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Contact thermography — a modern method and its role in breast cancer prevention

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ABSTRACT

Breast cancer is one of the most common oncological conditions among Polish women and is a serious health, social, as well as economic problem. Knowledge of early cancer detection methods, risk factors and prevention methods are key issues in the fight against breast cancer in women. Introduction of modern technologies using contact thermography can be both practical and complementary diagnostic method in relation to mammography or ultrasonography of mammary gland.

Key words: breast cancer; prevention; contact thermography; Braster

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INTRODUCTION

Malignant tumors in Poland are a growing health, social and economic problem. Malignant tumors are the second leading cause of death in Poland, causing about 26.3% of deaths among men and 23.1% among women. It constitutes a significant health problem mainly in young and middle-aged people. This phenomenon is particularly evident in the population of women under the age of 65 and is the most common cause of death among young (33% of deaths) and middle-aged women (49% of deaths). The most common malignant neoplasm in women is malignant breast cancer, which accounts for approximately 22.5% of the incidence of all cancers. The incidence of this cancer is systematically increasing. Annually, more than 20,000 Polish women face a diagnosis of breast cancer, of which one third dies. In the last thirty years there has been a twofold increase in the incidence of malignant breast cancer in women between 20 and 65 years of age. It is projected that in the next seven years there will be an increase in the incidence of malignant breast cancer in all age groups, especially in women aged between 50 and 69 years. Projections to 2025 indicate that further increases in the incidence of this type of cancer will be observed during this period, with the most pronounced increase in incidence in women over 50 years of age [1–5].

A significant problem in the fight against breast cancer is the low participation in screening and ineffective health care system in Poland. According to the data of the Main Coordination Center of the Breast Cancer Early Detection Program, only 35% of eligible women aged 50–69 participate in screening programs in Poland. It should be emphasized that early detection of breast cancer increases survival in women to 98.6%, but if the cancer is detected at a later stage with metastases to regional lymph nodes or is disseminated, the survival decreases to 83.8% and 23.3%, respectively. The dysfunctionality of the health care system in the area of screening — mammography, lies in recommending it only for women over 50 years of age. Diagnostic tests in the form of ultrasound and magnetic resonance imaging are recommended for women under 50. In the Polish population of young and middle-aged women, the incidence rate of malignant neoplasms is higher than in men, and epidemiological data indicate that approximately 7% of all breast cancer cases are diagnosed in women under 40 years of age [1, 5–8].

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BREAST CANCER DIAGNOSIS

The key issue in the fight against breast malignancy in women is knowledge of prevention methods and knowledge of methods and possibilities of cancer detection and diagnosis. In modern cancer prevention, activities are aimed at detecting the disease at the earliest possible stage. A factor that significantly affects the results of treatment is the detection of cancer at the earliest possible stage of development. Breast cancer diagnosis is based on palpation and physical examination. Mammography, ultrasound, magnetic resonance imaging, and microscopic examination, which are always performed when changes are found on palpation, play an important role in the diagnosis [8].

Breast palpation is the simplest clinical examination of the breast that allows early diagnosis of lesions. More than 90% of breast cancers are detected by women during breast self-examination [7]. Therefore, both palpation in the doctor's office and breast self-examination should be performed by every woman. Although breast self-examination is easy to perform, it should be kept in mind that incorrect technique and errors made while performing breast self-examination can lead to misinterpretation of the result, which consequently may result in failure to detect alarming changes [6, 7]. Thus, palpation examination, seems to be ineffective in detecting the early stage of the disease and is recommended mainly to increase breast cancer awareness in the female population. According to the recommendations of the American Cancer Society and the Polish Cancer Union, the best method for early detection of breast cancer in women without clinical symptoms is screening mammography (MMG). Mammography is a method that can significantly identify pathological changes in the breast tissue. Its sensitivity is the highest and is estimated to be 90–95% for postmenopausal women. Randomized clinical trials have shown a 25–30% reduction in breast cancer mortality among women aged 50–69 who had mammography annually or every two years. Ultrasound (US) is safe and widely used to evaluate palpable breast defects in young women. However, the false-negative rate for clinically latent lesions can be up to 47%, resulting in diagnostic and therapeutic delays. Ultrasound also has a relatively high false positive rate, i.e., as high as 8.1% when used without an adjunctive method. False-positive results are also a problem with MRI, which, combined with the high cost and requirement for contrast, means that MRI is not suitable as an early diagnostic tool. Therefore, a cost-effective method for early diagnosis of breast cancer in younger women is a necessity [8–12].

Consequently, the use of innovative technologies such as contact thermography, complementary to other diagnostic modalities points to a very interesting direction for the application of this method to improve the efficiency of lesion detection in young and middle-aged women as an important element in the diagnostic pathway.

CONTACT THERMOGRAPHY

Thermography is an imaging technique that involves recording the surface distribution of body temperature. The technique has been known since the 1960s, where Lawson noted in 1956 that the skin temperature above breast lumps was elevated. Thermographic breast imaging using infrared cameras has been used and tested as a tool for cancer detection. Despite promising results, this research was challenged in the early 1970s by a large research project called the Breast Cancer Detection and Demonstration Project (BCDDP) in the US. However, the technique was not validated for the early detection of breast cancer and the use of thermography in medical applications was virtually abandoned for an extended period, mainly due to the lack of standardized testing protocols and equipment, poor reproducibility, lack of authoritative guidelines for the interpretation of thermographic images, and poor quality of scientific articles. The end of the standstill in thermography research was initiated by the military, which in the late 1980s made available for public use the so-called Focal Plane Arrays (FPAs), which revolutionized the thermal imaging market. They replaced the single detectors or lines of detectors used in earlier versions of thermographs and the accompanying complex optomechanical signal recording systems. Another breakthrough was the use of uncooled thermal detectors in FPA arrays, which significantly reduced the price of thermal imaging arrays. Currently, we notice a great interest of researchers in the area of medical thermography. The modern use of non-contact methods of measuring body temperature is due to rapid advances in computer and information technology, particularly methods of digital image data analysis and processing. Thanks to technological advances, more advanced active dynamic thermography (ADT) began to be used, carrying information about the three-dimensional heat transfer over time that occurs in tissues under the influence of an external thermal stimulus. The measurement methods used in thermography have been widely applied in the last few decades not only in medicine and physiotherapy, but also in biomedical engineering in its broadest sense [13–17].

Thermography is the process of imaging, detecting and recording the temperature of the body under test, the organ under test. There is a distinction between remote thermography, in which the image is obtained without contact by recording heat exchange by radiation, and contact thermography, in which the image is generated on the basis of conduction heat exchange when in contact with the surface under test. Contact thermography is a fully non-invasive method of functional imaging of organ function. It uses

the so-called dermothermic effect, which consists in recording from the skin surface the biothermic processes occurring in the observed organs inside the body. Tumor cells, including breast cancer cells, are characterized by a higher metabolic rate, additionally within the tumor a dense network of capillaries is formed, this leads to the formation of hyperthermia foci (elevated temperature), which can be recorded on the surface of the examined organ as the so-called thermal marker. Pathological changes within the breast suspected of malignancy have a higher temperature than healthy areas and are visible on thermograms as colored areas, which allows to observe the pathomorphological change in the examined organ by registering the temperature increase in each area on the thermographic image. A multitude of relevant and worldwide reference studies indicate that the method of breast thermography examination is characterized by high sensitivity and specificity (80–90%) [15–17].

Braster is a Polish device employing contact thermography, which can be used as a supplement to standard diagnostic examinations. This device was patented by Polish scientists who developed a breakthrough way to use liquid crystals in diagnostics, creating a unique device in the world for breast examination. The Braster is a Class IIa certified medical device that uses liquid crystal thermography (LC) to produce high resolution contact thermographic images of the breast. It provides color images (thermograms) indicating temperature changes on the surface of the breast in direct contact with the LC film, the effect is to image the temperature distribution in three colors: red, green, and blue (RGB) [12]. The images are captured using a digital camera built into the device. Breast tumors appear on thermograms as areas of elevated temperature or thermal asymmetry. The Braster device consists of a camera, a light-absorbing dome, a light source, and removable LC films. Once the device is applied to the subject's breast, a series of images are taken, with the film held against the breast for 15 seconds before being removed and moved to another area of the breast, clockwise. Because a single application usually does not cover the entire breast, the test procedure includes several such application sequences covering each breast area (3 or 5 applications per breast, depending on breast size). The thermal images of the breast recorded by Braster are transmitted to an analysis system that interprets them and distinguishes between images of heat released, for example, by blood vessels and heat caused by the activity of tumor-forming cancer cells. Additionally, the interpretation system configured with Braster remembers the image of a given woman's breast and periodically compares all subsequent thermal images made by Braster, creating a kind of unique "fingerprint" of the organ [12, 18, 19].

Braster S.A. offers its product for consumer use as well as for medical offices — Braster Pro. The Braster device for consumer use offers the possibility of performing a reliable, monthly self-examination at home and receiving the results online. The consumer, through the Braster Device and the Braster Care mobile application installed on a smartphone or tablet, connects wirelessly to the device, and is intuitively guided through the entire examination process, and then sends the data to the Braster Telemedical Center for analysis. The user, via the mobile app, receives the results of the test within 48 hours. The Braster Pro system was introduced in 2018 and is used by professionals in the doctor's office. The Braster Pro system uses artificial intelligence algorithms that analyze the thermographic images of the breast, collected during the examination, which are then subjected to automatic interpretation through the mobile application. The result of the examination is the information transmitted to the doctor to what extent the standards for thermal asymmetry, both structural and superficial, of the examined breasts have been exceeded. On this basis, the doctor refers the patient for in-depth diagnostic tests [12, 20].

Between 2013 and 2016, three formal observational studies, ThermaCRAC, ThermaRAK, and ThermaALG, were conducted to compare the effectiveness of the Braster device with standard diagnostic procedures. The studies were conducted on women with diagnosed breast lesions who were referred for further diagnosis (over 1350 women in total). During the ThermaCRAC study (n = 736), the sensitivity of thermography was 72% and its specificity was 58% for the whole population, which allows us to conclude on the effectiveness and usefulness of the tested device; when thermography was combined with mammography, an increased efficiency of breast cancer detection was also found. Another study aimed at the development of an algorithm for the interpretation of thermographic images was the ThermaRAK project (n = 318), the clinical material obtained during the study was the basis for the development of supporting tools, such as an atlas of pathological thermographic images, which is a scientific aid for medical personnel performing and interpreting the obtained thermographic images obtained using the Braster [21, 22].

The ThermaALG study was a prospective study evaluating the method of contact thermography in relation to current diagnostic standards for breast disease. The study included 274 women aged 25–83 years, who were divided into two groups: under 50 years of age (50–) and over 50 years of age (50+). The results of this study showed a higher sensitivity of the Braster method in detecting potential breast lesions in women in the 50– group compared to the older 50+ group. Women under 50 years of age who had an abnormal breast ultrasound result, and a positive thermographic finding (presence of areas of hyperthermia) had a two-fold increased risk of breast cancer compared to the group of

patients with an abnormal ultrasound result and a negative thermographic finding (no foci of hyperthermia) [8, 12].

Based on the results of the Therma-ALG study and our own research, the Polish Society of Gynecologists and Obstetricians (PTGiP) issued an opinion on the usefulness of the medical device, the Braster System for Homeoprophylaxis of Breast Cancer. The authors of the opinion concluded that contact thermography is a complementary examination, supplementary to such methods as X-ray mammography or ultrasonography of the breast. It was indicated that in the future this technique may be a complementary diagnostic tool in the protocol of preventive examinations of breast cancer. At the same time, the experts emphasized that for this to happen, further studies should be conducted in sufficiently large populations to unambiguously determine the possibility of using the system in a breast cancer screening program [12].

A positive opinion on the usability of the Braster Pro system was also issued in 2018 by the Polish Society of Gynecologic Oncology (PTGO). This opinion was based on the manufacturer's research findings and data, as well as on their own tests of the device. Using the Braster Pro system, 169 patients were tested, with 134 negative results, 28 positive results (for in-depth diagnostics), and in the case of 7 patients, incorrect performance of the test prevented the result. In its conclusions, the PTGO assessed the device as useful, easy to use, and able to complement basic examination and breast ultrasound in gynecological offices. It was also indicated that research is still needed to evaluate the sensitivity and specificity of breast assessment by thermography [23].

In the economic perspective, the huge potential of the device was pointed out, in addition, Braster S.A. investigating ways to detect breast lesions could also plan to expand the use of thermographic diagnostics in the field of other organs [24].

In 2017, the European Society of Breast Imaging (EUSOBI) issued a statement advising against screening with thermography and other optical tools if they were to be an alternative to mammography, the use of which was considered a priority [25].

In February 2019, a U.S. Food and Drug Administration (U.S. FDA) opinion was released that also emphasized that thermography is not an effective alternative and should not replace mammography for screening and diagnosis of breast cancer. The opinion also indicated that there is insufficient scientific evidence to conclude that thermographic devices are an effective screening tool for breast cancer detection. At the same time, the agency emphasizes that thermography-based devices are approved by the FDA for marketing only for use with other tests such as mammography, not as stand-alone diagnostic tools. In the released document, the authors noted that in various types of health-related settings (e.g., health spas, homeopathic clinics) where thermography-based services have been offered, there has been misinformation convincing patients of the superiority of thermography over mammography, which could induce people who have had a thermography scan not to have a mammography test [26].

Not long after, in March 2019, a group of Polish oncologists issued a statement on the use of thermography in breast cancer diagnostics. The authors emphasized that there is no evidence to support the value of thermography in the detection and diagnosis of breast cancer, and no evidence for its value as a preventive screening test. Experts concluded that the use of thermographic methods instead of tests with proven efficacy may deprive patients of the chance of successful treatment because it carries a high risk of overlooking cancer [27].

Braster S.A. responded to the above opinions by emphasizing that their devices are not intended for independent diagnostics of breast cancer and cannot be used as an independent diagnostic method; the response also emphasized that Braster is an additional supplementary method to mammography and ultrasound of the breast. It was underlined that the Board of Directors of Braster S.A. does not feel that it is the addressee of the March 2019 opinion of Polish oncologists [28, 29].

Regarding the media publications in March 2019, the Polish Society of Gynecologic Oncology confirmed its opinion. The document emphasizes that despite its low sensitivity (21–41%), self-examination is an important element of breast cancer prevention, but it is not performed correctly or at all by most patients; it also points out that there is a lack of screening among young, healthy women, and mammography has limited effectiveness in this group. Experts see the Braster Pro as a helpful tool in the office of GP or gynecologist [30].

CONCLUSIONS

The introduction of modern technologies using contact thermography can provide a safe, practical as well as complementary method to mammography or breast ultrasound. The inclusion of the described method in the diagnostic algorithm of breast cancer and reliable health education on breast cancer prevention with the use of modern technologies, bring hope for increased health awareness among women. At the same time, there is a need for education related to the place of thermography in preventive measures — it should be emphasized that it is not a method that can be treated as sufficient for the prevention of breast cancer and it does not replace standard diagnostic procedures (breast ultrasound, mammography), it should be treated as a complement in the diagnosis of breast pathology.

Conflict of interest

All authors declare no conflict of interest.

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