti 2012 risk of LNM (SD)	35.3% (25.2%)
Unilateral visualization on SPECT, *n* (%)	5 (25)
Median initial PSA, ng/ml (IQR)	11.0 (7.4-17.0)

LNM = lymph node metastasis; PSA = prostate-specific antigen; SD = standard deviation; SPECT = single-photon emission computed tomography.

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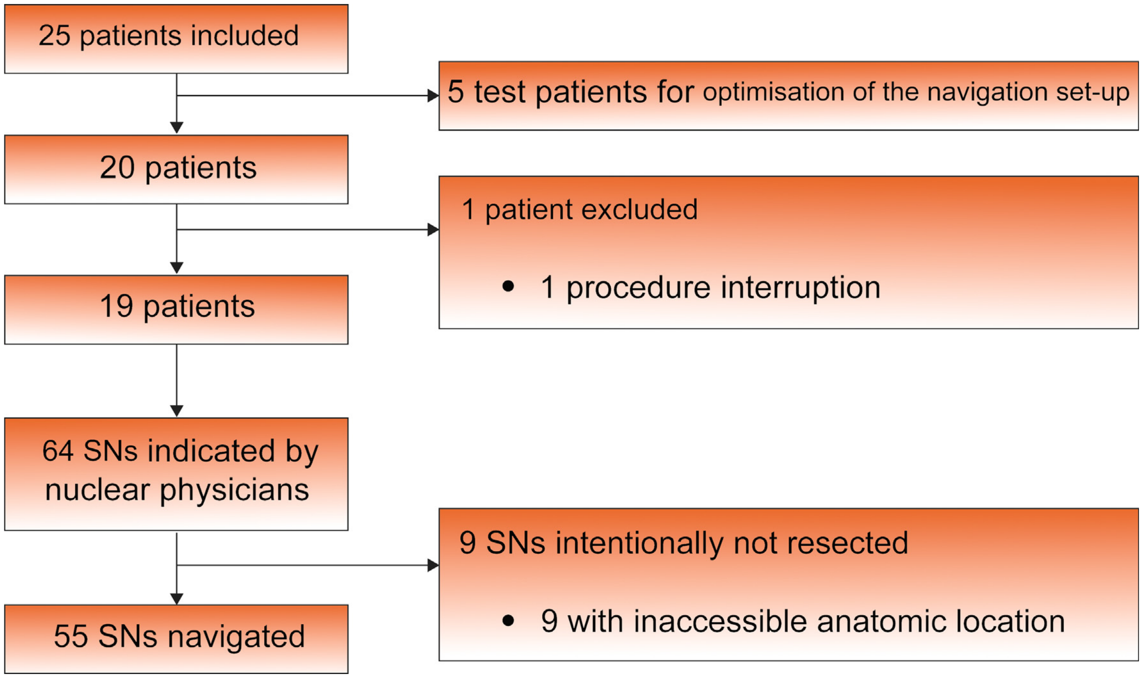

Fig. 2 – Patient inclusion flowchart for sentinel lymph node biopsy using electromagnetic tracking and image-guided navigation. SNs = sentinel nodes.

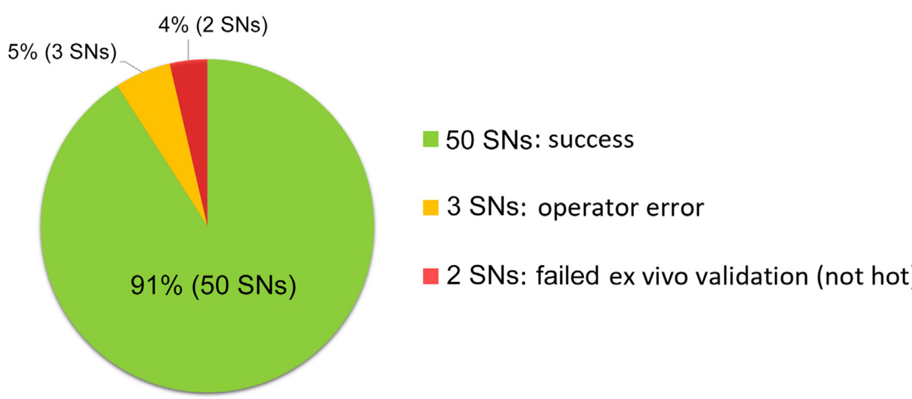

Fig. 3 – Feasibility results for sentinel node (SN)-based analysis.

abdominopelvic surgery. SN surgery was chosen for validation of this new minimally invasive surgical navigation as it requires localisation of small LNs at different anatomic locations within the pelvis. Our results show that IGSN was feasible, with 50 of 55 small LNs (91%) successfully located within the pelvis using this system.

IGSN was safe, with no navigation-related complications observed. Surgeons preferred using IGSN in comparison to the conventional strategy, and stated that the technology improved decisiveness during the procedure. In addition, the 3D model and the dynamic CT visualisation were a great aid for orientation throughout the surgical procedure. When SNs were located in challenging anatomic locations such as the presacral and obturator areas, navigation made it easier to determine the extraction path. SNs were localised at a median distance of 0.4 cm, which demonstrates the IGSN accuracy. Surgeons considered that IGSN was of additional help for SN localisation when the distance between pointer and the SN was <1.0 cm.

Our results show that IGSN with EMT is feasible for robot-assisted SLNB. This evidence paves the way for IGSN integration in other robot-assisted urological procedures, such as (salvage) node dissection for prostate-specific antigen membrane–positive LNs, partial nephrectomy, and retroperitoneal LN dissection in testicular cancer. Use of this technique in different oncological fields, such as gynaecological and gastrointestinal cases, may also result in significant surgical benefits.

Previous clinical studies have successfully validated the use of IGSN with EMT for open surgical procedures [7–10]. IGSN with EMT for tracking of nonrigid targets during robotic experiments has been investigated in bronchoscopy [17] and nephrolithotomy [18]. Phantom studies have demonstrated the potential of the da Vinci Xi configured

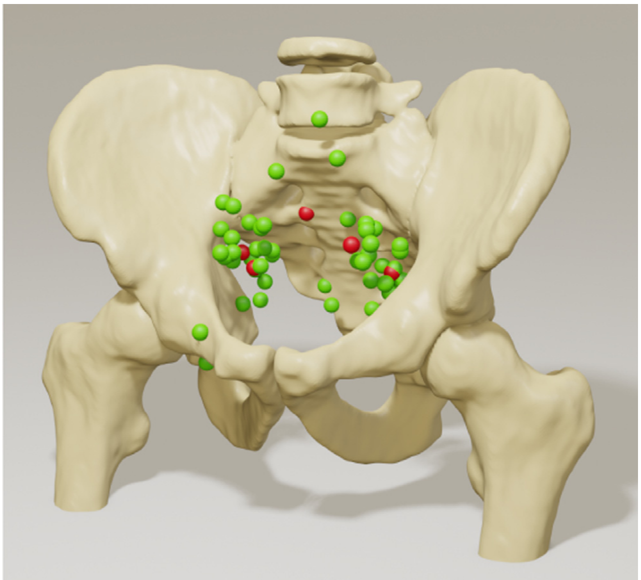

Fig. 4 – Distribution of sentinel nodes navigated according to successful removal (green) and failure (red). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

with EMT for IGSN in robot-assisted abdominopelvic surgeries [14]. However, there is no literature covering broader clinical studies. Optical tracking is another technique that has been used for clinical robot-assisted IGSN in patient case studies [19]. The advantage of optical tracking over EMT is the absence of potential distortions induced by ferromagnetic materials present during surgery. However, optical tracking requires a constant line of sight between the camera and the trackers, which is often obstructed during surgical procedures. An alternative approach is use of kinematics information regarding the position of the robot arms. This could solve the problem of instrument tracking; however, patient tracking would remain an issue. Phantom studies have shown high accuracy when tracking a single arm [20,21], but no patient study has been published to date. Fluorescence is currently used for SLNB in our hospital for visual localisation of the targets in vivo [5]. However, fluorescence is only visible in close proximity to the SNs, which can sometimes pose challenges when locating SNs. IGSN and navigation visualisation techniques, especially when integrated in urology, can enhance surgical procedures [22]. These visual extended reality tools involve virtual reality, mixed reality, and augmented reality.

The main strength of our study is that it is the first clinical feasibility trial to validate EMT in surgery performed using a da Vinci robot. The 3D model used for navigation was delineated on a low-dose CT scan 1 h before surgery. Despite the time-sensitive nature, the delineation results were accurate for navigation, which is crucial for effective surgical guidance [23]. The high success rate (91%) for SN localisation demonstrates the robustness of our IGSN.

While we achieved a high success rate, five SNs (9%) were not localised using IGSN. In three cases, this was because of an operator error (wrong robotic pointer calibration), which can be fixed by improving the workflow. The other two failures may have been caused by tissue manipulation by the surgeon. Our navigation set-up is best suited for targets that are semirigidly attached to the surrounding vasculature and/or bone, as in SLNB. However, dissection of the extraction path towards the target results in displacement of tissue. This could induce movement of the SN with respect to preoperative imaging. Preoperative training is essential for favourable outcomes. Although surgeons were familiar with IGSN and were specifically trained, their experience could have impacted the usability results. In comparison to results in our previous study (SUS score 75) [9], the SUS score of 60.9 was lower for the present study. This is mainly because of the additional set-up time (8 min) and the user interface, which need to be improved for integration with da Vinci robots and clinical translation. Furthermore, this was a single-centre feasibility study with a limited patient cohort. Multicentre validation with a larger sample size and an improved IGSN set-up are required for broader applicability. Our group has reported on the additional costs of navigation per procedure have in rectal cancer [24]. However, calculation of a fixed cost for this particular setting is challenging because it mainly depends on the level of usage of the navigation system.

Finally, it should be noted that the diagnostic value of SLNB in comparison to ePLND was not the aim of our study.

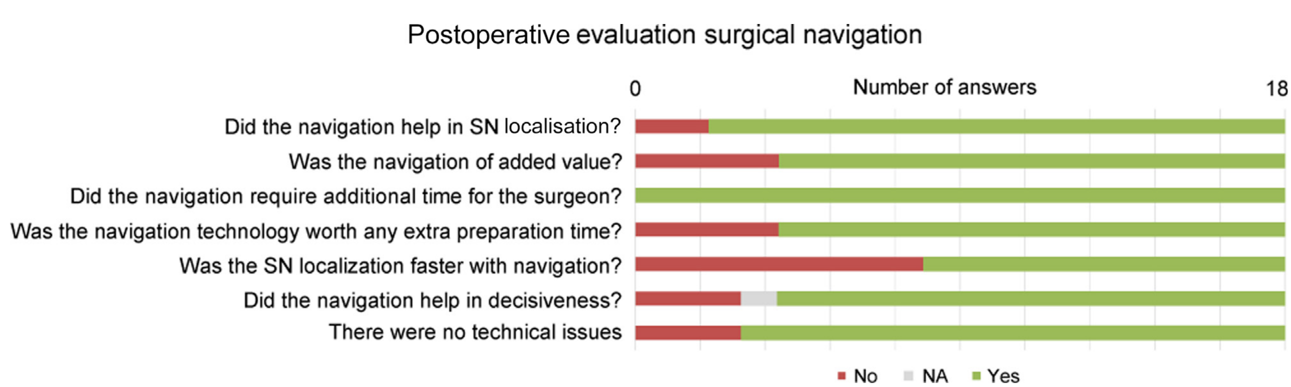

Fig. 5 – Results for the questionnaire on the use and application of surgical navigation. Eighteen questionnaires were completed by five individual surgeons. NA = not answered.

We agree that ePLND is the gold standard for detection of LN metastases in PCa. Nevertheless, previous studies have shown that SLNB has high diagnostic accuracy in detecting positive LNs in PCa [11]. In addition, image-guided surgical strategies can help in visualising individual lymphatic drainage patterns and SNs in PCa patients [5].

In future work, we aim to simplify the registration method. We will transition from the current CBCT, which requires specific personnel and logistics, to ultrasound registration; this involves scanning the pelvic bone on the surgical table, which is aligned to the preoperative model [25]. We will also improve the workflow for model generation by enhancing the preoperative image quality and further standardising the model creation process. We will enhance the visualisation by showing anatomic models with the 3D view functionality of TilePro and will replace the robotic pointer with tracked instruments. We expect that these improvements will considerably enhance the IGSN usability and workflow and should help in its implementation in robotic surgery.

5. Conclusions

Our study demonstrates that integration of IGSN with EMT during robot-assisted SLNB is feasible. Navigation helps in reaching target SNs in a safe and effective way, leading to a feasible technique for locating target SNs and visualising the anatomy in robotic surgery.

Author contributions: Laura Aguilera Saiz had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Aguilera Saiz, Heerink, Groen, van Leeuwen, van der Poel, Ruers.
Acquisition of data: Aguilera Saiz, Heerink, Groen, Hiep, van Leeuwen, van der Poel, Wit, Roeleveld, Nieuwenhuijzen.
Analysis and interpretation of data: Aguilera Saiz, Heerink, Groen, Hiep, van Leeuwen, van der Poel.
Drafting of the manuscript: Aguilera Saiz, Heerink, Groen, van Leeuwen, Ruers.
Critical revision of the manuscript for important intellectual content: Aguilera Saiz, Heerink, Groen, Hiep, van Leeuwen, van der Poel, Wit, Roeleveld, Nieuwenhuijzen, Donswijk, Vis, Ruers.
Statistical analysis: Aguilera Saiz.
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Supervision: Heerink, Groen, van Leeuwen, van der Poel, Ruers.
Other: None.

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Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.eururo.2024.07.022.

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