



Cryolampectomy or Vacuum Removal of "Small" Forms of Benign Breast Tumors

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Abstract

One of the problems of breast cancer prevention (BC) lies in the way of an integrated approach - mammological screening and minimally invasive technologies for removing identified dangerous foci.

Aim: To develop a method and device that provide ablasy and antiblasty, complete minimally invasive removal of small tumors of the breast in comparison with a vacuum device, reduce ergonomics and economic costs of performing the surgical procedure.

The article presents an analysis of the effectiveness of biopsy and removal of small tumors by cryomammotome in 98 patients and a vacuum device of the American company "SENORx" on 8 postoperative preparations and in 11 women. It was found that the latter requires multiple insertion of a stiletto and a trocar sleeve through the tumor under the control of ultrasound of its absorption and multiple excision of fragments (vacuum curettage). There is a violation of the integrity of the tumor, the principles of ablasy and antiblasty in the case of a malignant tumor.

Cryolampektomia allows the biopsy and removal of focal diseases of the breast of whole, which is greater than vacuum biopsy, without violating the basic principles of Oncology. Cryolampektomia in comparison with the vacuum procedure allows to approximate the sensitivity, specificity and accuracy of 100% ($P < 0.0023$).

Keywords: Breast Screening; Vacuum-minimally Invasive Diagnosis and Treatment; Criolampektomia; Blastica and Antiblastica

Introduction

Mass screening (MS) of women, based on the use of highly sensitive mammography (MG), allows detecting a variety of phases of breast tumor diseases (BIRADS 2-5) (palpable and non-palpable, up to sagsinoma in situ), curable by modern surgical (organ-preserving) intervention and reducing mortality from this pathology by 30% [1].

The main diagnostic method that allows you to determine the type of tumor is a biopsy (fine needle and trepanobiopsy). How-

ever, the value of this method is limited to obtaining material for morphological research and immunohistochemistry.

With MS, there is a need not only for morphological verification of tumor-like formations of unclear genesis to a wide range of people, but also for their removal, since sooner or later they can be reborn.

There is a known method for vacuum removal of "small" breast tumors by means of an apparatus developed by the American company SenoRx by a small dissection of the skin, the introduction of

an ultrasound-controlled device containing a stiletto and a trocar sleeve (Figure 1.a), followed by vacuum suction and multiple excision (Figure 1b) of tissues [2,3].



a)

b)

Figure 1: Vacuum device for fragmentary removal of tumors.

The vacuum system consists of a suction device, a single connecting tube, a glass jar for collecting tissue fragments and cellular elements and a second connecting tube to the stiletto.

Elements and a second connecting tube to the stiletto. However, the procedure is performed through a skin incision by inserting a stiletto and a trocar sleeve through the tumor under the control of ultrasound of its absorption and repeated cutting off of fragments (vacuum curettage). With repeated insertion of a tube with a stiletto, not only the integrity of the tumor is violated, but also the principles of ablasy and antiblasty in the case of a malignant tumor. Moreover, with a strong vacuum discharge, the cellular elements are scattered throughout the system, despite the fact that the main part falls into the jar. The cost of such a one-time system for each manipulation costs 4 thousand rubles. This device was presented to us by the company for testing. The approbation was carried out on 8 postoperative preparations, and then in 11 women. In one case, after a histological examination, an invasive cancer was detected, which required radical resection of the MG, and in another case, after 5 months, a residual tumor was detected on ultrasound, we refused to continue using this device.

The Purpose of the Work

To develop a method and a device that provides ablasy and antiblasty, the completeness of minimally invasive removal of small

tumors of the MG in comparison with a vacuum device, reducing ergonomics and economic costs for performing a surgical procedure.

Material and Results

Since 2008, the Novgorod Regional Clinical Dispensary annually conducts from 19 to 25 thousand women on 2 digital highly sensitive mammographs, one of which is mobile for the early diagnosis of breast diseases. It was found that the detectability of nodular mastopathies averaged $26.3 \pm 2.3\%$, including $5.7 \pm 0.6\%$ up to 2 cm. Diffuse mastopathies were found in 33.8% and cancer was found in 0.48-0.5% of patients after morphological examination, including in 0.22-0.26% (on average, 0.24%), malignant tumors were not palpable (up to 1-1.5 cm) and at the level of Ca in situ with the presence of calcinates.

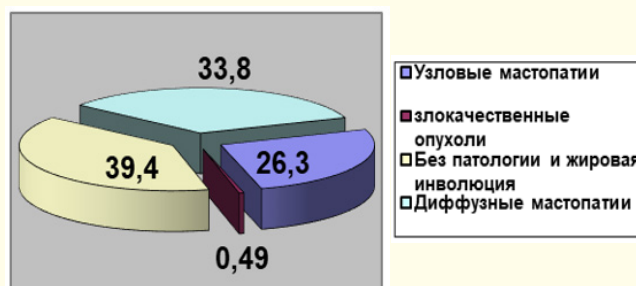


Figure 2: Diagramma of the ratio of the detected pathology.

Taking into account the high need for the removal of "small" (up to 2 cm) tumors, we have developed and implemented a method and device for its implementation [4]. Removal of non-palpable MG formations is based on "freezing" under intravenous anesthesia by introducing a tubular applicator with a diameter of 3 mm with a cryogenic effect at the working end and the "ERBE krio 6" device, which allows for a set negative temperature for 1 min) under the control of an ultrasound device with an intraoperative sensor to a pathological focus. Previously, the probe is inserted into a tubular gun with a lock, handles and branches for cutting off. The last device for the probe (cryomatom-Figure 3a) was manufactured by the medical production company "PPP", Kazan).

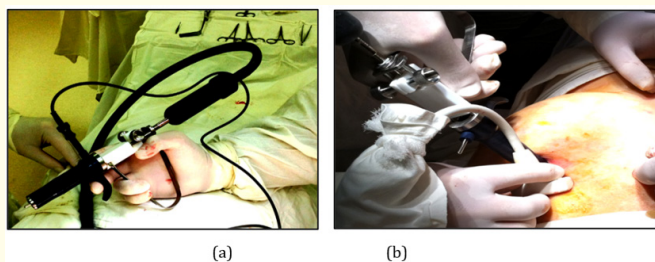


Figure 3: a) Cryomammotom assembled by cryosonde; b) Insertion of the probe into the soft tissues of the breast under ultrasound control.

The blunt end of the cryogenic probe is tightly pressed to the focus under the control of ultrasound (Figure 3b), the device "ERBE krio 6" is turned on, frozen to a temperature ($120-150^{\circ}$), turning it into an "ice ball", firmly fixing the pathological focus to the end of the probe. Using the handle of the upper branch of the "pistol", a cryogenic probe with a frozen focus is freely drawn into the cylinder, a "trigger" connected to the "Surgitron" device is pressed, and the end of soft tissues below the frozen focus is cut off with pointed arc-shaped coagulators. The device is removed from the wound. The cut-out section of tissue is sent in a container for urgent histological examination. Control of hemostasis and in the case of a benign tumor or proliferative changes, the manipulation is completed by applying a cosmetic suture. In the case of cancer, we evaluated the purity of the edges of the micropreparation, the stage of the disease.

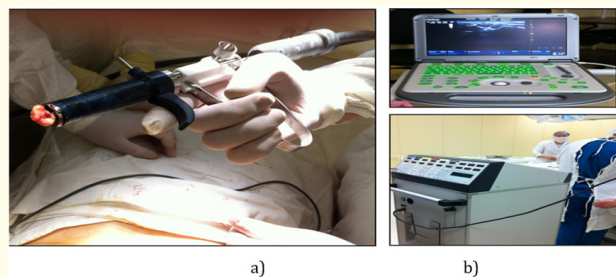


Figure 4: a) Incised tumor of the breast; b) ultrasound device and ERBE krio 6.

Depending on the stage and histotype of the tumor, the further treatment plan was determined (whether it would be limited to this intervention in combination with radiation therapy or increase the volume of surgery). In 5 women with MG, up to 5 foci were determined in adjacent quadrants, which were removed from one access.



Figure 5: Removal of multiple tumor foci from a single access.

We performed cryolampectomy in 98 patients (aged 47 to 79 years), including one on both sides, with nodular formations of unknown origin (after a puncture biopsy, they were found to have cells in a state of dysplasia and in 9 cases with grouped microcalcifications. As can be seen from table 1, in almost all cases, the formations were completely removed, with the exception of 1 case of the location of 2 calcifications at a distance of 2 cm.

The latter, as it turned out, did not need to be removed after an urgent histological examination. During ultrasound control, the boundaries of the frozen tissue were clearly defined.

The average time of manipulation (from skin dissection to suturing) was 12 ± 3.0 minutes, while the vacuum removal of focal formations reaches 1 hour. In 2 cases ($2.04 \pm 1.1\%$), an urgent histological examination revealed a breast cancer of 0.7 and in another Ca in situ. In the first case, with a microinvasive form of cancer and a close location of tumor cells to the edge of the removed focus, the operation was expanded to an organ-preserving radical resection of the MG, and in the second, cryolampectomy was sufficient. The patient has been observed for more than 4 years. No complications were observed.

Pathology	Number of patients	Diagnosis		Pathological focus has been removed	
		Confirmed	Changed	Completely	Partially
ONG syndrome *	39	38	1	39	-
Nodular mastopathy, FAM/cyst	48	46	2	48	-
Microcalcinate syndrome	9	8	1	8	1
BC (0-1a stud.)	2	1	1	2	-
Total	98	93	5	97	1**

Table 1: Results of morphological verification and completeness of removal of "small" tumor formations.

Note: * ONG is a tumor of unknown origin; ** 2 calcinates, located 2 cm from the main group, were not removed, which was confirmed by the control MG.

The average time of manipulation (from skin dissection to suturing) was 12 ± 3.0 minutes, while the vacuum removal of focal formations reaches 1 hour. In 2 cases ($2.04 \pm 1.1\%$), an urgent histological examination revealed a breast cancer of 0.7 and in another Ca in situ. In the first case, with a microinvasive form of cancer and a close location of tumor cells to the edge of the removed focus, the operation was expanded to an organ-preserving radical resection of the MG, and in the second, cryolampectomy was sufficient. The patient has been observed for more than 5 years. No complications were observed.

Discussion

Cryolampectomy is easy to perform, allows for a biopsy and removal of focal diseases of the MG in one piece, which is significantly superior to a vacuum biopsy, without violating the principles of ablasy and antiblasty. It is no coincidence that in 2011, at the ALL -Russian Competition in the field of oncology "In Vita Veritas", a diploma of the nominee "For achievements in diagnostics" was received.

Comparative statistical processing of the research results is shown in figure 6 and 7. As can be seen in the diagrams and scatterogram, at a distance of 2 cm. The latter, as it turned out, did not need to be removed tissue were clearly defined.

With "small" focal formations, cryolampectomy, in comparison with the vacuum procedure, allows us to bring the sensitivity, specificity and accuracy indicators to 100%. Spearman's regression coefficient $r = 0.87$ ($P < 0.0023$).

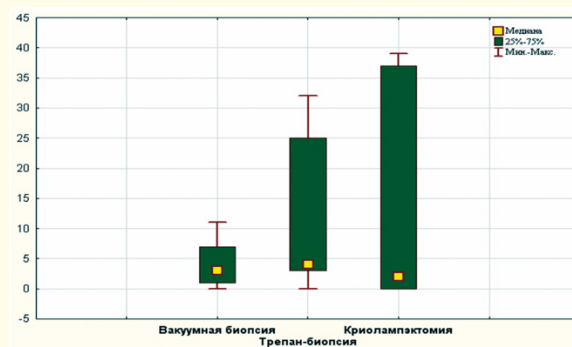


Figure 6: Comparative effectiveness of three types of biopsies.

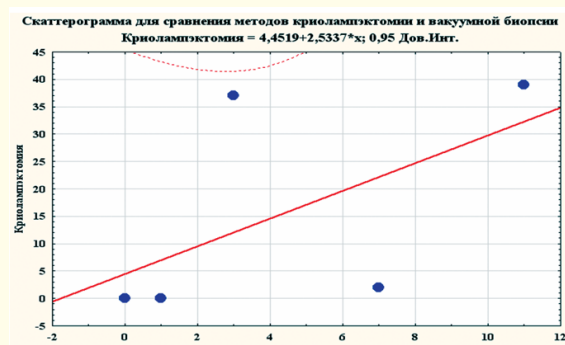


Figure 7: Scatterogram of the relationship between the effectiveness of cryolampectomy in comparison with vacuum removal.

Naturally, removing the most dangerous focal forms of mastopathy, we pursue the goal, first of all, of medical prevention, taking into account risk factors [5], followed by observation and treatment with the appointment of drug therapy.

Conclusion

The developed method (cryolampectomy) under the control of ultrasound, it is not traumatic, it does not require expensive one-time tools for its implementation in comparison with vacuum removal, based on negative temperature, it provides reliable fixation and complete removal of focal diseases of the MG, without violating the principles of ablasy and antiblasy. The accuracy, sensitivity and specificity of the cryolampectomy method is approaching 100% ($P < 0.0023$).

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