



POLISH SOCIETY OF ONCOLOGICAL GYNECOLOGY

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OPINION FROM THE POLISH SOCIETY OF ONCOLOGICAL GYNECOLOGY REGARDING THE USABILITY OF BRASTER PRO SYSTEM AS A COMPLEMENTARY METHOD FOR BREAST CANCER DIAGNOSTICS IN THE CLINICAL SETTINGS

Introduction

Cancer is one of the most common causes of death in Poland and in the world. According to the National Cancer Registry data, in 2015, 23.6% of women died because of cancer. In 14.1%, the cause of death in women was breast cancer.¹

By introducing new therapies, the mortality rate decrease, however the morbidity is constantly increasing.¹ In order to provide the best accuracy and benefit from the latest methods of treatment, it is necessary to ensure the widest possible access to effective secondary prevention.

According to the report from the Supreme Audit Office, from January 2018; "in Poland there is no comprehensive, consistent and functional system of secondary health prophylaxis, including planning activities in this area, supervision of their implementation and evaluating the obtained effect."² In 2017, doctors providing basic healthcare services implemented limited health prevention tasks to their practice. In the case of a breast examination, we have information about the examination or its refusal in only 13.5% of patients.² We can therefore assume that 86.5% of women were not offered a breast examination at the general practitioner's clinics.

According to a survey conducted by the Chair and Department of Preventive Health, Faculty of Health Sciences, at Poznan University of Medical Sciences, the most common source of knowledge and preventive activities for women is from a gynecologist (35.2%).³

In light of the above data, as oncological-gynecologists, we face the question of how to provide our patients with fast and effective secondary prevention for breast cancer.

In the process of early detection of breast cancer, an important element of prophylaxis, despite low sensitivity (21-41% depending on the patient's age), is self-examination.⁴ Many patients do not self-examine their breasts because they are not aware of how to do

so. The highest sensitivity in detecting breast cancer at an early stage, reaching almost 90%, could be performed by combining self-examination of the breasts with a radiological examination.⁵

Unfortunately, the costs associated with imaging examinations and their limited availability, force us to look at alternative paths that will give the greatest possible effectiveness of prophylaxis with easy access and low costs.

The Braster Pro System is a possible method that can meet the above requirements. Braster Pro is a medical device, based on liquid crystal contact thermography, used as a controlled breast examination. The device detects thermal changes, differentiating cancerous from health tissue, and can therefore be an effective tool in the office of a general practitioner or a gynecologist before standard diagnostic procedures (breast ultrasound, mammography). Braster Pro uses artificial intelligence algorithms that subject the thermographic images obtained during the examination to automatic interpretation. The result of the examination is information provided to the doctor, to what extent the thermal asymmetry has been exceeded of both the structural and surface parameters of the breasts, and therefore if there is a suspicion of neoplastic changes in the breast and whether there is a need for in-depth diagnostics.

According to the manufacturer's data obtained after conducting observational studied on a total of 1500 woman, the effectiveness of Braster Pro in women under 50 is:

81,5% sensitivity (95% CI [64,1; 92,6])

87% specificity (95% CI [79,7; 92,4])

71% PPV (95% CI [53,7; 85,8])

92,2% NPV (95% CI [83,7; 97]).⁶

According to the manufacturer, breast size and structure do not affect the effectiveness of the method. The smallest neoplastic lesion detected by the Braster Pro System was 3mm (breast with mixed structure, USG – BIRADS 4B, ductal carcinoma).⁷

Thus far, there are no results of large, well-planned and statistically significant studies that would unequivocally evaluate the effectiveness of thermography in the prevention of breast cancer.

Evaluation of Braster Pro System

As part of the activities of the Polish Society of Oncological Gynecology, Braster Pro System tests were carried out to assess the usefulness of the system as a complement method to breast diagnostics in a clinical setting. .

During the period from June to September 2018, tests of the Braster Pro System were carried out in the centers selected by the Polish Society of Oncological Gynecology. In the discussed period, **169 patients** were examined using the aforementioned tool. A positive result was obtained in **28 patients**. A negative result was obtained in **134 patients**. In 7 cases, the examination was not performed correctly, and the result could not be obtained.

The researchers assessed on the basis of their experiences:

1. Selected elements of the Braster Pro testing procedure, including:
 - Instructions on how to navigate the application of the system
 - Ease of use – intuitive application
 - Preparation for the examination – conditions necessary to conduct the exam (ambient temperature, acclimatization).
 - Matrix selection during the examination
 - Clarity of the examination procedure
2. Usefulness of the Braster Pro System as a complementary method to standard diagnostic procedures, including:
 - Whether the thermographic examination (TMG) result can be included in the diagnostic process.
 - If in the case of an ambiguous ultrasound/MMG result, is it worth performing an examination with Braster Pro System before deciding on further diagnostic procedures?
 - Is performing an examination using the Braster Pro System useful in the clinical setting ?
 - Is there a place for the Braster Pro System as a screening method for women under 50 years of age?
3. Confidence in the interpretation of the performed examination
4. Readability of the examination result
5. Usefulness of the Braster Pro System in everyday medical practice.

Each participant in the study, after carrying out examinations using the Braster Pro System, filled out a questionnaire, which answered the above questions based on his own experience.

The analysis of the collected questionnaires and additional information obtained from the researchers revealed the following results:

The procedure using the Braster Pro System is simple and understandable.

The application instruction as well as ease of use and the application's intuitiveness were rated very highly.

Matrix selection usually did not cause any problems.

The requirements to prepare the patient for the examination were slightly cumbersome.

The necessity to ensure proper ambient temperature and acclimatization of the patient were assessed in most cases at 4 (on a scale of 1 to 6).

In one case, the entire test procedure was rated as average and the selection of the matrix and the need to ensure conditions as troublesome or difficult.

When assessing the usefulness of the Braster Pro System, most of the researchers considered that the result of the thermographic examination could be include in the diagnostic process of breast cancer and that they would like to use the Braster Pro System in their clinic. At the same time, the researchers believe that there is a useful combination of Braster Pro with an ultrasound examination in women under 50 years of age (not covered by the screening program) and see the opportunity using the System for screening in this group of women.

In the case of an ambiguous result in ultrasound / MMG, the result of the examination from the Braster Pro System exam prior to deciding on further diagnostic procedures proved to be less useful.

One of the investigators completely negatively assessed the usefulness of the system.

To sum up the assessment, the investigators assessed the obtained test result as readable and comprehensible. They rated their confidence in the performed examinations as average to high (in one case, the investigator rated low).

Most doctors have confirmed the ease of use of the Braster Pro System in their daily medical practice. This examination may, according to the investigators, be a complementary tool to the basic examinations and breast USG in the gynecologist's office. The possibility of monthly testing gives hope for greater effectiveness of secondary breast cancer prevention.

It is necessary to conduct studies assessing the sensitivity and specificity of thermographic breast evaluation in the diagnosis of this organ's tumors.



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Opinions of individual experts are available for inspection at the secretary of the Polish Society of Oncological Gynecology.

The tested device and evaluated on request from:

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REFERENCES:

1. Didkowska J, Cancer in Poland 2015, Krajowy Rejestr Nowotworów, <http://onkologia.org.pl/publikacje/>
2. Raport NIK, Dostępność i efekty leczenia nowotworów, styczeń 2018, <https://www.nik.gov.pl/plik/id,15932,vp,18449.pdf>
3. Stanisławska J, Assessment of women's knowledge on prevention of breast cancer and cervical cancer, *Probl Hig Epidemiol* 2016, 97(1): 38-44
4. Baxter N., Canadian Task Force on Preventive Health Care: Preventive health care, 2001 update: Should women be routinely taught breast self-examination to screen for breast cancer? *CMAJ* [Internet]: 2001 [cytowany 25 kwietnia 2017];164(13):1837–1846. Adres: <https://www.ncbi.nlm.nih.gov/pubmed/11450279>
5. Wiszniewska M, The prophylactic operational model integrated with occupational healthcare – Prophylactic of some types of cancers among women, *Medycyna Pracy* 2018;69(4):439–455
6. Hodorowicz-Zaniewska D. et al. A prospective pilot study on use of liquid crystal thermography to detect early breast cancer, In press
7. Raport z badania ThemaMED : Badanie obserwacyjne oceniające skuteczność diagnostyczną i przydatność kliniczną urządzenia Tester BRASTER w diagnostyce patologii piersi u kobiet.