Role of Microwave Radiometry in Mammology

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Annotation

Clinical trial data of the RTM-01-RES radiometer are represented to estimate its diagnostic abilities and to determine its role as a method for diagnosis of breast cancer in medicine practice.

The diagnostic techniques may be divided into two groups. The first one includes X-ray examination (mammography), ultrasonography. These methods and some others such as tomography investigate anatomical structure of the breast and detect abnormalities, e.g. tumors.

The second group includes thermal methods, namely infrared thermometry and radiometry. These methods detect physiologic pathologies represented by thermal abnormalities and thermal differentials.

Each method included in these groups is independent and has its own benefits and imperfections.

In 1956 Lawson was the first who used infrared thermography for detection of breast cancer. This method reads the infrared heat radiating from the surface of the body and displays distribution of the temperature as a thermogram. Analysis of the thermogram allows to obtain a qualitative assessment of the image and numerical criteria of temperature gradients [8, 9].

The method allows to detect pathologic processes accompanied by changes in tissue temperature. Temperature changes may be caused by inflammation or tissue degeneration. In a thermogram malignant tumors are displayed as hyperthermia, i.e. the skin temperature increases. Experiments have shown that temperature increases as a result of increased metabolism (exothermal metabolism reactions) and the fact that blood vessels in the tumor are engorged [5-7, 9].

The method providing a doctor with information on breast tissues by measuring temperature differentials is very promising. Thermography was viewed as a method for diagnosis of breast cancer as well as for the differential diagnosis of malignant and benign tumors, the monitoring of treatment, detection of complications occurred after surgery and tumor recurrence. However investigators have not been satisfied with obtained results absolutely. Many false positive results, a relatively low sensitivity (false conclusions in women with the first stage cancer or non-palpable tumor is 22-27% [2,10]) restricted abilities of the method and were a cause that the method was underestimate by physicians [3,4].

One of the causes was that the equipment was not appropriate. Also the attempt to replace mammography with thermography was an error, as thermal methods detect the first stages of the tumor growth that is accompanied with temperature changes. At the same time mammography detects anatomical changes that follow the temperature changes. According to Cockburn [13] thermal abnormalities occur 8-10 years earlier than mammography can detect anatomical changes. And so these results were considered false positive results.

In 1975 Barrett with colleagues [14] used other thermal method for investigating the breast. It was microwave radiometry. This method measures natural electromagnetic radiation from internal tissues at microwave frequencies. For waves of this a length the tissues of the body are “transparent” enough, so radiometry provides a doctor with more information than infrared thermography that measures the temperature of the epidermis.

In Russia radiometry has been developed by Troitskiy [15]. For the last 20 years hardware and diagnostic methods have been improved [11,12,17,21-23].

In 1997 RES, Ltd. developed the RTM-01-RES computer-based radiometer. The device includes internal and skin temperature sensors. The method provided by the RTM-01-RES radiometer has some advantages in comparison with the methods used in mammology. It allows to detect non-invasively pathological conditions in the internal organs, e.g. malignant tumors, at their earlier stages, as changes in temperature caused by inflammation or increased cell metabolism precede the anatomical changes that can be detected by mammography or ultrasonography.

Radiometry can select patients with the most dangerous tumors, as, according to current data, the tumor doubling time is higher, the tumor is hotter. Therefore radiometry selects patients with fast growing tumors first of all [19,21,24]. Also the method is absolutely harmless for patients of all ages and with any disease as well as for medical personnel. Thus the procedure can be performed repeatedly to detect pathological conditions and monitor treatment without extra radiation.

An abnormality can be detected at the depth of 3-7 cm. The accuracy of measurement is 0.2°C. Also computer processing helps to estimate results. Results of a radiometric examination may be represented as a table, thermogram, internal temperature field where the measured points are marked and isotherm lines are drawn though points with the same temperature. The data may be printed out or displayed on the monitor [12].

The advantage of the RTM-01-RES radiometer is that it includes an expert system for differential breast cancer diagnosis. The expert system ana-

lyzes data basing on several parameters such as thermal differentials, dispersion of the temperature in one breast, and others.

Note that the device is very simple in operation. Therefore an examination can be performed by secondary medical personnel. At the same time it is cheaper than other diagnostic methods. This advantage allows to use RTM-01-RES widely in our country at the current step of mammology service development, when there is lack of high-qualified specialists.

RTM-01-RES has undergone technical tests and clinical trials that estimate its ability to detect breast cancer and select patients that should have a complete (complex) examination in specialized centers. The clinical trials have been conducted at the Clinical Oncology Institute of the Oncology Science Center of the Russia Academy of Medical Science, at the Clinical Hospital #40, and the Moscow Mammology Health Center. A total of 900 patients have been examined. The trials have shown that the device is effective enough:

Sensitivity - 85 – 94%;

Accuracy - 77.6 – 90.4%;

Specificity - 76.5 – 81.8%.

Specialists of the Municipal Clinical Oncology Health Center with General Surgery Department of Moscow Medical Stomatological Institute has analyzed effectiveness of the radiometric examinations (RTM-Diagnosis) to estimate diagnostic abilities of RTM-01-RES and to determine its role in mammology, in particular, for selecting patients with breast cancer and risk group patients that must be examined further at oncology and mammology centers.

The conducted clinical trial had the following features:

6. The internal temperature was measured in conjunction with the skin temperature. As trials have shown relation between skin and internal temperatures is a very important parameter. It allows to detect subtle processes, in particular, proliferation in breast tissues.

7. The results of RTM-Diagnosis were compared with results reported by mammography and ultrasonography. So RTM-Diagnosis could be compared with other methods fairly.

8. During the clinical trial investigators estimated abilities of RTM-Diagnosis to detect breast cancer, and also to select patients that must be examined at mammology health centers. This group includes patients with proliferative fibroadenoma and mastopathy.

In this trial 57 women ages 28 – 76 (an average age is 51) with suspicion of breast cancer were engaged. 31 of these women were diagnosed with breast cancer, 17 women had non-cancer diseases and 10 women were diagnosed with proliferative mastopathy and fibroadenoma. All patients were examined by RTM-Diagnosis. RTM-results were compared with results of CBE, mammography, and ultrasonography results. Efficacy of RTM-Diagnosis was determined basing on comparison of RTM-results with histology conclusions.

The internal and skin temperatures were measured on the 6 – 10 days from the beginning of the menstrual period. Menopause women can be examined at any time. Examined patients laid on the back with their hands behind their head in order to normalize the arrangement of the measured points and increase the total accuracy of measurement due to the fact that the breast was flattened naturally and lymph nodes were open in this position. Skin and internal temperatures were measured at 10 sites including lymph nodes, area, centers and borders of the quadrants [22]. The method efficacy was estimated by comparison the sensitivity, accuracy and specificity of the method with the same parameters of mammography and ultrasonography. These parameters were calculated for the whole selection, for the patients with breast tumors that were less than 2 cm and for the patients with breast tumors that were larger than 2 cm.

The RTM-Diagnosis sensitivity for breast cancer diagnosis is 89.66%. It is higher than sensitivity of other diagnostic methods: sensitivity of ultrasonography is 85.18%, for mammography it is 80%. These results are represented in Table 1.

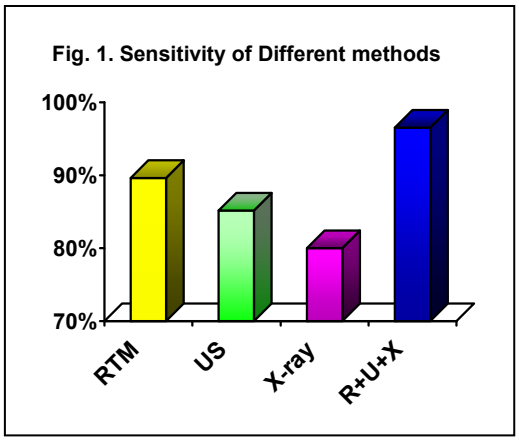
Table 5

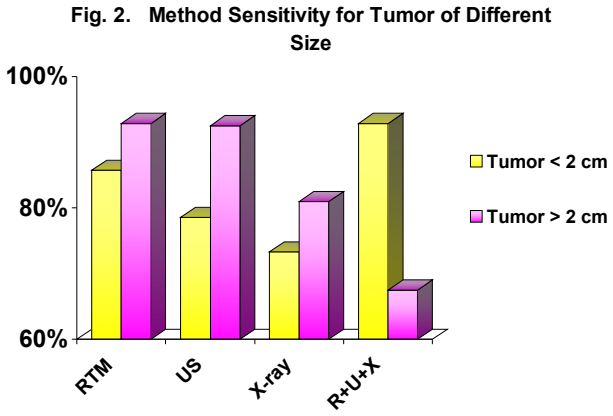
	Ultrasonography	***Mammography***	***RTM-Diagnosis***
Number of breast cancer patients examined	26	29	29
Number of positive results	21	25	26
Number of false results	1 – fibroadenoma 4- mastopathy	4- mastopathy	3
Detective ability (sensitivity)	80,8 %	86,2 %	89,6 %

The investigation has shown that the larger size of tumours, the higher sensitivity of all methods. When tumors were less than 2 cm, RTM-Diagnosis sensitivity was 89.6%. At the same time the sensitivity of ultrasonography and mammography was 78.57% and 73.3% respectively. When tumors were more than 2 cm, the sensitivity of RTM-Diagnosis increased up to 92.86% and kept highest. Ultrasonography was 92.3% and mammography – 86.67%.

Therefore the RTM-Diagnosis sensitivity is higher than it is for other methods, when the tumor has a small size.

The results are illustrated in Fig. 1 and Fig. 2.





The investigation has shown that RTM-Diagnosis can distinct mastopathy and fibroadenoma with proliferation from mastopathy and fibroadenoma without proliferation. Therefore it can select patients who may get cancer under unfavorable conditions. These patients should have an complex examination in specialised health centers. The results are represented in Table 2.

Table 6

Disease	*Number of examined patients*	*Ultrasonography*	*Mammography*	*RTM-Diagnosis*
Mastopathy and fibroadenoma with proliferation	10	2 – cancer 5- mastopathy 3- fibroadenoma	4 – cancer 4 – mastopathy 2- fibroadenoma	8- Thermogram shows RTM-features of risk group 2- there are no RTM-features
Mastopathy and fibroadenoma without proliferation	18	14- mastopathy 4- fibroadenoma	12 – mastopathy 1 – fibroadenoma 3 – cancer 2 – not performed	4 – Thermogram shows RTM-features of risk group 14– there are no RTM-features

The table shows that RTM-Diagnosis distinct mastopathy and fibroadenoma with proliferation from mastopathy and fibroadenoma without proliferation enough well. Thus one of the advantages of RTM-Diagnosis is to se-

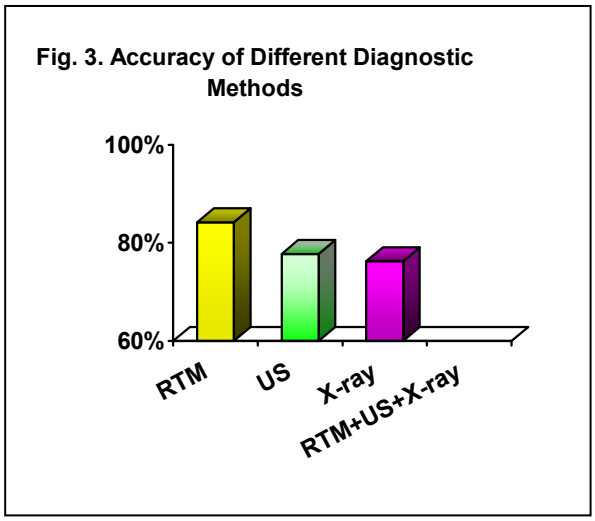
lect patients with fibroadenoma and mastopathy with proliferation. Other diagnostic techniques can not do this as they detect anatomical changes in the breast. RTM-Diagnosis provides a doctor with information on active processes in the breast.

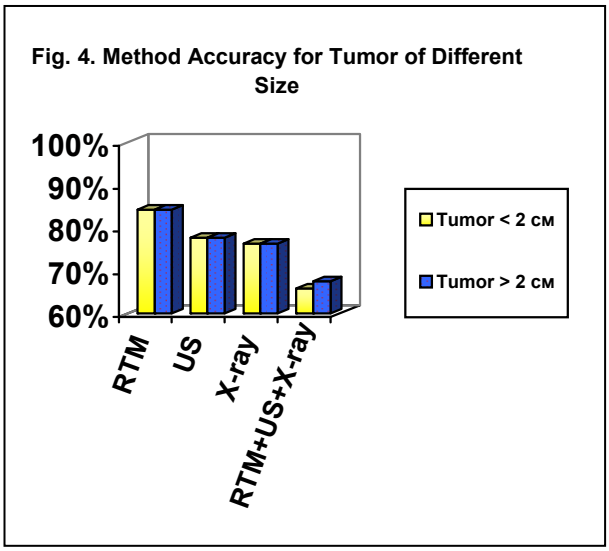
Thus in 80% of all cases RTM-Diagnosis selected proliferative mastopathy and fibroadenoma as risk group patients correctly. Ultrasonography selected 20% and mammography - 40%.

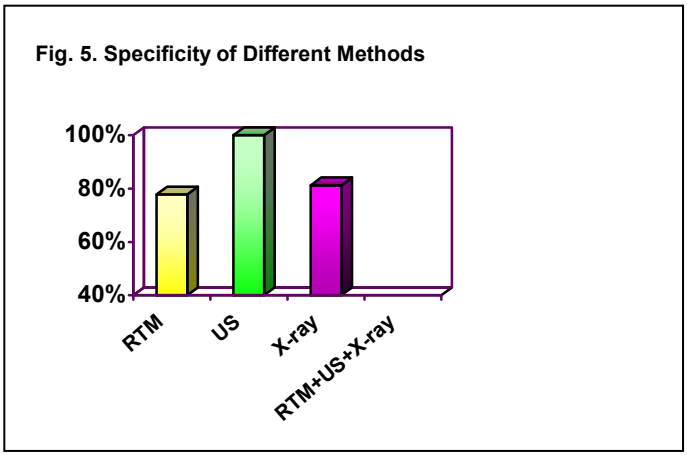
The specificity and accuracy for selection of the risk group patients is represented in Table 3 and Fig. 3 – 5.

Table 7

	RTM-Diagnosis (RTM)	*Ultrasonography (US)*	*Mammography (X-ray)*	*RTM + US + X-ray*
Sensitivity	87,2%	66,7%	74,3%	
Accuracy	84,2%	77,7%	76,3%	
Specificity	77,8%	100%	81,2%	







Note that during the investigation RTM-results were base on a dual concept – “thermogram has features of breast cancer” or “thermogram has no features of breast cancer”. Thus the diagnosis of patients included in the risk group were not differed. Current algorithms and method of RTM-Diagnosis do not allow to perform differential diagnosis. When breast cancer RTM-Diagnosis is performed in patients with other diseases, its specificity is 57.69%. At the same time in this case the specificity of ultrasonography and mammography is higher. It is 92.59% and 85.18% respectively. Lower specificity of RTM-Diagnosis exists as this method can not distinguish cancer from mastopathy and fibroadenoma with proliferation.

Due to higher sensitivity of RTM-Diagnosis (it is very important for small tumors) as well as that it is harmless and cheaper other methods, we believe that the method may be used effectively for annual screening, detection of breast cancer, selection patients fallen in the breast cancer risk group as well as the monitoring of breast treatment.

For decades mammography has been the main screening method for earlier detection of breast cancer [3, 4, 7]. However its abilities as a screening methods are limited as a result of risk factors related to radiation, its high cost and its low efficiency for young women, when a woman breast has more glandular tissue (according to L. Nystzom, mammography can not detect breast cancer in 40% of the women under 40) [3, 7]. Many authors suggest ultrasonography as an alternative method to mammography. But it has some restrictions as it is required a high-qualified specialist and if there are not data about existence and localization of disease of if tumor is located in fat, it makes many false-negative conclusions (especially for large breast). However ultrasonography can detect cancer in glandular tissues [3, 4].

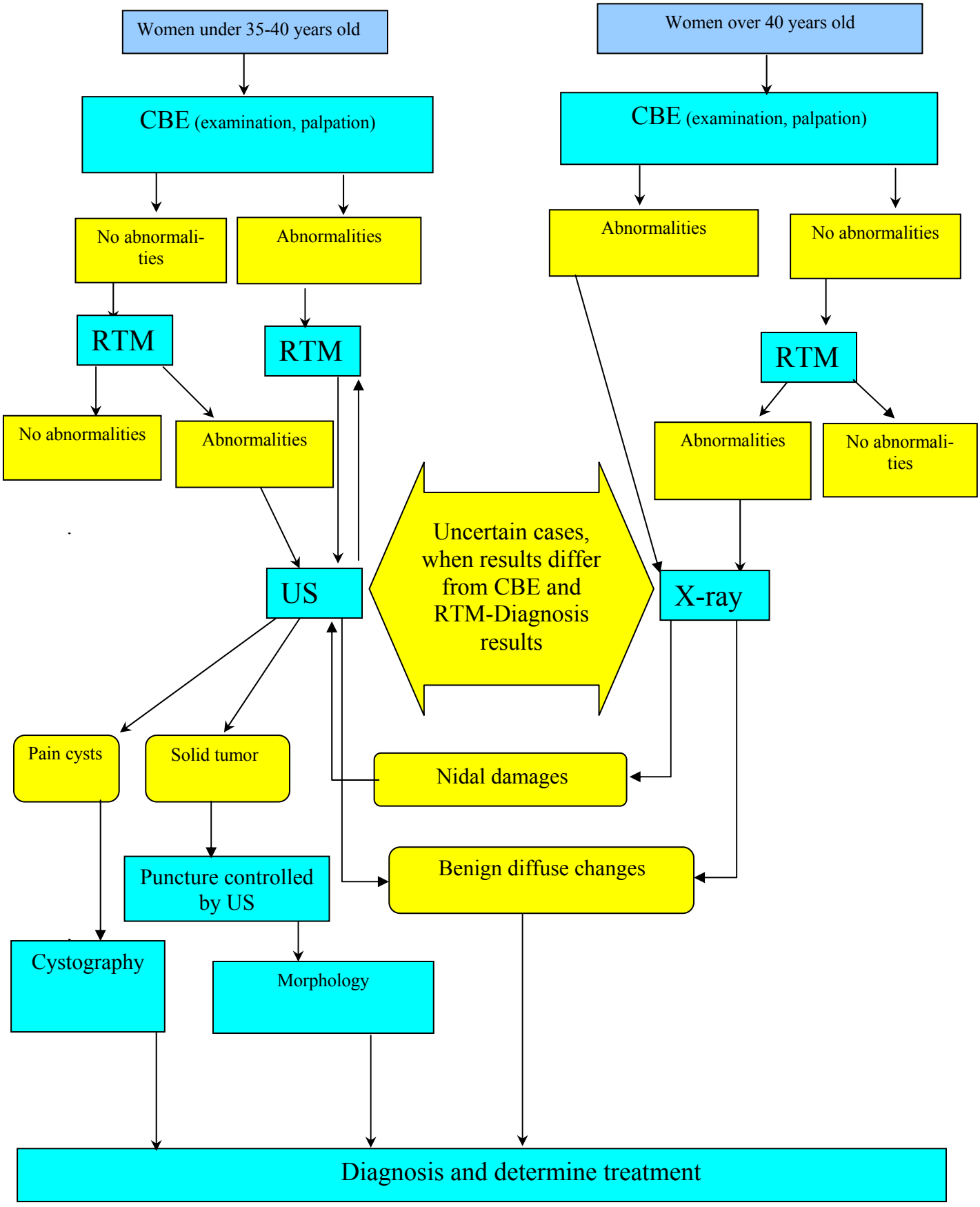
Therefore we suggest the following screening method for women with more glandular than fatty breasts, ages 35 – 40, and women with fat breasts, older than 40. All women older than 15 should have a screening including BCE and palpation and RTM-Diagnosis once two years (or oftener). Once a positive conclusion is made, a woman under 40 should has ultrasonography, and a woman after age 40 - mammography. Once a clinical breast examination detects tumor-like mass young women should undergo RTM-Diagnosis and ultrasonography; women after 40 should have mammography. (RTM-Diagnosis is not included as mammography shows a whole structure of breast cancer and it is used to detect a type of pathology). If ultrasonography can not make a conclusion (if ultrasonography results are not confirmed by CBE and RTM-Diagnosis), mammography should be performed. In the case of uncertain mammography results ultrasonography and RTM-Diagnosis should be performed. The final step of diagnostic investigation should be fine needle aspiration biopsy guided by ultrasonography, and then morphology. Women, whose positive RTM-Diagnosis is not confirmed by other methods

(including morphologic investigation), should be included in the breast cancer risk group, have a regular examination in oncology room and an RTM-examination.

Therefore RTM-Diagnosis as a harmless, high-sensitive and cheap method can be useful in conjunction with for routine screening to detect breast cancer at its earlier stage other methods.

We believe that the described screening method increases the number of breast cancer detection with minimum expenses, time and high-qualified specialists.

This breast cancer diagnostic scheme including thermal methods can be made more exact as it will be apply in larger selection in medical centers.


Women under 35-40 years old
Women over 40 years old
CBE (examination, palpation)
CBE (examination, palpation)
No abnormali-ties
Abnormalities
Abnormalities
No abnormalities
RTM
RTM
RTM
No abnormalities
Abnormalities
Abnormalities
No abnormali-ties
Uncertain cases, when results differ from CBE and RTM-Diagnosis results
US
X-ray
Pain cysts
Solid tumor
Nidal damages
Puncture controlled by US
Benign diffuse changes
Cystography
Morphology
Diagnosis and determine treatment

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