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BRIEF REPORT

Axillary staging for breast cancer during pregnancy: feasibility and safety of sentinel lymph node biopsy

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Abstract

Background Safety of sentinel lymph node (SLN) biopsy for breast cancer during pregnancy is insufficiently explored. We investigated efficacy and local recurrence rate in a large series of pregnant patients.

Patients and methods Women diagnosed with breast cancer who underwent SLN biopsy during pregnancy were identified from the International Network on Cancer, Infertility and Pregnancy, the German Breast Group, and the Cancer and Pregnancy Registry. Chart review was performed to record technique and outcome of SLN biopsy, locoregional and distant recurrence, and survival.

Results We identified 145 women with clinically N0 disease who underwent SLN during pregnancy. The SLN detection techniques were as follows: ^{99m}Tc-labeled albumin nanocolloid only ($n = 96$; 66.2%), blue dye only ($n = 14$; 9.7%), combined technique ($n = 15$; 10.3%), or unknown ($n = 20$; 13.8%). Mapping was unsuccessful in one patient (0.7%) and she underwent an axillary lymph node dissection (ALND). Mean number of SLNs was 3.2 (interquartile range 1-3; missing $n = 15$). Positive SLNs were found in 43 (29.7%) patients and 34 subsequently underwent ALND. After a median follow-up of 48 months (range 1–177), 123 (84.8%) patients were alive and free of disease. Eleven patients experienced a locoregional relapse, including 1 isolated ipsilateral axillary recurrence (0.7%). Eleven (7.6%) patients developed distant metastases, of whom 9 (6.2%) died of breast cancer. No neonatal adverse events related to SLN procedure during pregnancy were reported.

Conclusions SLN biopsy during pregnancy has a comparably low axillary recurrence rate as in nonpregnant women. Therefore, this method can be considered during pregnancy instead of standard ALND for early-stage, clinically node-negative breast cancer.

Keywords Breast cancer · Pregnancy · Sentinel lymph node · Lymphoscintigraphy

Introduction

In patients with early-stage, clinically node-negative breast cancer, sentinel lymph node (SLN) biopsy has become the standard of care for axillary staging [1, 2]. This method prevents the anatomic disruption caused by axillary lymph node dissection (ALND), which can result in possible long-term side effects such as lymphedema, nerve injury, and shoulder dysfunction. However, in the subset of women diagnosed with breast cancer during pregnancy (BCP), the SLN procedure remains controversial. Reluctance for SLN during pregnancy is mostly caused by fear of radiation exposure to the fetus, because a ^{99m}Tc-labeled compound is used. The American Society of Clinical Oncology (ASCO) Expert

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Panel concluded in 2005 that there were insufficient data to recommend SLN during pregnancy; this was reaffirmed in the recent 2014 update [1, 2]. Also in the 5th edition of 'Diseases of the Breast' [3], pregnancy is considered a relative contraindication to perform SLN biopsy. However, measurements of radiation exposure and fetal dose estimates after SLN procedure during pregnancy have shown negligible exposure to the fetus [4–8]. Although limited clinical experience has been published, several European centers [9] and recent international guidelines [10] have advocated the use of SLN biopsy for women with BCP. The general advice is to perform lymphatic mapping with ^{99m}Tc-labeled colloids alone, without blue dye to avoid risks of allergic reactions.

In this paper, we present the data on efficacy and local recurrence as parameters for maternal safety in a cohort of breast cancer patients who underwent SLN procedure during pregnancy.

Patients and methods

This is a joint retrospective analysis of three ongoing registration studies on breast cancer during pregnancy [The International Network on Cancer, Infertility and Pregnancy (INCIP, www.cancerinpregnancy.org; German Breast Group (GBG) http://germanbreastgroup.de/, and the US Cancer and Pregnancy Registry, http://www.cooperhealth.org/departments-programs/cancer-and-pregnancy]. Approval by the ethics committees was obtained, and written informed consent from the patient was obtained before prospective inclusion. Retrospective registration was largely done without informed consent. These three registration studies are registered with ClinicalTrials.gov (INCIP study, NCT00330447; GBG study, NCT00196833; Cancer and Pregnancy Registry NCT02749474). Within these databases, we searched for women undergoing SLN biopsy during pregnancy for breast cancer staging purposes. Patients were treated at the discretion of the local physician and local hospital protocols. They originated from seven different countries [United States (US), Belgium, Denmark, Italy, Germany, Greece, and the Netherlands]. Twelve patients from Italy were previously reported in 2010 [9]. We documented parameters of the SLN mapping technique, complications, and outcome defined as ipsilateral axillary relapse (patients with negative findings on SLN who are subsequently diagnosed with disease in the ipsilateral axillary lymph nodes). The SLN procedure was performed according to local standard operating procedures and differed slightly between hospitals. The two European centers where most patients were operated (IEO Milan and UZ Leuven) performed lymphatic mapping without blue dye. Lymphoscintigraphy was performed with subdermal peritumoral injection of ^{99m}Tc-labeled colloids on the day of surgery. The main difference between both centers was the administered activity, 10–12 MBq in 0.2 ml versus 40 MBq in 0.2 ml at IEO, and UZ Leuven, respectively. Planar antero-posterior and oblique images were acquired 15–30 min post injection and SLN localization was marked on the skin. Preoperatively, a gamma probe was used to identify the location of the SLN. The SLN was then removed via a small axillary skin incision and histopathological examination was performed according to the local protocol.

Results

We identified a total of 145 women (INCIP $n = 81$; GBG $n = 14$, and the US Cancer and Pregnancy registry $n = 50$) in whom a SLN procedure was performed during pregnancy. Country of origin was as follows: Belgium $n = 17$ (11.7%), Italy $n = 40$ (27.6%), Greece $n = 15$ (10.3%), the Netherlands $n = 19$ (13.1%), Denmark $n = 3$ (2.1%), Greece $n = 1$ (0.7%), and United States $n = 50$ (34.5%). Median age at diagnosis was 35 years (range 28–45). Breast cancer diagnosis was made before pregnancy, in the first, second, or third trimester in 10, 54, 48, and 23 patients, respectively (unknown $n = 10$). All patients had clinically N0 disease.

SLN techniques and tumor characteristics are summarized in Tables 1 and 2, respectively. Mapping was unsuccessful in one patient, who had subsequent axillary lymph node dissection (ALND). Mean number of SLNs was 3.2 (interquartile range 1–3; missing $n = 15$). Positive SLNs were found in 43 (29.7%) patients (missing $n = 15$) and 34 subsequent ALNDs were performed. The median number of lymph nodes removed at ALND was 2 (range 1–15) and the median number of positive nodes at ALND was 1 (range 0–8). Nine patients with positive SLNs (2 micrometastases, 2 isolated tumor cells, 5 unknown) did not undergo subsequent ALND.

The median follow-up was 48 months (range 1–177), and median disease-free survival was 37 months (range 1–158). Eleven patients experienced a locoregional relapse: ipsilateral breast ($n = 9$; 6.21%), chest wall ($n = 1$; 0.69%), and axilla ($n = 1$; 0.69%). Two (1.38%) patients developed a new primary breast cancer in the contralateral breast. Eleven (7.59%) patients developed distant metastases, of whom 9 (6.21%) died of breast cancer.

Table 1 Sentinel lymph node technique detection method

	N	%
^{99}Tc-albumin nanocolloid only	96	66.2
Blue dye only	14	9.7
Combined technique	15	10.3
Unknown	20	13.8

Table 2 Tumor characteristics

	N	%
AJCC stage		
In situ	3	2.1
I	54	37.2
II	71	49.0
III	6	4.1
Missing	11	7.6
Histology		
Ductal	122	84.1
Lobular	1	0.7
Other	11	7.6
Missing	11	7.6
Grade		
1	5	3.4
2	23	15.9
3	71	49.0
Missing	46	31.7
Estrogen receptor		
Positive	82	56.6
Negative	51	35.2
Missing	12	8.3
Progesterone receptor		
Positive	71	49.0
Negative	62	42.8
Missing	12	8.3
Her-2		
Positive	35	24.1
Negative	96	66.2
Missing	14	9.7

Postoperative complications were reported in 2 patients, both after lumpectomy (1 × wound infection treated with intravenous antibiotics; 1 × large hematoma which required surgical evacuation twice). No postoperative complications after SLN biopsy were reported. Lymphedema rates were not registered.

Gestational outcome

Of the 145 women, 2 (1.37%) had a miscarriage and 5 (3.45%) underwent termination of pregnancy (TOP). One patient decided to undergo TOP due to antenatal diagnosis of trisomy 21. Unfortunately, the reason for miscarriage or TOP for the other patients is unknown.

All information on gestational outcome was missing in 8 patients. A total of 132 children were born (2 twins). Mean Apgar score was 9 (range 2–10) and 9 (range 7–10), after 1 and 5 min, respectively. Further details on gestational outcome are presented in Table 3. No gestational adverse events related to SLN procedure were found.

Table 3 Gestational outcome of 132 neonates born during the study period

	N (range)	%
Birth weight (gr)	2669 (790–4110)	–
Missing	20	15.2
Delivery mode		
Spontaneous	53	40.2
Operative vaginal	2	1.5
Cs	48	36.4
Missing	29	22.0
Apgar score		
After 1 min	9 (2–10)	
After 5 min	9 (7–10)	
Missing	58	
Admission to neonatal unit		
Yes	27	20.5
No	87	65.9
Missing	18	13.6

Discussion

We report the largest series to date of women who underwent SLN biopsy during pregnancy. The SLN detection rate was 99.3%. There was one case of axillary recurrence (0.7%). Our results are comparable to reports in nonpregnant patients and support our current practice to perform SLN biopsy for breast cancer during pregnancy. When considering safety of SLN mapping during pregnancy, fetal and maternal safety are two distinct entities that need to be evaluated. Although there are missing details about the (spontaneous) abortions that were registered in this study, the abortion percentage of 4.8% found in the current study is well below the 12% found in our previous study with a larger cohort of patients diagnosed with BCP [12].

Gestational physiological changes to the breast and lymphatic system may alter tracer migration properties that can theoretically cause inaccurate lymphatic mapping and a higher false-negative rate. The exact changes of the lymphatic system during pregnancy are still unknown. We believe that it would not be possible to conduct a study in which pregnant women undergo both a SLN procedure and an ALND to exactly investigate the identification rate of SLN, but based on our results pregnancy does not seem to negatively influence the identification rate. Dubernard et al. [11] have raised the concern that BCP patients eligible for SLN are infrequent and that even among these patients the nodal involvement rate is high. In our previously published cohort [12], 58% of BCP patients had pathological nodal involvement, very similar to the 60% node-positive rate reported in a literature review [13]. Taylor et al. stated that SLN biopsy was not performed in any of their pregnant

patients because the role of SLN in BCP has not been properly evaluated, but reported that 43% percent of their patients were pN0 and would thus have benefited from SLN biopsy [14]. In our previously published cohort of 123 BCP patients from the INCIP database [15], 35 (74%) of 47 patients with cN0 disease underwent upfront ALND (SLN biopsy $n = 12$), although 38 (81%) of 47 patients with cN0 disease were shown to have pN0 axillary staging. In these cases, ALND was unnecessary and these patients experienced no benefit but all potential complications (e.g., lymphedema, sensory loss, and shoulder abduction deficits) from the procedure. Another advantage of SLN is that it allows extensive evaluation with increased accuracy of the few nodes removed compared with the examination of 15–20 lymph nodes removed by ALND.

Concerns for fetal radiation exposure have been the main reason to avoid SLN biopsy during pregnancy. Deterministic radiation effects to the fetus, such as mental retardation, growth restriction, and congenital malformations, can occur above a threshold dose of 1–2 10^5 µGy (100–200 mGy) [8]. Any fetal radiation from radiocolloids localized in the breast and axillary lymphatics depends on biodistribution, distance from the fetus, and accumulation in tissues involved in metabolism of the radiocolloids such as the bladder. Fetal safety is based on the fact that ^{99m}Tc-labeled colloids have a short half-life (6 h) and radiotracer remains trapped at the injection site or within the lymphatics [16]. Kal et al. reported an estimated dose to the affected breast and abdomen of 2200 µGy and 450 µGy, respectively, during SLN procedure (0.45% of the deterministic threshold dose) [8]. The latter is comparable to 55 days of natural background radiation (average background radiation is 3000 µSv per year or 8.2 µSv per day) [17].

Table 4 shows fetal radiation dose estimates from direct measurements and phantom models [4–7]. The administered activities in these studies are slightly different, mainly related to local clinical practice and experience, but also the absorbed doses and the absorbed doses per unit activity vary within a wide range. This can be explained by the different methods applied for dose evaluations (thermoluminescent dosimeters [4], hypothesis of activity distribution in phantoms and software for dosimetry [5, 6], gamma probe for radiosurgery [7]). Nonetheless, coherent dose evaluations are derived when using similar approaches [5, 6]. As a note, the very low values reported by Spanheimer et al. [7] can be explained, at least partially, by the suboptimal detection technique used in their study. The results of this study, which have been estimated with the phantom- and software-based method, are in line with the previous results reported in the literature and are all well within the safety margins [4, 6]. To date, very few direct measurements in pregnant patients are available, but Spanheimer et al. reported that the radiation doses measured in vivo in one pregnant patient were similar to the doses measured in nonpregnant patients, suggesting that pregnancy itself is unlikely to significantly alter the biodistribution of radioactivity [7].

Isosulfan blue dye can potentially cause life-threatening anaphylactic reactions with cardiovascular collapse in up to 1% of cases [18]. Methylene blue dye can be used as an alternative for lymphatic mapping. In the 1980s, intra-amniotic

Table 4 Measurement of uterine radiation exposure from lymphoscintigraphy

	Patients	Lymphoscintigraphic technique	Methods	Results
Gentilini 2004	$N = 26$ premenopausal nonpregnant patients	Peritumoral injection 12 MBq ^{99m}Tc-HSA nanocolloids	Thermoluminescent dosimetry measurements of skin surface dose + urine and blood dose	Maximum dose: 40–320 µGy at epigastrium 120–250 µGy at umbilicus 30–140 µGy at hypogastrium
Keleher 2004	$N = 2$ nonpregnant patients	Peritumoral injection (2-day protocol) 92.5 MBq ^{99m}Tc-sulfur colloid	Whole-body gamma-camera images performed 1 h after injection	Worst-case scenario (all of the injected radiocolloid is instantaneously transported to the bladder, where it remains and is eliminated only by physical decay): fetal dose: 0.043 Gy
Pandit-Taskar 2006	$N = 1021$ nonpregnant patients	Single site intradermal injection 3.7 MBq (1-day protocol) or 18.5 MBq (2-day protocol) ^{99m}Tc-sulfur colloid	Retrospective analysis Internal dose assessment	SLN procedures lead to a negligible dose to the fetus of 0.000014 Gy or less
Spanheimer 2009	$N = 13$ nonpregnant patients $N = 1$ pregnant patient	Injection at primary tumor site (one or two day protocol) 39 ± 20 MBq ^{99m}Tc-sulfur colloid	Dosimetry measurements of skin surface dose and urine dose	Mean dose to the uterus 1.14 ± 0.76 µGy (range 0.20–2.76 µGy). Uterine dose for the pregnant patient (16w) was 1.67 µgr

injection of 2.5 mg methylene blue dye was used during pregnancy to diagnose premature rupture of membranes [19]. In this setting, several adverse events were observed, varying from fetal intestinal atresia, phototoxicity, hyperbilirubinemia, Heinz body hemolytic anemia, meta-hemoglobinemia to respiratory distress, and death. Fetal exposure to methylene blue in the case of SLN is much lower, because it is administered ex utero. Pharmacokinetics of methylene blue dye was measured in 10 nonpregnant women and the results were extrapolated to estimate fetal exposure to the dye [20]. After adjustment for physiologic changes of pregnancy that would affect pharmacokinetics, the estimated maximal dose (i.e., worst-case scenario, if all the subareolar dose enters the systemic circulation) to the fetus was 0.25 mg (5% of the administered dose). In our study, 99% of the SLNs could be identified using radiolabelled colloid, and therefore the standard use of blue dye seems unnecessary. In selected cases during pregnancy, in which SLN mapping with radioisotope administration is unsuccessful or refused by the patient, methylene blue may be considered as an alternative. In the patients from our study who received blue dye, no maternal or fetal side effects were reported.

Table 5 summarizes the 5 previous publications on the clinical use of SLN for breast cancer during pregnancy. It becomes clear from this table that a comparable accuracy rate can be achieved in pregnant patients compared to nonpregnant patients [9, 21–23]. Also for other cancer types, the SLN procedure has been used during pregnancy. Two case reports [24, 25] and a recent retrospective study [26] have been published on the use of SLN biopsy for melanoma during pregnancy. Andtbacka et al. [26] reported 15 women diagnosed with melanoma who underwent SLN biopsy with a combination of radiocolloid or blue dye during pregnancy without adverse effects. After a median follow-up of 54.4 months, none of the women had disease recurrence and all children were healthy [26]. Successful SLN biopsy has also been reported in two patients with cervical cancer [27] and vulvar cancer [28].

As this study was part of three independently conducted multicentre registration studies, the procedures used to identify the sentinel lymph node, surgical techniques, and pathological examination techniques were mainly at the discretion of treating physician and information was not available for all patients. Another difficulty is the lack of a standardized procedure for performing SLN biopsy during pregnancy. On the other hand, this patient cohort reflects daily clinics/common practice, where execution of the SLN technique can differ per center. As this is a voluntary registration study, selection bias also cannot be excluded.

Conclusion

In this large international cohort of 145 pregnant women with breast cancer, identification rate was high and axillary recurrence rate was very low (0.7%), suggesting oncological safety for the mother. Therefore, in our opinion there is no rationale to contraindicate SLN biopsy in pregnant patients with breast cancer. Based on these data and considerations, we recommend the same indication for SLN procedure during pregnancy as in nonpregnant women, using radioactive colloid and a single-day protocol for lymphatic mapping.

Table 5 Clinical experience with SLN biopsy during pregnancy as reported in the literature

Author	Period	No of pts	Tracer method	No of SLN (mean)	Maternal follow-up	Gestational outcome
Mondi 2006	Na	9		2.3	Na	No birth defects; term deliveries
Khera 2008	1994–2006	10		4.3	22 months 3 DOD	No problems
Gentilini 2009	2001–2007	12		2	32 months 3 Systemic Recurrences 1 Local recurrence	1 × VSD
Cardonick 2010	1996–2010	30	Majority radioactive material without blue dye injection	Na	Na	$N = 2$ miscarriages $N = 3$ SGA $N = 1$ asymptomatic pulmonary artery fistula $N = 1$ hydrocephalus not requiring shunt
Gropper 2014	1996–2013	25	^{99}Tc alone $n = 16$ Blue dye alone $n = 7$ Combined technique none Unknown $n = 2$	2 (Median)	Median FU 2.5 years, 1 Locoregional recurrence 3 Systemic recurrences 1 New primary contralateral tumor	$N = 24$ healthy liveborn infants $N = 1$ cleft palate

SGA small for gestational age (birth weight less than 10% for gestational age at delivery

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Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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