Original Article

Interest of a hand-held gamma camera (TReCam) in breast SNOLL procedure

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Background: Sentinel node and occult lesion localization (SNOLL) in breast cancer surgery is a safe procedure for detection of sentinel lymph node (SLN) and radio-guided occult lesion localization (ROLL). We evaluated a hand-held gamma camera (TReCam) in this procedure.

Methods: This study was prospective, randomized, non-comparative during SNOLL breast procedure with 2 arms: one without TReCam (group 1) and the other with TReCam (group 2). In both groups, the rate of surgical resumption, histologic characteristics of the lumpectomy specimen and cosmetic results were collected. In group 2, concordance between standard lymphoscintigraphy (LS) and TReCam images and the operators' feelings about the use of the camera were collected during the procedure.

Results: Forty-seven patients were enrolled: 25 patients in group 1 and 22 patients in group 2. The excision rate with satisfactory margins was 92% in the group 1 and 86% in the group 2. The average duration of the SNOLL surgery in group 1 was 73.5 minutes (extremes: 40–130) and 71.2 minutes (extremes: 45–127) in group 2. The cosmetic results were excellent or good in 98% of cases. The duration of pre-operative use of TReCam averaged 7.3 minutes (extremes: 1–15). Overall, handling TReCam was very easy or easy in 72% of procedures. TReCam was able to detect at least as many SLN as LS. During surgery, the use of the gamma camera was very easy in 86.4% of cases.

Conclusions: TReCam is an interesting tool in SNOLL procedure for breast cancer. Its use is easy and is not time consuming.

Keywords: Intraoperative portable gamma camera; breast cancer; sentinel node biopsy; radio-guided surgery; radio-occult lesion localization

Received: 28 December 2019. Accepted: 09 May 2020; Published: 30 June 2020.

doi: 10.21037/abs-19-108

View this article at: http://dx.doi.org/10.21037/abs-19-108

Introduction

Non-palpable breast cancers are extremely frequent at the diagnosis time and represent around 25% to 35% of breast cancers (1). Main difficulty of surgery for non-palpable breast cancers is the intraoperative access to the precise location and limits of the cancer. The complete excision with sufficient carcinologic margins while respecting as much as possible the healthy breast tissue is one of the goals. Inadequate margins are one of the main factors of local recurrence (2). The radio-guided occult lesion localization (ROLL) consists in injecting radiolabelled nanoparticles directly into the non-palpable tumor under mammographic or ultrasound control. This technique is considered to be one of the techniques of choice for the identification of non-palpable lesions for surgery (3). When the ROLL procedure is associated with a sentinel node procedure (SNP), it is called sentinel node occult lesion localization (SNOLL). As well as other surgical isotopic methods, ROLL and SNOLL procedures are subject to logistical constraints with most often a quality control by scintigraphy and/or SPECT-CT.

Thanks to technological advances, portable gamma cameras are developed. They remain seldom used and must be evaluated in various radio-controlled surgical procedures. One of them, called TReCam (Tumor Resection Camera), was developed by the IMNC laboratory (4). It was evaluated previously in the SNOLL procedure in a non-interventional study (5). In order to proceed with its assessment, we conducted an interventional study with this portable gamma camera in the SNOLL procedure. We present the following article in accordance with the CONSORT reporting checklist (available at http://dx.doi.org/10.21037/abs-19-108).

Methods

This study was prospective, randomized, non-comparative with 2 arms, one without TReCam (group 1) and the other with TReCam (group 2). All included patients came from two different hospitals and were over 18 years of age and required SNOLL procedure for subclinical invasive breast cancer (ultrasound target). Randomization was performed after obtaining the patient's written consent.

The mini gamma-camera TReCam has a square field of view of 5×5 cm^2 (25 cm^2), and its detection head consists of a parallel hole collimator, a continuous LaBr scintillator, a pixelated photomultiplier and multi-channel electronics, allowing the dynamic formation of the nuclear image during the examination. Its measured sensitivity at 140 keV is 300 cps/MBq, its spatial resolution 2 mm in contact and its energy resolution 11%. During the quick image formation, the user simply lays the camera directly in contact of the patient's skin or in a sterile housing when needed. *Figure 1A* shows the whole device: camera, case containing electronics and lap top. Below one can see the kind of images obtained by TReCam in a few seconds: the left image shows the two injection sites, and on the right one can see a SLN (*Figure 1B*). *Figure 2* shows TReCam in a sterile housing during surgery.

In both groups, the day before surgery, two injections of nanocolloids coupled to ^{99m}Tc (30 MBq for each) were performed. The first injection was at the superficial pole of the lesion, the second was injected at its deep pole. Standard lymphoscintigraphy (LS) images were acquired 10 minutes and 2 hours after injection. The LS made it possible to locate and count the radioactive sentinel lymph nodes (SLN). The good quality of the injection for surgery was also checked. In group 2, in addition to LS, breast and axillary area explorations were performed with TReCam the day before surgery and just before anaesthesia induction in a chirurgical position.

In both groups, after the induction of general anaesthesia, a subdermal injection of patent blue was performed in the periareolar region. This was followed by a massage of the injection site, then the skin incision of the armpit began 10 minutes later.

Under general anaesthesia, the surgeon performed the removal of SLN before the removal of the breast tumor. Radioactive SLN were identified in the axillary area after an elective cutaneous incision using the single-pixel probe. All radioactive and/or bluish SLN were collected. At the end of SNP and before skin closure, the TReCam imager was used in group 2 in addition to the single-pixel probe to verify that all radioactive lymph nodes had been removed.

In both groups, when the SNP was completed, the single-pixel probe was used to identify the lumpectomy site before the incision. In group 2, an additional breast exploration was performed before lumpectomy by the gamma portable imager. The skin incision was made according to the usual carcinologic and cosmetic constraints. Lumpectomy was performed from the subcutaneous superficial plane to the pre-pectoral deep plane. Once the excision was performed, the surgeon ensured that there was no residual radioactivity in the bed of the lumpectomy using the single-pixel probe. In group 2, during this exploration, TReCam was used in

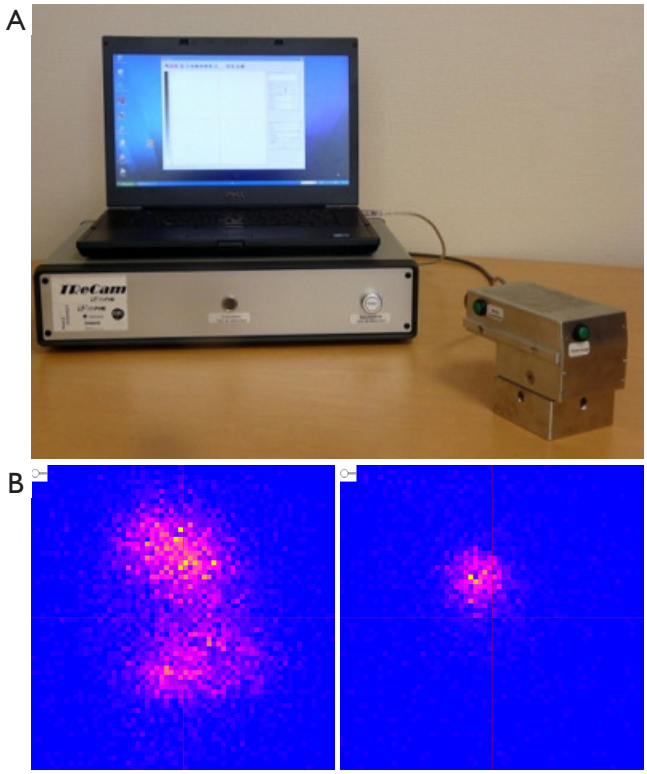

Figure 1 The mini gamma-camera TReCam. (A) The whole device: camera, case containing electronics and lap top. (B) Typical images obtained by TReCam in a few seconds: the left image shows the two injection sites, and on the right one can see a SLN.

addition to the single-pixel probe.

The SNP was followed by axillary lymphadenectomy at the same time if no SLN were found. Axillary lymphadenectomy can be carried out secondarily according to the definitive histological results.

In group 2, the evaluation of data acquisition difficulties and imaging results obtained by the TReCam imager were reported at the end of each intervention.

In both groups, imaging (radiological or ultrasound) and an extemporaneous examination of the lumpectomy specimen were performed. Additional cavity shavings were performed at the surgeon's discretion in both groups.

The size of the tumor and the volume of the lumpectomy specimen were collected. The ratio of lumpectomy specimen volume to tumor volume was calculated. The lumpectomy margins and the cosmetic result were mentioned. The indication for surgical resumption was defined for insufficient margins (<3 mm), positive SLN requiring resumption. In group 2, concordance between LS and TReCam images and the operators' feelings about the use of the camera were collected at the various stages of the procedure.

Figure 2 TReCam in a sterile housing during surgery.

All research was performed in accordance with relevant guidelines and regulations and in accordance with the 1964 Helsinki declaration. This experimental protocol was approved by the Comité de Protection des Personnes de l'Ile de France X, Hôpital ROBERT BALLANGER, Boulevard Robert Ballanger Bât. Central n° 8-3ème étage, 93602-AULNAY-SOUS-BOIS, cpp.iledefrance10@ch-aulnay.fr, under the number 2013-A00856-39. Informed consent was obtained from all participants. This study is declared on US National Library of Medicine (https://clinicaltrials.gov/ct2/show/NCT02101320).

Results

Characteristics of the population

Forty-seven patients participated and were randomized into two groups: 25 patients in group 1: SNOLL procedure without TReCam and 22 patients in group 2: SNOLL procedure with TReCam. The average age of all patients was 64.9 years (extremes: 44–83) with an average body

Table 1 Characteristics of the population

Characteristics	Group 1: SNOLL without TReCam	Group 2: SNOLL with TReCam	Total
Number of patients	25	22	47
Age (years)			
Mean ± statistics gap (min; max)	65.7±10.0 (45; 82)	63.9±10.0 (44; 83)	64.9±9.9 (44; 83)
BMI (kg/m^2)			
Mean ± statistics gap (min; max)	26.0±3.8 (18; 34)	28.7±5.5 (22;41)	27.3±4.8 (18;41)
Histologic type, n (%)			
Ductual carcinoma	25 (100.0)	16 (72.7)	41 (87.2)
Lobular carcinoma	0 (0.0)	3 (13.63)	3 (6.38)
Mucinous carcinoma	0 (0.0)	2 (9.1)	2 (4.25)
Micro papillary carcinoma	0 (0.0)	1 (4.55)	1 (2.14)
Ultrasound tumoral size			
Mean ± statistics gap (min; max)	8.7±3.9 (3; 20)	9.8±3.0 (6; 16)	9.2±3.5 (3; 20)
Dose of Tc99m (MBq)			
Mean ± statistics gap (min; max)	65.2±14.5 (30; 120)	64.2±5.4 (54; 74)	64.7±11.1 (30, 120)

mass index (BMI) of 27.3 (extremes: 18–41). The mean preoperative cancer size for group 1 was 8.7 mm (extremes: 3–20) and 9.8 mm (extremes: 6–16) for group 2. On average, 0.9±0.7 SLN was displayed (1±0.7 in group 1 and 0.8±0.6 in group 2). The histological characteristics, ultrasound characteristics and ^{99m}Tc injection doses are shown in *Table 1*.

During preoperative LS, an average of 0.9 radioactive axillary SLN was detected per patient (extremes: 0–2). The double detection allowed the removal of an average of 1.8 SLN per patient (extremes: 0–5) in group 1 and an average of 2.1 per patient (extremes: 0–8) in group 2. The SLN procedure failed despite the double detection in 6 patients, 3 in each group.

Surgical resumption rate

The excision rate with satisfactory margins was 92% in the group 1 and 86% in the group 2. In group 1, 2 surgical resumptions were carried out. One for inadequate lumpectomy margins without a residual lesion found and the other also required a mastectomy for a multifocal lesion. In group 2, 3 surgical resumptions were necessary, including 2 mastectomies (multifocal lesion or lesion greater than 4 cm and not in sano). By taking into account the confidence intervals the surgical resumption rate is less than 26% and 35% respectively in group 1 and group 2. A total of 7 SLN had tumor involvement: 5 micrometastasis (lymph node involvement between 0.2 and 2 mm) and 2 metastasis (greater than 2 mm). In view of the recommendations and discussions at the multidisciplinary consultation meeting, none of the patients in the study had to have a new operation for an isolated axillary cleaning.

Evaluation of the SNOLL procedure

The average duration of the SNOLL procedure in group 1 was 73.5 minutes (extremes: 40–130) and 71.2 minutes (extremes: 45–127) in group 2. All data evaluating lumpectomy in the SNOLL procedure are shown in *Table 2*. The mean size of the tumor lesion was 12.0 mm (extremes: 6–30) for group 1 and 16.2 mm (extremes: 7–36) for group 2. The ratio of the volume of the lumpectomy to the volume of the lesion was 186.3 (extremes: 2–1,173) in group 1 and 79.6 (extremes 2–305) in group 2. The cosmetic results were considered excellent or good in 98% of cases. Seven patients had complications (an abscess, 3 lymphoceles, 1 anaphylactic reaction to the injection of the blue diagnosed in the recovery room and 2 minimal skin burns).

Evaluation of the TReCam gamma camera in the SNOLL procedure

The pre-operative use duration of TReCam averaged 7.3 minutes (extremes: 1–15). Overall, handling TReCam was

Table 2 Characteristics and results of the lumpectomy during the SNOLL procedure in both groups

Characteristics	Group 1: SNOLL without TReCam	Group 2: SNOLL with TReCam
Surgery duration (mn)		
Mean ± statistics gap (min; max)	73.5±28.2 (40; 130)	71.2±20.5 (45; 127)
Histologic results		
Weight of lumpectomy specimen (g)		
Mean ± statistics gap (min; max)	45.5±38.5 (17; 217)	37.5±14.1 (14; 65)
Histologic tumor size (mm)		
Mean ± statistics gap (min; max)	12.0±5.6 (6; 30)	16.2±7.5 (7; 36)
Breast excision volume (lumpectomy + cavity shaving)/tumoral volume		
Mean ± statistics gap (min; max)	186.3±284.2 (2; 1,173)	79.6±82.5 (2; 305)
Number of removed sentinel nodes		
Mean ± statistics gap (min; max)	1.8±1.5 (0; 5)	2.1±1.8 (0; 8)
Cosmetic results, n (%)		
EXCELLENT (the treated breast is almost identical to the untreated breast)	9 (36.0%)	10 (45.4%)
GOOD (minor difference between treated and untreated breast)	15 (60.0%)	12 (54.6%)
PASSABLE (obvious difference between treated and untreated breast)	1 (4.0%)	0 (0.0%)

considered very easy for 13 patients (59.1%), easy for 3 patients (13.6%) and difficult for 6 patients (27.3%). The difficulties mainly concern the detection of SLN. Indeed, the identification of the injection site with identification of the excision area was considered easy with an excellent topographic concordance between ultrasound data and TReCam data with good image quality in 100% of cases. On the other hand, the quality of the images obtained when locating SLN in preoperative with TReCam was considered good for 15 patients (68.2%), average for 5 patients (22.7%) and poor for 2 patients (9.1%) (*Table 3*). Seventeen SLN were seen in LS, i.e., an average of 0.8 SLN per patient (extremes: 0–2), 18 SLN were seen in preoperative with TReCam, i.e., an average of 0.8 SLN per patient (extremes: 0–3). It should be noted that it is possible to detect up to 3 different SLN in the same patient with TReCam. In the preoperative period, the agreement between the LS and TReCam was observed in 14/22 cases. TReCam counted more preoperative SLN than LS in 4/22 cases and less SLN in 4/22 cases. All the additional SLN seen preoperatively by TReCam compared to the LS were indeed found intraoperatively (*Table 4*).

The overall evaluation of the use of gamma camera during the SNOLL surgery was considered to be very easy in 19 cases (86.4%), difficult in 2 cases (9.1%) and impossible in 1 case (4.6%). This latter case corresponded to a failure of the camera on the day of the operation that required some repair and did not allow its use during surgery. The identification and concordance rate between the data obtained by TReCam during surgery and those available in preoperative ultrasound was 100% for the lumpectomy site. The use of TReCam during surgery detected in 5 patients the persistence of a radioactive signal in the tumor bed with 3 cases of re-excision. In 2 cases, the operator performed 4 systematic cavity shavings, one of which concerned the residual radioactive site. In one case, the operator performed a single cross-check guided by the residual signal detected by TReCam and the monopixel probe. In this case, there was a correlation between the persistence of residual radioactivity in the tumor bed and the extemporaneous examination. In the other 2 cases, the residual radioactivity corresponded to the diffusion of a subcutaneous part of the radioisotope at the time of injection and no additional excision was performed. In 10 cases (47.6%) the use of TReCam helped the surgeon during the lumpectomy procedure. The duration of the

Table 3 Evaluation of TReCam the day before surgery

Using TReCam in pre-operative care	Values
Correlation of injection site and location with TReCam, n (%)	
Matching ultrasound detection/radioactive site detected with TReCam	22 (100.0)
TReCam images quality for detecting the tumor site, n (%)	
Good	22 (100.0)
TReCam image quality for identification of SLN images, n (%)	
Good	15 (68.2)
Medium	5 (22.7)
Poor	2 (9.1)
Handling TReCam, n (%)	
Very easy	13 (59.1)
Easy	3 (13.6)
Difficult	6 (27.3)
Duration of use of TReCam for global preoperative acquisition (minutes)	
Mean ± statistics gap (min; max)	7.3±4.0 (1; 15)

Table 4 Comparison of the different modes of SLN detection

Comparison items	LS	TReCam (the day before surgery)	TReCam (during surgery)	Monopixel probe
Number of radioactive detected SLN	17	18	17	33
Mean ± statistics gap (min; max)	0.8±0.6 (0; 2)	0.8±0.9 (0; 3)	0.7±0.8 (0; 2)	1.5±1.4 (0; 5)
Matching between LS/TReCam for number of detected SLN the day before surgery	Same: 14/22 (63.6%)	Less detection with TReCam: 4/22 (18.2%)	More detection with TReCam: 4/22 (18.2%)	
Matching between LS/TReCam for number of detected SLN during surgery	Same: 13/22 (59.1%)	Less detection with TReCam: 5/22 (22.7%)	More detection with TReCam: 4/22 (18.2%)	
Matching between TReCam before and during surgery for number of detected SLN	Same: 15/22 (68.2%)	Less detection during surgery: 3/22 (13.6%)	More detection during surgery: 4/22 (18.5%)	
Matching between monopixel probe/TReCam for number of detected SLN during surgery	Same: 14/22 (63.6%)	Less detection with TReCam: 8/22 (36.4%)	In 2 cases TReCam detected SLN not initially seen by the monopixel probe	

use of TReCam for lumpectomy was estimated to 1.0 min (extremes: 1–2) (*Table 5*). During the SLN procedure, 17 SLN were seen intraoperatively by TReCam. On average, TReCam during surgery identified 0.7 SLN (extremes: 0–2). For one procedure, no SLN was visualized due to an imager failure. The single-pixel probe in perioperative mode allowed the identification of 33 radioactive SLN, which corresponds to an average of 1.5 SLN per patient (extremes: 0–5). The agreement between the number of SLN visualized with TReCam the day before and the day of the intervention was 15/22. In 3 cases, fewer SLN were visualized on the day of the intervention and in 4 cases, more SLN were visualized on the day of the intervention. The agreement between TReCam intraoperatively and the single-pixel probe was 14/22. In 2 cases, TReCam visualized two SLN not initially detected by the single-pixel probe that were found to be blue and low in radioactivity (*Table 4*). The manipulation of TReCam during surgery

Table 5 Use of TReCam during the SNOLL surgery

Use of TReCam during lumpectomy	Values
Matching ultrasound detection/radioactive site detected with TReCam	21 (100.00%)
Duration of acquisition of TReCam images for detecting the tumor site	
Mean ± statistics gap (min; max)	1.0±0.2 (1; 2)
Discovery of residual radioactivity after lumpectomy with TReCam	
Yes	5 (23.8%)
Complementary excision after use of TReCam	
Yes	3 (13.6%)
Did TReCam provide any assistance in performing the lumpectomy?	
Yes	10 (47.6%)
Handling TReCam for SLN surgical procedure	
Easy	13 (59.1%)
Difficult	5 (22.7%)
Impossible	4 (18.2%)
Duration of use of TReCam for the surgical SLN procedure (minutes)	
Mean ± Gap statistic (min; max)	3.5±2.9 (1; 10)
Did TReCam provide any assistance in performing the SLN procedure?	
Yes	4 (18.2%)
Overall difficulty in acquiring data with TReCam during the SNOLL procedure, n (%)	
Easy	19 (86.3%)
Difficult	2 (9.1%)
Impossible	1 (4.6%)

was considered easy in 13 cases (59.1%), difficult in 5 cases (22.7%) and impossible in 4 cases (18.2%). It should be noted that among these 4 latter cases, one corresponded to the imager failure and another case corresponded to a procedure without detection of radioactive SLN. In this latter case, the operator considered it impossible to use TReCam in the absence of SLN detection, which is in fact in accordance with the results of the surgical procedure. The duration of use of the TReCam camera during the SNP was estimated at an average of 3.5 minutes (extremes: 1–10). The longest acquisition times correspond to cases where SLN identification was impossible.

Discussion

There are few published data on the use of a portable gamma camera in the SNOLL procedure for breast cancer (5,6). This work follows the feasibility study on the use of TReCam in the SNOLL procedure (5).

The use of TReCam the day before the intervention, lasted on average few minutes with ease of use in almost 60% of cases. Identification of the lumpectomy site was easy and reliable with TReCam. The image provided by TReCam are unambiguously and confirm the absence of any other radioactive breast site that could have resulted from a misidentification (e.g., skin contamination). Lack of knowledge of this type of incident could affect the surgical procedure. TReCam find as many SLN as LS in 81.8% of patients. The non-inferiority of this type of imager compared to the LS has been demonstrated with another camera called POCI (7). The duration of use of TReCam is shorter than that required for the realization of LS and allows to obtain information that seems equally relevant. These cameras appear to be an alternative to LS. Actually,

SPECT-CT could be performed instead of LS but its accessibility remains limited. Nevertheless, next studies will have to compare the performance of portable gamma cameras with SPECT-CT.

During surgery, using TReCam does not seem to increase the operating time. Its use lasts about 5 minutes and is considered very easy in more than 86% of cases. During lumpectomy, the rapid ultimate exploration with TReCam before incision is quick and allow to determine the location and size of the injection site. Its contribution to this operating time for lumpectomy is considered useful in around 50% of cases by operators with visual comfort. These imagers allow a control of the quality of the lumpectomy by ensuring that the radioactive signal of the specimen corresponds to the one visualized in the preoperative. During the lumpectomy surgery, there is a complementarity between the monopixel probe and portable imagers. The highly directional nature of the monopixel probe can lead to a failure to detect a small and low activity radioactive residue. TReCam provides simple control over the quality of the lumpectomy surgery. TReCam can guide the use of the monopixel probe for exploring the lumpectomy bed and increase its detection performance. The use of TReCam for lumpectomy was easy and fast, both to locate injection sites and to explore the tumor bed after removal. Paredes *et al.* point out that dual quality control of the removal quality of the radioactive signal with their gamma camera and the single-pixel probe is interesting when extemporaneous examination is not possible (8).

The interest of our camera use for evaluation of the quality margin is limited by our study design. It does not allow us to take a position on the impact of the use of TReCam on the rate of reoperation for inadequate margins. The size of this study is insufficient and all patients have had an extemporaneous histologic examination and per imaging (X-ray or ultrasound) of the lumpectomy specimen. However, in another published study on the SNOLL procedure with use of a hand-held camera like TReCam, 12% of patients required a second operation for close or tumor positive surgical margins (6). In our study, most patients who were re-operated, presented at final histologic results multifocality or extended lesions. In these cases, radical treatment was the right treatment. There was in fact no place for SNOLL procedure. We also found an underestimation of the size of cancers in ultrasound compared to the histological size.

The value of using portable gamma cameras during breast SNP have been already studied (9). The camera provides visual information and quality control at the end of the procedure to ensure that no SLN is missed during SNP with the monopixel probe. TReCam's field of view allows for quick and complete exploration with few shots. During difficult explorations with the monopixel probe, it is possible to take pictures with TReCam to confirm or invalidate the presence of radioactivity and help in the location of SLN. Double control by the monopixel probe and imager could improve quality, especially since metastatic SLN are not necessarily the most radioactive and easy to detect. This double detection is not time-consuming. In about 60% of cases, the operator's assessment is favorable and the imager provides assistance in nearly 20% of cases by allowing SLN initially ignored by the monopixel probe or atypical axillary locations to be viewed. TReCam appears as a complementary tool to the monopixel probe. Although less manageable, TReCam allows a global vision of the axillary cavity while the monopixel probe is directional and imposes a step-by-step exploration. TReCam brings an individual benefit in some cases by allowing, for example, the detection of the unique negative SLN and thus avoids lymphatic clearing or, the detection of the unique metastatic SLN with low radioactivity, thus modifying the therapeutic strategy. However, the size of our study is far too small to highlight these situations.

Conclusions

Hand held gamma cameras like TReCam are interesting tool in the different times of SNOLL procedure for breast cancer. Their use is easy and is not time consuming. In preoperative time, these imagers could legitimately subsist in the realization of a post-injection LS and alleviate already heavy logistics in nuclear medicine department. During surgery, using these devices with the classic monopixel probe allows a double control (visual and sound) of the surgical procedure. It may be a help in difficult SNOLL procedures.

Acknowledgments

Funding: The study was supported by La Fondation de l'Avenir, used for the logistics of the study. The funding source had no involvement in study design, in the collection, analysis and interpretation of data, in the writing of the report and in the decision to submit the article for publication.

Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at http://dx.doi.org/10.21037/abs-19-108.

Data Sharing Statement: http://dx.doi.org/10.21037/abs-19-108

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/abs-19-108). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All research was performed in accordance with relevant guidelines and regulations and in accordance with the Declaration of Helsinki (as revised in 2013). This experimental protocol was approved by the Comité de Protection des Personnes de l'Ile de France X, Hôpital ROBERT BALLANGER, Boulevard Robert Ballanger Bât. Central n° 8-3ème étage, 93602 AULNAY-SOUS-BOIS, cpp.iledefrance10@ch-aulnay.fr, under the number 2013-A00856-39. Informed consent was obtained from all individual participants included in this study.

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doi: 10.21037/abs-19-108
Cite this article as: Bricou A, Benbara A, Verdier MA, Bouvet-Lefebvre F, Pinot L, Ménard L, Sellier N, Soussan M, Vicaut E, Duval MA, Charon Y. Interest of a hand-held gamma camera (TReCam) in breast SNOLL procedure. Ann Breast Surg 2020;4:8.