Original article

Electrical impedance scanning for classifying suspicious breast lesions: first results

A. Malich¹, T. Fritsch¹, R. Anderson², T. Boehm¹, M. G. Freismeyer¹, M. Fleck¹, W. A. Kaiser¹

¹ Institute of Diagnostic and Interventional Radiology, Friedrich-Schiller University Jena, Bachstrasse 18, 07740 Jena, Germany
² Siemens–Elema AB, SPS–Marketing, Women’s Health and Mobile Generators, Röntgenvägen 2, 171 95 Solna, Sweden

Received: 10 February 2000; Revised: 29 May 2000; Accepted: 30 May 2000

Abstract. It has long been established that cancer cells exhibit altered local dielectric properties compared with normal cells. Consequently, different electrical conductivity and capacitance are measurable in malignant vs normal tissues. In this study we evaluated the reliability of electrical impedance scanning (EIS), a new technology, for the classification of suspicious lesions: differentiating benign from malignant, and as a primary means of detection of breast cancer. Fifty-two women with 58 sonographically and/or mammographically suspicious findings were examined using electrical impedance scanning. Two different examination modes of TransScan TS2000 (Siemens, Erlangen, Germany), the standard-resolution mode for a routine overview examination, and the targeted high-resolution mode for a local examination of the suspicious lesion were used. All patients were additionally imaged by MR mammography (MRM) and underwent core-biopsy and/or surgical treatment after the EIS examination. With respect to the histopathological findings (29 malignant and 29 benign lesions) 27 of 29 (93.1%) malignant lesions were correctly identified using the high-resolution mode of EIS, whereas 19 of 29 (65.5%) benign lesions were correctly identified as benign (10 of 29 benign lesions showed as false-positive findings). Negative and positive predictive values of 90.5 and 73.0% were observed, respectively. Using the standard-resolution mode 22 of 29 malignancies were correctly detected (sensitivity 75.9%), whereas 22 of 29 were correctly identified as benign (specificity 72.4%). Electrical impedance scanning appears to be a promising new technology providing a relatively high sensitivity for the verification of suspicious mammographic and/or sonographic lesions especially using the high-resolution mode for local examinations. Artifacts, such as signals from superficial skin lesions, poor contact, and air bubbles, are currently a limitation.

Key words: Electrical impedance – Scanning – Breast cancer detection – New diagnostic technology

Introduction

Breast carcinoma is the most common malignant tumor in women in the western world. Statistically, almost every eighth woman is affected by carcinoma of the breast during her lifetime with the incidence currently rising [1, 2]. Early detection and treatment of breast tumors are critical for a favorable prognosis. Among the established diagnostic procedures for breast screening and work-up, palpation, mammography, and ultrasound represent the current standard of care. However, these classical techniques offer yet insufficient selectivity for biopsy. As depicted by Elmore and coworkers, the estimated cumulative risk of a false-positive result was 49.1% after ten mammograms (9762 screening mammograms were introduced in that study) [3]. This comparatively high number of biopsies – of 5 patients biopsied, only one tissue sample leads to a malignant histological diagnosis – illustrates that the established methods still do not offer adequate specificity [4]. In addition, an estimated 10–25% of breast cancer lesions are not detectable by the aforementioned methods in a 2-year follow-up [5, 6, 7]. This lower sensitivity is often attributed to dense breast tissue common among younger patients, and to post-menopausal women undergoing hormone replacement therapy (HRT) [7].

An active topic of scientific research since the 1920s is the principle that the electrical impedance properties of tissues can offer interesting and potentially valuable information – quantifiable as the parameters of conductivity (1/resistance of an alternating current) and capacitance (storage of electrical potential) [8]. In the normal breast, moderate variations in impedance values are observed, reflecting the differences among various types of breast tissue [8]. In contrast to these observations in normal tissue, malignant tumors show substantially in-
creased capacitance and conductivity values resulting in a decreased impedance [9, 10, 11]. In vitro studies have shown 20- to 40-fold higher values for both parameters in malignant as compared with normal tissue [9]. These differences are attributed to changes of cellular water content, amount of extracellular fluid, membrane properties, packing density, and orientation of malignant cells. Of key importance is the fact that most benign lesions exhibit the electrical properties of normal tissue, and not of malignancies, thereby leading to the potential to differentiate benign vs malignant [10, 11, 12].

These principles are the basis upon which the development of EIS as a new diagnostic technology was invented. In 1990 Piperno et al. published initial promising results of electrical impedance screening examinations [13]. During the past decade, the technical equipment and application mode underwent significant refinement. TransScan TS2000 (TransScan Research and Development Co., Israel; distributed by Siemens, Erlangen, Germany) is the present EIS system that has recently been approved for use by the American Food and Drug Administration (FDA). TS2000 is a real-time, non-invasive method by which the increased conductivity and capacitance of a malignant tumor is measured in the breast. Limited clinical experience in the field of impedance has been published to date.

The primary goal of this study was to evaluate the clinical accuracy of this new technique in identifying cancers. The following two distinct issues were addressed:

1. Is it of value to use EIS as an adjunct to mammography in order to classify mammographically and/or sonographically equivocal breast lesions?
2. To which extent could EIS be used as an additional routine screening technique, and what are the limitations?

**Patients and methods**

All patients having an abnormal finding in mammography and/or ultrasound at our institution between April and October 1999, and who accepted the additional examination of EIS after receiving materials about this new technique, were included in the study. For entrance criteria it was not of importance whether the lesion was visible in both or just one of the techniques.

In total, 52 patients with 58 suspicious lesions underwent mammography and ultrasound under standard conditions. The mammographic and sonographic results were classified by an experienced radiologist according to the LOS (level of suspicion) categorization method:

1. Category 1: no lesion
2. Category 2: benign lesion
3. Category 3: lesion most probably benign
4. Category 4: lesion probably malignant
5. Category 5: lesion very suspicious for malignancy

Patients with lesions of category 2–5 underwent EIS using TS2000. The EIS examinations were performed by a different radiologist with full knowledge of the results of mammography and ultrasound. The procedure is performed as follows:

1. A low-level, biocompatible electrical current, applied via a metal cylinder (base electrode) held in the recumbent patient’s hand, flows through the patient’s body.
2. The hand-held scan probe is applied on the breast. Good contact is facilitated with the use of ultrasound gel.
3. The matrix of sensors on the scan probe measures electrical current.
4. The computer calculates tissue-related conductivity and capacitance, based on the values of electrical current measured on skin surface.
5. The recordings of each breast are done in a preprogrammed sequence in accordance with the image acquisition technique (frequency range 100 up to 2000 Hz).

The display of both the conductivity and the capacitance “maps” of the breast are separately presented in a 256-gray scale on the monitor. An increased conductivity only or conductivity and capacitance (decreased impedance) value is visible as a “bright white spot.”

If an artifact can be excluded, the spot is identified as a positive finding (indicative of malignancy) [14].

Each patient was examined in two modes, targeted mode for work-up of the lesion in high resolution (16 × 16 sensor array), and scanning mode for the entire breast in standard resolution (8 × 8 sensor array with 4: 1 bindings).

**Targeted mode**

The high-resolution application was used only for examining the location of a known suspicious mammographic or sonographic lesion. In this case each of 256 points in the sensor array individually measured and reported the values [14]. Results were registered in a five-sector image (see Fig. 1). The clinical values as characterized by the resulting sensitivity, specificity, false-positive rate, false-negative rate, positive predictive value, and negative predictive value were evaluated with respect to the suspicious lesion. One examination lasted 5 min.

**Scanning mode**

The “standard resolution” is used for acquiring the overview images or “impedance maps” of both entire breasts. In this mode all patients were examined bilaterally in order to evaluate the system for its potential application in screening. One examination lasted 10 min.

Resulting bright spots (focal brightness in one of the sectors clearly more luminous than its surroundings) were interpreted. In Fig. 2 a typical EIS finding is shown. Each spot representing high conductivity or capacitance, which was not caused by an artifact such as skin lesion, scar, mole, contact artifact, bone, or air bubble,