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Prostate Cancer Survival Criteria in a Modern Interpretation

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Abstract: According to the World Health Organization (WHO), the incidence of prostate cancer is constantly increasing worldwide and it is the third most common cancer in our country, after malignant tumors of the lung and stomach. Up to 40% of men between 60 and 70 years of age and 70% of men over 80 years of age have different stages of prostate cancer [1, 4].

Due to the specific features of the clinical course, the prostate tumor may not only not affect the patient's well-being for many years, but also not manifest itself in any way. The results of modern studies have shown that none of the currently used non-invasive methods can provide one hundred percent information about the presence of prostate cancer [2, 3].

In this regard, in order to improve the diagnosis and detection of the oncological process in the prostate at an early stage, the revolutionary HistoScan device was created and is successfully used [5]. This is a patented technology for differentiation, characterization and imaging of prostate tissue based on the analysis of ultrasound backscattering. This device can perform ultrasound examination of the prostate with a high degree of accuracy and identify areas of tissue suspicious for cancer. Thus, histoscan allows to suspect prostate cancer (stages T 1 - T 2). By displaying this information in the form of a 3D model and a map of the prostate, it is possible to determine the location and size of tumor tissue, obtain targeted tissue samples during a biopsy, reduce the number of tissue columns of biopsy material, as well as reduce the non-radical condition allows observation. cancer therapies, and furthermore, we are considering the possibility of targeting using histoscan mapping during focal therapy of prostate cancer.

Key points: Materials and methods, Histoscan map, Prostatic sextants.

Materials and methods

Our work was aimed at identifying people with prostate cancer, verifying the diagnosis using two well-known diagnostic methods (PSA prostate-specific antigen, digital rectal examination, transrectal ultrasound, transrectal dopplerography of prostate vessels) and a new method - histoscopy. In the course of the work, a comparative analysis of standard research methods and diagnostic capabilities of histoscan for prostate cancer and hyperplasia was carried out. In addition, the diagnostic value of the method related to early detection of cancer, the accuracy of staging the process and the impact of the results obtained on the planning of polyfocal prostate biopsy and the choice of subsequent treatment tactics were determined.

First, a retrospective group of patients (hereinafter referred to as the first group) was identified and examined: 67 patients with suspected prostate cancer underwent prostate biopsy between 2009 and 2011. It performed a standard diagnostic complex for a patient with suspected prostate cancer, consisting of clinical and biochemical blood tests, detection of prostate-specific antigen (total and, according to the instructions, free (total PSA > 4 ng/ml), PSA density), general urine analysis, 3-well test, uroflowmetry, transabdominal and transrectal ultrasound of the prostate, as well as Doppler ultrasound of the prostate vessels, after which a transrectal polyfocal biopsy was performed.

Then, to directly address the aims and objectives of our study, we examined 701 patients using the Histoscan device. All these patients underwent the standard diagnostic complex mentioned above. The distribution of prostate-specific antigen levels was from 1.09 to 209 ng/ml.

Patients with elevated PSA levels who underwent histoscopy were divided into 3 groups based on the degree of increase. Thus, 67 patients (to compare prostate biopsy results with and without histoscopy) and two control groups were identified.

In the first four groups (patients with suspected prostate cancer), all patients underwent a prostate biopsy.

With the introduction of Histoscan, each patient arriving at our clinic with an elevated PSA level (or with a normal PSA level, but prostate cancer was suspected by other examination methods) was assigned to one of the above groups. Then, the patients were examined according to the scheme developed for this study. This was a classic examination of a patient suspected of prostate cancer. The first step was a digital rectal examination (DRE). Seven (1.5%) of the 456 patients in the second group had areas suspicious of prostate cancer. In the third group of 112 patients, 17 (15.3%) DREs were suspicious of cancer. In the fourth group, during DRE, 63 out of 70 patients had suspicious areas, which was 87.5% of the patients in this group. In the fifth group – a conditional control group – none of the 20 patients had any suspicious areas detected during digital rectal examination. In the sixth group, none of the subjects had suspicious areas during DRE.

In the first group of 67 patients, 15 (22.3%) had areas suspicious for prostate cancer on digital rectal examination (Table 2).

Identification of suspicious areas during DRE in patients from research groups.

After that, a classic gray ultrasound - transabdominal and transrectal examination was performed, after which a Doppler examination was performed. According to the examination data, the presence or absence of foci suspicious for prostate cancer was recorded (Figure 6). It should be mentioned here that we did not take into account changes according to TRUS and Doppler data, characteristic of prostatitis and prostate adenoma.

In none of the 456 patients in the second group, we found changes characteristic of prostate cancer according to TRUS and Doppler examination of blood flow of prostate vessels. In the third group with PSA thresholds of 10-20 ng/ml, no ultrasound signs of prostate cancer were found in any of the patients, as in the second group. In the fourth group, 30 out of 70 patients, or 43.8%, have ultrasound signs characteristic of prostate cancer. In the fifth group, TRUS and Doppler ultrasound of the prostate did not reveal changes specific to prostate adenocarcinoma in any of the patients. No changes were found in the young people of the sixth (control) group.

In the first group of 67 patients, 11 had classic hypoechoic areas suspicious for prostate cancer, or 16.4% of all patients in the group.

The second step of the study consisted of performing a histoscopy with prostate mapping for biopsy. Histoscopy begins with a transrectal ultrasound.

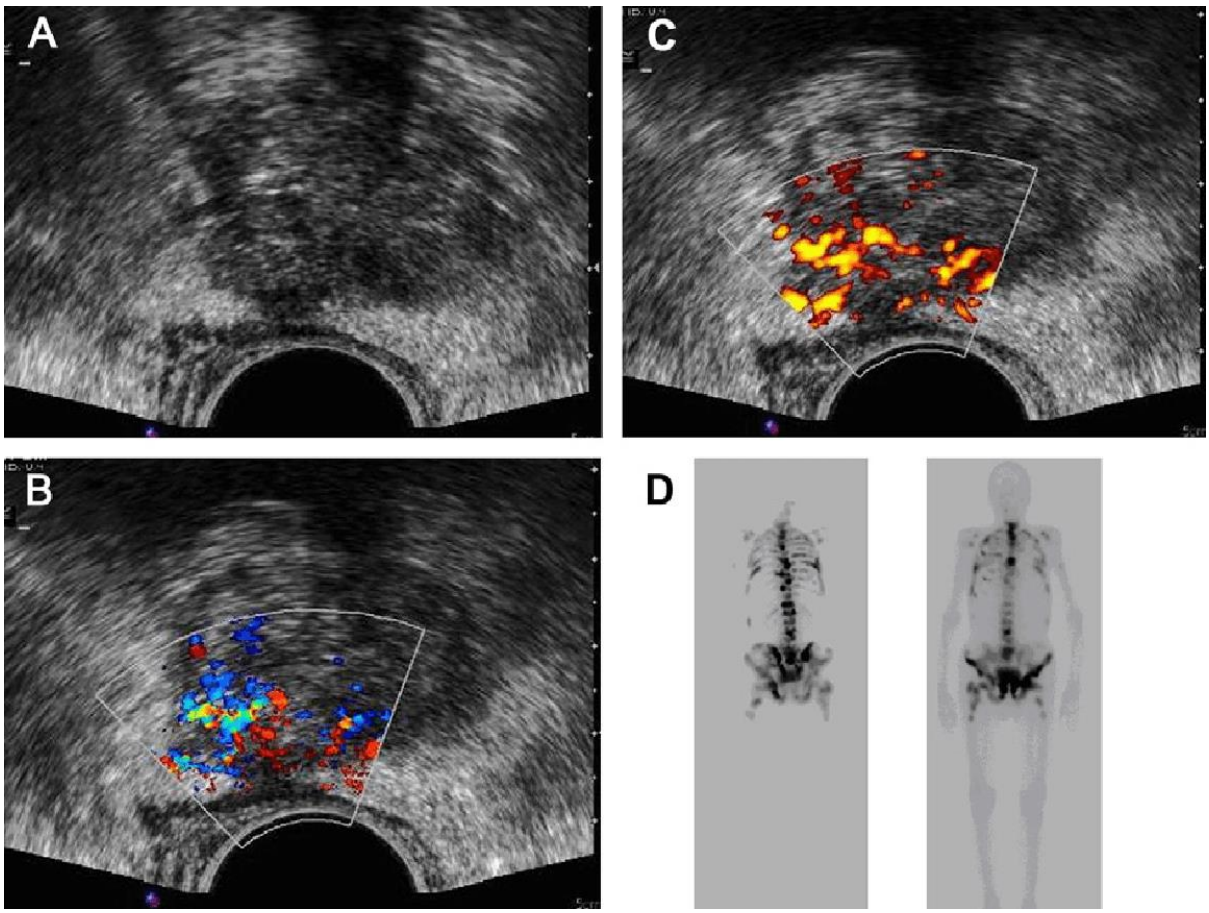
Transrectal ultrasound is performed in two projections: the prostate is imaged in transverse projection, then in sagittal projection. Then the prostate is scanned in the sagittal plane. This is possible due to the fact that the sensor is mounted on a special magnetic coil that rotates 180° when it is in the rectum.

After that, the ultrasound data of the prostate are processed by the HistoScan device. During processing, the histoscan creates three projections of the prostate. The first two - sagittal and transverse - are obtained by ultrasound.

Prostate with construction of a 3D model in 3 projections.

Prostate gland in 3 projections and 3D model with histoscopic tissue (suspected of prostate cancer) shown in green.

In the 3D model, the histoscan tissue (suspicious for prostate cancer) is shown in green.



Then, the HistoScan device (hereinafter referred to as histoscan), based on these data, independently constructs the third virtual plane of the prostate - frontal (cranial). Based on the information obtained from the three projections, the histoscan creates a 3D model of the prostate, which can be oriented in space according to the needs of the researcher.

After creating all the prostate projections and creating a 3D model, the researcher further defines the boundaries of the prostate, which he first defines independently. The ultrasound data of the prostate are then processed by the Histoscan device. Thus, in the 3D model, we obtained areas suspicious of prostate cancer. Then, a prostate map was created for biopsy, where the areas suspicious of prostate cancer were also marked.

In the third stage of the study, some patients with a high risk of cancer, i.e. some patients in groups 3 and 4, underwent MRI with an endorectal coil, and several of them additionally underwent CT scanning of the pelvic organs.

The fourth stage of the examination was a polyfocal transrectal biopsy of the prostate under ultrasound guidance for patients in groups 2, 3 and 4 (groups 1, 5 and 6 - control).

It should be noted here that, unlike patients of the first group, in this case, the prostate biopsy was performed according to the prostate maps obtained by histoscanning. To facilitate the evaluation of the results of the technique, each studied prostate is divided into 6 zones - sextants. Histoscan provides information in cubic centimeters about the volume of each of these sextants, as well as the volume of pathological tissue in a given sextant. The device then adds and displays the total volume of the gland, as well as the total volume of lesions suspicious for prostate cancer in the specific prostate studied. This information, due to computer processing, is more accurate than the size of the gland measured during ultrasound.

Note that the number of sextants for each patient is constant and equal to 6 (Figure 2). But the number of sites taken during biopsy varied and depended on the size and number of suspicious sites according to histoscopy. Biopsies from these areas were considered suspicious. We assessed the

presence or absence of a suspicious lesion based on the histoscopic data of a certain sextant and then on the morphological picture of this area - this is the first way to compare the data of histological examination and the morphological conclusion. The morphological results of the study were the gold standard for detecting prostate cancer. Then, the data from all studies were compared with each other.

Sextants in the prostate.

Prostate sextants - sagittal projection on the left, cranial on the right (suspected prostate cancer tissue is shown in pink)

Sagittal projection of the prostate on the left, cranial projection on the right. Pink in both projections indicates tissue suspicious for prostate cancer. Arrows in the cranial projection of the prostate indicate sextants.

Also, in order to optimize and simplify the calculation of the results of patient examination using histoscan, a second method for assessing the sensitivity and specificity of histoscan was developed. First, we counted the number of tissue cores obtained from suspicious areas during polyfocal prostate biopsy for each patient and summed their number. These were standard sutures of tissue taken from suspicious areas and additional sutures taken from suspicious areas. For example, the total number of suspicious columns of prostate tissue in the second group of patients was 2,684.

Second, in the same way, we calculated for each of these patients the number of columns of tissue obtained during polyfocal biopsies of the prostate from areas not modified according to histoscan. The number of these columns of prostate tissue was 3,700. In other words, the number of columns of non-suspect prostate tissue was 3,700. This number constitutes the standard column of prostate tissue.

Sampling scheme for tissue columns for prostate biopsy.

Tissue column sampling scheme for prostate biopsy

Prostate map, arrows indicate sites of additional tissue sampling during prostate biopsy. Thus, a total of 16 columns of prostate tissue were obtained from this patient: 12 standard and 4 from suspicious sites.

Histoscan map.

Histoscan Map - locations of collections in additional columns are indicated by arrows

Grid locations for additional messages are indicated by arrows.

Then, we evaluated the morphological image of all prostate tissue columns and compared it with the histoscan results.

After receiving these data, we calculated the sensitivity and specificity of the method for detecting prostate cancer using the Histoscan device.

In addition to the above, we developed a third method for assessing the morphological picture of suspicious areas according to histoscopic data, which consists in performing an additional postoperative biopsy after radical prostatectomy, in which both suspicious areas and unchanged tissues according to histoscopic data are taken. For this purpose, the removed gland is specially marked in 5 × 5 mm quadrants. This feature made it possible to correctly spatially project suspicious areas from histoscopy data into the prostate. After numbering the tissue columns, we sent them for morphological examination, which was performed blindly, i.e. the morphologists did not know which areas of the prostate they were examining (Figure 3).

Comparison of prostate mapping for blinded postoperative biopsy.

Photo of the removed prostate on the left, histoscopic plane on the right

On the left is a photograph of the removed prostate (specially marked 5x5 mm), on the right is a map taken from a histoscan (also marked 5 × 5 mm).

The data of the morphological study were then compared with the data of histoscopy. This comparison was carried out in collaboration with expert morphologists after radical prostatectomy. It should be noted here that there are several methods of postoperative assessment of the prostate. We used the following method: first, the entire prostate was cut by a morphologist as an "open book": sections of the organ were made from the base to the apex with a slice 2-3 mm thick and were incomplete. end, that is, in comparison with an open book, the area became "the binding of this book". The results of the morphological study fully confirm the data of the histoscan: according to the data of the histoscan, the node is macroscopically located in the right lobe, and during the morphological study, the node is adjacent to the prostate capsule in the right lobe (Fig. 5); .

Macroscopic specimen and map of the prostate.

A macroscopic sample of the prostate - part of the tumor tissue is surrounded in red

A. Macroscopic preparation of the prostate in open book view, with some tumor tissues circled in red.

Schematic map of the prostate - blue arrow indicates dotted line

B. Prostate map with dotted line indicated by blue arrow.

Thus, using histoscan data, 638 prostate biopsies were performed, their morphological results were compared with data from 67 prostate biopsies performed without histoscopic data, as well as with data from 53 morphological studies after prostatectomy.

Results

More than 700 patients suspected of having prostate cancer were examined by histoscopy.

It was found that during histoscopy, prostate cancer in the peripheral parts of the prostate is usually observed on a gray scale without suspicious foci, and the urethral area is stained and it looks like this on the map made during histoscopy. prostate with a light (gray) peripheral zone, where in the central zone (urethral projection zone) red or pink areas appear (false suspicious areas - a variant of the norm).

The following data were obtained by analyzing the possibilities of early diagnosis of prostate cancer by histoscopy. The majority of patients screened were patients with a baseline PSA level of less than 10 ng/mL. In the majority of patients in this category, none of the currently generally accepted non-invasive methods for diagnosing prostate cancer provided information about the presence of suspected prostate cancer. The number of patients in this group was 456, or 64.3% of all patients examined. At the initial stage, we predicted that the lower limit of the PSA level for this group would be 4 ng/ml, but during the study, we identified patients after histoscan examination, although the PSA level in the blood was normal (less than 4 ng/ml), a prostate biopsy is indicated.

In patients with suspected prostate cancer, a prostate biopsy was performed according to the prostate map obtained by histoscan. The number of prostate tissue columns obtained during biopsy is individual for each patient and varies depending on the size and number of areas suspicious for prostate cancer according to the histoscan data. As a rule, during transrectal biopsy, we collected 12 conventional tissue columns and one or more additional columns, depending on the presence of suspicious areas according to the histoscan data.

It should be noted that in 317 patients of the second group (patients with suspected prostate cancer with a PSA level of up to 10 ng/ml) during the classical polyfocal biopsy of the prostate, according to histoscopic data, suspicious, completely prostatic areas fell on the sampling sites. Accordingly, we did not obtain additional columns from these patients, and we marked as suspicious standard columns of prostate tissue from suspicious sites.

But in the remaining 139 patients in the second group, suspicious areas in standard biopsies were partially or completely not included in the tissue sampling sites. These patients had additional cores obtained during prostate biopsy that were marked as suspicious. Thus, a total of 6,384 columns of

prostate tissue were obtained for all patients in the second group, including 3,804 standard columns and 2,580 additional columns of prostate tissue.

The following method was developed to optimize and simplify the calculation of patient examination results using Histoscan. First, we counted the number of tissue cores obtained from suspicious areas during polyfocal prostate biopsy for each patient and added their number. These were standard sutures of tissue taken from suspicious areas and additional sutures taken from suspicious areas. The total number of suspicious columns of prostate tissue in the second group of patients was 2,684. Second, for each of the same patients, the number of columns of tissue obtained during polyfocal biopsy from unaffected areas of the prostate according to histoscopic data was calculated. the same. The number of these columns of prostate tissue was 3,700. That is, the number of columns of non-suspect prostate tissue is 3,700. This number corresponds to the standard column of prostate tissue.

Then, we evaluated the morphological image of all prostate tissue columns and compared it with the histoscan results.

By comparing the results, the following information was obtained. Of the 2,684 prostate tissue samples collected from suspicious sites, 2,389 were found to have prostate cancer. Of the 2,684 suspected high-grade PINs, 157 were morphologically identified in the prostate tissue. Of the 2,684 suspicious columns, 138 columns were labeled “no cancer or stage III PIN code.”

Additionally, out of 3,700 non-suspect columns of prostate tissue, we found prostate cancer in 22 years.

After obtaining these data, we calculated the sensitivity and specificity of the histoscan method in early detection of prostate cancer. The total number of prostate columns obtained during biopsy from all patients in the second group was 6,384. The number of prostate columns with suspicious areas during histoscopy was 2,684. detected during histoscopy, during which cancer was confirmed according to morphology, was 2389.

Thus, a statistical treatment was established: the sensitivity of histoscan in the early diagnosis of prostate cancer is 89%, the specificity is 96%.

During histoscopy, suspicious areas were identified, the number of prostate tissue columns with a high-level PIN code according to their morphology was 157. Of this total, the false-positive result of histoscanning was determined, which was 11%. and the false-negative result was 0.6%.

In addition, in cooperation with morphologists, a method of macroscopic diagnosis during morphological examination was developed. We developed a technique for counting sextants in the prostate. When mapping the prostate after histoscopy, sextants were obtained when the glands were automatically divided into 6 zones. Thus, the total number of sextants for the second group is determined by the following formula: the number of patients in the group is multiplied by six ($456 \times 6 = 2736$).

For each patient, in addition to the evaluation of tissue columns, the results of prostate histoscopy were evaluated using sextants, that is, we evaluated the prostate map, where the areas suspicious for prostate cancer were drawn. In each specific case, the number of sextants involved was determined, and then the morphological picture of these sextants was compared.

Later, after prostate biopsy, in collaboration with expert morphologists, a correspondence was established between the location of the tumor focus according to the histoscan data and the morphological study of prostate tissue biopsies.

The following information was obtained. In the second group, 456 studies were conducted in patients with PSA levels up to 10 ng/ml. The total number of sextants for the second group is 2,736 ($6 \times 456 = 2,736$). Of the total number of sextants, 1,642 are sextants in which suspicious areas were identified based on histoscopic data. A positive result was obtained in 1,445 sextants when evaluating morphological data. In other words, according to the results of histoscopy, prostate

cancer was morphologically confirmed in 1,445 out of 1,642 sextants with suspicious areas. Thus, the sensitivity of histoscan in the second group using sextant evaluation in the statistical processing of the obtained data confirms the sensitivity data in the evaluation of biopsy cores and is equal to 88%.

Analyzing the data obtained after the morphological evaluation of histoscopy results, we first determined our data on the sensitivity and specificity of the histoscanning technique. The sensitivity of the histoscopy technique in the early diagnosis of prostate cancer was 88%, and the specificity was 96%. Our data confirm the European data and clearly show that histoscopy is the most effective non-invasive method for the early diagnosis and localization of prostate cancer. Histoscan also allows you to plan a biopsy, create a prostate map, and then plan your treatment. According to our data, histoscopy is very effective in detecting lesions suspicious of prostate cancer at an early stage. At these stages, neither digital rectal examination nor ultrasound data - TRUS and Doppler provide such information about the prostate tumor.

Patients with low cancer risk and localized prostate cancer underwent radical prostatectomy. After radical prostatectomy, in close cooperation with expert morphologists, the results of histoscopy were evaluated and compared with the results of pathological examination of the organ. We implemented the technique of blind biopsy of the prostate after surgery. The essence of the technique is that the gland removed after radical prostatectomy is specially marked in quadrants measuring 5 × 5 mm. Later, according to the prostate map, a postoperative biopsy was performed. During the biopsy, areas suspicious of prostate cancer according to histoscopy and not affected by histoscopy were removed. After numbering the tissue columns, they were sent to a morphological study, performed blindly, i.e. 53 comparisons. Macroscopic concordance of prostate cancer with histoscopic data was found in 2 cases. I would like to emphasize here that macroscopically, prostate cancer areas are rarely visible. According to the postoperative biopsy, it was found that the histoscopic data corresponded to the morphological data of the research in 88% of cases, which further confirms our data on the sensitivity and specificity of the technique in the first group of patients.

Later, by analyzing the data obtained after the morphological evaluation of histoscopy results in the third group of patients, we obtained data on the sensitivity and specificity of the histoscanning technique. For patients in the third group, the sensitivity of the histoscopy technique for the diagnosis of prostate cancer was 96%, and the specificity was 97%. We can also compare the sensitivity and specificity of histoscanning and magnetic resonance imaging. Histoscopy is superior to existing non-invasive methods for diagnosing prostate cancer.

After the morphological evaluation of histoscopy results in the fourth group of patients, we obtained information about the sensitivity and specificity of the histoscanning technique. In patients of the fourth group, the sensitivity of the histoscopy technique for the diagnosis of prostate cancer was 99% and the specificity was 97%. We can also compare the sensitivity and specificity of histoscanning and magnetic resonance imaging.

I would like to emphasize that the first group of patients was determined to evaluate the effectiveness of prostate biopsy without histoscanning and without histoscanning - a retrospective evaluation. Thus, the effectiveness of prostate biopsy without histoscopy was 50%, with the help of histoscopy it increased by 22% and reached 72%, respectively.

Thus, our data (Table 4) confirm the European data and clearly show that histoscopy is the best non-invasive method for early diagnosis and localization of prostate cancer [5].

Summary

So, usually on the histoscopic map, the prostate is presented as a prostate with a light (gray) peripheral zone, where red or pink areas appear in the central zone (urethral projection zone). On the histoscopic map, prostate cancer is presented as red or pink colored areas, the total volume of which exceeds 0.2 cm^3 in a sextant. Staining of the urethral zone does not indicate the presence of prostate cancer. The histoscopic map with prostatic hyperplasia shows colored areas in the urethral

zone (normal variant), and small scattered colored areas appear on the sextant, the total volume of which does not exceed 0.2 cm³. When the clinical and morphological comparison of the results of histoscopy and the data of morphological examination was determined, in 91% of cases it was found that the localization and size of prostate cancer foci were completely consistent. Histoscan has a sensitivity of 88% and a specificity of 96% for detecting prostate cancer in patients with a PSA level of 4 to 10 ng/ml; In patients with a PSA level of 10 to 20 ng/ml, the sensitivity of histoscan is 96%, the specificity is 97%; In patients with a PSA level above 20 ng/ml, the sensitivity is 99%, the specificity is 97%. The information content of a prostate biopsy using histoscan data is 22% higher than without prior mapping of the prostate with a histoscope. Histoscopy is an additional non-invasive method for the early diagnosis of prostate cancer, which allows to increase the information content of prostate biopsy and is not intended to assess extracapsular spread of prostate cancer, the state of paraprostatic tissue and regional adenopathy.

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