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Modern Diagnosis of Early Symptoms of Prostate Cancer

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

In the first group of 67 patients, 15 (22.3%) had areas suspected of prostate cancer on digital rectal examination (Table 2). According to the World Health Organization (WHO), the incidence of prostate cancer is steadily increasing worldwide and it is the third most common type of 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 prostate cancer at various stages [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 a 100% statement about the presence of prostate cancer [2, 3].

In this context, the revolutionary HistoScan device has been developed and is successfully used to improve the diagnosis and detection of oncological processes in the prostate at early stages [5]. It is a patented technology for differentiation, characterization and imaging of prostate tissue based on ultrasound backscatter analysis. This device can perform ultrasound examination of the prostate with high accuracy and identify areas of suspicious tissue for cancer. Thus, Histoscan allows to suspect prostate cancer (stage T 1 – T 2). By presenting 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, to take targeted tissue samples during biopsy, to reduce the number of tissue columns from biopsy material, as well as reducing the non-radical state allows observation. cancer therapies, and in addition, we are considering the possibility of targeted application of Histoscan mapping during focal therapy of prostate cancer.

Key points: Materials and methods, histoscanning map, prostate sextants.

Materials and methods

Our work was aimed at identifying people with prostate cancer and verifying the diagnosis using both known diagnostic methods (prostate-specific antigen PSA, digital rectal examination, transrectal ultrasound, transrectal Dopplerography of prostate vessels) and a new method - histoscopy. . As part 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 in terms of early detection of cancer, the accuracy of staging the process, as well as the impact of the results obtained on planning a polyfocal prostate biopsy and the choice of subsequent treatment tactics were determined.

Initially, a retrospective group of patients (hereinafter referred to as the first group) was identified and studied - 67 patients with suspected prostate cancer underwent a prostate biopsy from 2009 to 2011. He conducted 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 free according to the instructions (PSA total > 4 ng / ml) and PSA density), general urinalysis, 3-cup test, uroflowmetry, transabdominal and transrectal ultrasound of the prostate, as well as Doppler ultrasound of the veins of the prostate, then transrectal polyfocal biopsy was performed.

To directly address the objectives of our study, we subsequently examined 701 patients with the Histoscan device. All of these patients underwent the standard diagnostic complex mentioned above. The distribution of prostate-specific antigen levels in them was between 1.09 and 209 ng/ml.

Patients with high PSA levels who underwent histoscopy were divided into three groups based on the degree of increase. Thus, 67 patients (to compare the results of prostate biopsy 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.

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

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

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

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

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

The transrectal ultrasound examination is performed in two projections: the prostate is visualized in a transverse projection, then in a sagittal projection. The prostate is then scanned in the sagittal plane. This is possible because the sensor is mounted on a special magnetic coil that rotates 180° in the rectum.

The ultrasound data of the prostate is then processed by the HistoScan device. During processing, Histoscan creates three projections of the prostate. The first two: sagittal and transverse - are obtained by ultrasound examination.

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

Prostate in 3 projections and 3D model with histoscopy tissue (suspicious for prostate cancer), shown in green.

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

Then, based on this data, the HistoScan device (hereinafter referred to as Histoscan) 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 the researcher can orient in space as required.

After all the projections of the prostate have been created and a 3D model has been created, the researcher further defines the boundaries of the prostate, which he initially defines independently. The ultrasound data of the prostate is then processed by the Histoscan device. This is how we identified suspicious areas for prostate cancer in the 3D model. A map of the prostate was then created for biopsy, on which suspicious areas for prostate cancer were also marked.

In the third phase of the study, some patients at high risk of cancer, i.e. some patients in groups 3 and 4, underwent an MRI with an endorectal coil, and some of them also underwent a CT scan of the pelvic organs.

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

It should be noted that, unlike the patients in the first group, in this case the prostate biopsy was performed using the maps of the prostate obtained by histoscanning. To better evaluate the results of the technique, each examined 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 particular sextant. The device then adds up and displays the total volume of the gland, as well as the total volume of lesions suspicious of prostate cancer in the examined prostate gland. This information, due to computer processing, is more accurate than the size of the gland measured during ultrasound examination.

It should be noted that the number of sextants for each patient is constant and is 6 (Figure 2). However, the number of sites taken during biopsy varied and depended on the size and number of suspicious spots 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 in a particular sextant and then the morphological picture of this area - this is the first way to compare the histological examination data and the morphological conclusion. The morphological results of the study were the gold standard for detecting prostate cancer. Then the data of all studies were compared with each other.

Sextants in the prostate.

Prostate sextants – left sagittal projection, right cranial (tissue suspected of prostate cancer is shown in pink)

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

In addition, to optimize and simplify the calculation of patient examination results using Histoscan, a second method was developed to evaluate the sensitivity and specificity of Histoscan. First, for each patient, we counted the number of tissue cores taken from suspicious areas during polyfocal prostate biopsy and summed their number. These were standard sutures of tissue from suspicious areas and additional sutures from suspicious areas. For example, the total number of suspicious prostate tissue columns in the second group of patients was 2684.

Second, in the same way, for each of these patients, we calculated the number of tissue columns obtained in polyfocal prostate biopsies from areas that were not altered according to histoscan. The number of these prostate tissue columns was 3700. That is, the number of columns containing non-suspicious prostate tissue was 3700. This number represents the standard column of prostate tissue.

Sampling scheme for tissue columns for prostate biopsy.

Sampling scheme for tissue columns for prostate biopsy

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

Histoscan map.

Histoscan map – locations of additional column collections are indicated by arrows

Grid positions for additional posts are indicated by arrows.

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

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

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

Comparison of prostate mapping for blinded postoperative biopsy.

Left photo of the removed prostate, right histoscopy map

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

Then the morphological study data were compared with the histoscopy data. This comparison was carried out together with experienced morphologists after radical prostatectomy. It should be noted here that there are several methods for postoperative assessment of the prostate. We used the following method: first, the entire prostate was cut by a morphologist like an “open book”: sections of the organ were made from the base to the apex with a cut 2-3 mm thick and were incomplete. End, that is, in comparison with an open book, the zone became the “cover of this book”. The results of the morphological study fully confirm the histoscan data: according to the histoscan data, macroscopically the node is 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 prostate map.

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

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

Schematic map of the prostate – blue arrow indicates dashed line

B. Prostate map with dashed line indicated by a blue arrow.

Using histoscan data, 638 prostate biopsies were performed and their morphological findings were compared with the data of 67 prostate biopsies without histoscopic data and with the data of 53 morphological studies after prostatectomy.

Results

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

It was found that during histoscopy, prostate cancer in the peripheral parts of the prostate is usually visible on a gray scale without suspicious foci, and the urethral zone is colored and looks like this on the map obtained during histoscopy. Prostate with a clear peripheral zone (gray), with red or pink

areas appearing in the central zone (projection area of the urethra) (false suspicious areas - a variant of the norm).

The following data were obtained when analyzing the possibilities of early detection of prostate cancer using histoscopy. The majority of patients examined 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 evidence of the presence of suspicion of prostate cancer. The number of patients in this group was 456, or 64.3% of all patients examined. At the initial stage, we planned that the lower limit of the PSA level for this group would be 4 ng/ml, but during the study we identified patients after the Histoscan examination, although the PSA level in the blood was normal (less than 4). ng/ml), a prostate biopsy is indicated.

In patients suspected of having prostate cancer, a prostate biopsy was performed based on the prostate map created with the Histoscanner. The number of prostate tissue columns taken during the biopsy is individual for each patient and varies depending on the size and number of suspicious areas for prostate cancer according to Histoscan data. Typically, during the transrectal biopsy, we took 12 conventional tissue columns and additionally one or more columns depending on the presence of suspicious areas according to 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), in the classic polyfocal biopsy of the prostate, according to histoscopic data, suspicious areas, completely prostate fall on sampling sites. Accordingly, we did not receive additional columns from these patients, and standard columns of prostate tissue from suspicious sites were marked by us as suspicious.

However, in the remaining 139 patients in the second group, suspicious areas were partially or completely omitted from the tissue sampling sites during standard biopsies. In these patients, additional cores were taken during the prostate biopsy and marked as suspicious. Thus, a total of 6384 columns of prostate tissue were obtained for all patients in the second group, of which 3804 were standard columns and 2580 were additional columns of prostate tissue.

In order to optimize and simplify the calculation of patient examination results using Histoscan, the following method was developed. First, for each patient, we counted the number of tissue cores taken from suspicious areas during polyfocal prostate biopsy and summed their number. These were standard sutures of tissue from suspicious areas and additional sutures from suspicious areas. The total number of suspicious prostate tissue columns in the second group of patients was 2684. Second, for each of the same patients, the number of tissue columns obtained from unaffected areas of the prostate during polyfocal biopsy according to histoscopic data was calculated. the same. The number of these prostate tissue columns was 3700. That is, the number of columns with non-suspicious prostate tissue is 3700. This number is the standard column with prostate tissue.

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

Comparing the results, the following information was obtained. Of the 2,684 prostate tissue samples obtained 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."

In addition, over a period of 22 years, we have identified prostate cancer in 3,700 non-suspicious collections of prostate tissue.

Having obtained these data, we calculated the sensitivity and specificity of the Histoscan method in the early detection of prostate cancer. The total number of prostate columns obtained during biopsy from all patients in the second group was 6384. The number of prostate columns with suspicious areas during histoscopy was 2684. During histoscopy, cancer was confirmed by morphology, 2389 people were detected.

Accordingly, the statistical processing was established: The sensitivity of the 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 these, the false positive result of histoscanning was determined, which was 11%, and the false negative result was 0.6%.

In addition, in collaboration with morphologists, a method of macroscopic diagnosis in morphological examination was developed. We have developed a technique for counting sextants in the prostate. When mapping the prostate after histoscopy, sextants were obtained by automatically dividing the glands into 6 zones. Accordingly, 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 × 6 = 2736).

For each patient, in addition to the evaluation of the tissue columns, the results of the histoscopy of the prostate using sextants were evaluated, ie we evaluated the map of the prostate on which suspicious areas for prostate cancer were marked. In each individual case, the number of affected sextants was determined and then the morphological picture of these sextants was compared.

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

The following information was obtained. In the second group, 456 studies were conducted on patients whose PSA level increased to 10 ng/ml. The total number of sextants for the second group is 2736 (6 × 456 = 2736). Of the total number of sextants, 1642 are sextants in which suspicious areas were identified based on histoscopy data. When evaluating morphological data, a positive result was obtained in 1445 sextants. That is, according to the results of histoscopy, prostate cancer was morphologically confirmed in 1445 out of 1642 sextants with suspicious areas. Thus, the sensitivity of histoscan in the second group using sextant evaluation in statistical processing of the obtained data confirms the sensitivity data when evaluating biopsy cores and is 88%.

By analyzing the data obtained after the morphological evaluation of the histoscopy results, we first determined our data on the sensitivity and specificity of the Histoscan technique. The sensitivity of the histoscopy technique in the early diagnosis of prostate cancer was 88%, and the specificity was 96%. Our data confirm European data and clearly show that histoscopy is the most effective non-invasive method for early detection and localization of prostate cancer. Histoscan also allows you to plan a biopsy, create a map of the prostate 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 are available - TRUS and Doppler sonography 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 experienced morphologists, the results of histoscopy were evaluated and compared with the results of pathological examination of the organ. We put into practice 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 of 5 × 5 mm. Later, a postoperative biopsy was performed according to the prostate card. During the biopsy, areas that were suspicious for prostate cancer according to histoscopy and were not affected by histoscopy were removed. After the tissue columns were numbered, they were subjected to a morphological study, which was performed blindly, so 53 comparisons were made. In 2 cases, macroscopic correspondence of prostate cancer with histoscopic data was noted. At this point I would like to note that prostate cancer areas are rarely visible macroscopically. According to postoperative biopsy, it was found that the histoscopic data in 88% of cases corresponded to the morphological research data, 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 the histoscopy results in the third group of patients, we obtained data on the sensitivity and specificity of the histoscan technique. In the patients of the third group, the sensitivity of the histoscopy technique in diagnosing 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 the existing non-invasive methods for diagnosing prostate cancer.

After 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 in diagnosing prostate cancer was 99% and the specificity was 97%. We can also compare the sensitivity and specificity of histoscan 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 the use of 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 European data and clearly show that histoscopy is the best non-invasive method for early detection and localization of prostate cancer [5].

Summary

Thus, on the histoscopy map, the prostate is usually depicted as a prostate with a clear peripheral zone (gray), with red or pink areas appearing in the central zone (projection area of the urethra). On the histoscopy map, prostate cancer is represented by red or pink colored areas, the total volume of which exceeds 0.2 cm^3 in a sextant. Discoloration of the urethral area 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 cm^3. When comparing the results of histoscopy and morphological examination data clinically and morphologically, it was found that in 91% of cases the location and size of the 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 based on Histoscan data is 22% higher than without prior mapping of the prostate with a histoscope. Histoscopy is an additional non-invasive method for early detection of prostate cancer, which allows to increase the information content of the prostate biopsy and is not intended to assess the extracapsular spread of prostate cancer, the condition of the paraprostatic tissue and regional lymphadenopathy.

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