LITERATURE REVIEWS

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ROBOT-ASSISTED PROSTATECTOMY FOR PT3. ONCOLOGICAL AND FUNCTIONAL OUTCOMES

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In 2020, prostate cancer (PCa) ranked third in the structure of the most significant oncological diseases. In the Russian Federation, in terms of the frequency of detection among men, prostate cancer is second only to tumors of the upper respiratory tract and lungs, accounting for 14.9%. Radical prostatectomy (RP) in various modifications is still the most common treatment for localized prostate cancer, despite the existence of alternatives such as active surveillance, hormonal and radiation therapy, cryoablation, and others. And the technological pinnacle of the surgical treatment of prostate cancer at the moment is robot-assisted prostatectomy, the widespread use of which was marked by the publication of J. Binder back in 2002. This technology combined the advantages of minimally invasive laparoscopic RP with improved surgeon ergonomics and technical ease of vesicourethral anastomosis reconstruction and has now become the preferred minimally invasive approach. This article will consider the use of a robot-assisted technique in the stage of T3 prostate cancer.

K e y w o r d s: prostate cancer, robot-assisted prostatectomy, stage pT3

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In 2020, prostate cancer (PCa) took third place in the structure of the most prevalent oncological diseases [1]. In the Russian Federation, PCa is the second only to upper respiratory tract and lung tumors, amounting to 14.9% of all malignant lesions [2]. Radical prostatectomy in various modifications still remains the most common and only definitive treatment for localized PCa, despite the availability of active surveillance, hormonal and radiation therapy, cryoablation and others [3]. The technological pinnacle of surgical treatment of PCa at the moment is robot-assisted prostatectomy (RARP), the popularization of which was marked by the publication of J. Binder back in 2002 [4]. This technology combined the advantages of minimally invasive laparoscopic radical prostatectomy (LRP) with improved ergonomics and technical ease of vesicourethral anastomosis creation and has now become the preferred approach. The first comparative studies were presented already in 2003, when A. Tewari et al. demonstrated the advantages of robotic technology over open radical prostatectomy (ORP), mainly in the aspect of urinary continence [5]. A randomized phase III trial demonstrated in 2016 that RARP reduced hospitalization time and intraoperative blood loss in comparison with OPR, providing similar oncological outcomes [6]. It should be noted in that study a robotic surgeon had experience in 200 procedures, while a surgeon who performed ORP had experience in about 1500 cases [7]. Currently, more and more scientific works are being published, according to which ORP, LRP and RARP are equally effective, and the results depend mainly on the qualifications and experience of the surgeon [8, 9]. Most of publications include patients with clinical stages T1–T2. In this regard, the issue of expanding the indications for RARP and studying the oncological results in men with a stage T3 becomes extremely relevant.

One of the first publications which it would be logical to begin this review with is a work of Vipul R. Patel from November 2006, presenting the results of 500 patients with PCa who underwent RARP. Among them, 15% (75) had pathological stage T3a and 5% (25) had stage T3b. The results showed that stage T3 is not associated with the increased incidence of intraoperative complications. After one year, 95% of patients didn't have biochemical relapse (prostate-specific antigen level [PSA] was <0.1 ng/ml) [10].

Six years later, in 2012, a large meta-analysis under the leadership of Novara with the participation of Alexandre Mottrie and Vipul R. Patel was published in European Urology that examined the oncological results of RARP. Data from 12,900 patients were evaluated. One of the

studies was carried out by Nazareno Suardi in 2012, where the 5-year oncological outcomes of patients with high-risk PCa who underwent RARP were assessed [11]. It involved 184 patients treated in ORSI Hospital (Aalst, Belgium). The average age of patients was 62 years, PSA 8.7 ng/ml. A total of 56 (30.4%) men had clinical stage T3a, 15 (8.2%) had stage T3b, Gleason score was 6 or lower in 111 (60.5%), 7 in 53 (29 %) and 8–10 in 20 (10.5%) cases. The median follow-up was 67.5 months. Disease-free survival for patients with stage T3a during 3.5 and 7 years of follow-up was 94%, 84 and 84% compared to 69%, 43 and 43% for stage T3b, respectively.

In 2014, Mehrdad Alemozaffar published a paper in European Urology, dedicated to the postoperative results of RARP and ORP. The authors included 903 patients who underwent ORP (n=621) or RARP (n=282) between 2000 and 2010. Of the 282 patients in RARP group, 22.2% had a stage T3. The 5-year disease-free survival rate in RARP group was 88.0%.

In the same year and in the same journal, Jim C. Hu et al. presented a large retrospective analysis of 13,402 men with PCa, comparing the efficiency of ORP (n=7878) and RARP (n=5524) between 2004 and 2009 in terms of tumor progression [12]. The study revealed an interesting finding regarding the incidence of positive margins in stage T3a. In RARP group, it was 28.8% (286) compared with 37.2% (334) in ORP group. This work also demonstrated the advantage of RARP in terms of relapse-free survival, since lower proportion of patients received additional therapy (radiation or hormonal) within 12 (95% CI: 0.79) and 24 (95% CI: 0.72) months.

In February 2017, Lei Wang et al. published a large meta-analysis in Springer Science that assessed 5- and 10-years oncological outcomes in patients who underwent RARP. A total of 19,954 patients from 20 studies were analyzed. From them, 34.5% (n=6884) had pathological stage T3. The 5-year disease-free survival rate in the high-risk group was 71% (95% CI: 0.66–0.77). The cumulative 5-year cancer-specific survival rate was 97% (95% CI: 0.96–0.98). No significant heterogeneity or publication bias was noted. When studies were stratified by preoperative PSA level, 5-year cancer-specific survival was 97% (95% CI: 0.96–0.99) for low- and intermediate-risk and 98% (95% CI: 0.96–0 ,99) for high-risk PCa. When studies were stratified by time to adjuvant therapy, 5-year cancer-specific survival was 98% (95% CI: 0.95–0.99) for patients who did not receive adjuvant therapy and 97% (95% CI: 0 .96–0.98) for those receiving adjuvant therapy after the development of biochemical relapse. During the 10-year follow-up, 79% (95% CI: 0.72–0.86) out of 11,408 patients didn't have any signs of the disease [17].

One of the key studies comparing RARP with other surgical treatments for PCa, in particular LRP, was presented in November 2016 in European Urology by Francesco Porpiglia et al. [18]. The authors carried out a prospective randomized controlled trial comparing 5-year oncologic outcomes between LRP and RARP. The study included 120 patients with localized PCa who were treated from 2010 to 2011. PSA levels were assessed after 1, 3, 6 and 12 months with subsequent measurements every 6 months within 5 years. Patients with stage T3 accounted for 36.7% (22 people) in both groups. RARP has demonstrated an undeniable functional advantage. Relapse-free survival of patients in both groups was comparable and amounted to 81.6% during the 5-year follow-up.

In July of 2016, Huang Xing et al. published a large meta-analysis in Springer that compared intraoperative, functional, and oncologic outcomes between LRP and RARP. A total of 9178 patients were included in the meta-analysis (n=5064 and 4114, respectively). A stage pT3 was diagnosed in 383 patients in LRP group and in 359 in RARP group. It is worth emphasizing that the rate of positive surgical margins was approximately the same and amounted to 35.8 and 34.3%, respectively.

John W Yaxley et al. in 2016 demonstrated the results of a landmark phase III randomized trial that compared oncological outcomes after ORP and RARP [19]. A total of 326 patients undergoing surgery at the Royal Brisbane & Women's Hospital (RBWH) from 23/08/2010 to 25/11/2014 were randomized. Both groups included 163 patients. Stage pT3 was diagnosed in 30 (10%) patients, including 12 (8%) after ORP and 18 (11%) in RARP group. RARP was shown to be advantageous in terms of such parameters as operation time, volume of blood loss and length of hospitalization.

Another interesting work was presented in the European Urology in April 2017 by Annika Herlemann et al. The publication also assessed surgical outcomes after open and robotic prostatectomy [20]. In addition to oncological outcomes, urinary continence and erectile function were also evaluated. The study included 1892 patients with localized PCa who had undergone radical prostatectomy and did not have neoadjuvant and/or adjuvant therapy. ORP group included 1137 patients vs. 755 in RARP group. Stage pT3 was confirmed in 112 (10%) and 116 (17%), respectively. Authors concluded that the rate of positive margins was approximately equal between the groups (9% vs. 10%, respectively). Disease-free survival rates were also similar (87% vs. 85%).

Concerning the quality of life after surgery, it is necessary to mention the prospective study of Anna Wallerstedt, published in the European Urology Focus in December 2017 [21], which compared ORP and RARP. Data from 4,003 men from 14 different clinics were analyzed. There were 942 men in ORP group, and 2764 in RARP group. According to the results of the morphological study, stage pT3 was diagnosed in 252 (28%) patients in ORP group and 753 (28%) in RARP group. It should be noted that, even significant percentage of patients had pT3 stage, there were no differences in quality of life within 24 months between two approaches.

In 2018, Lan Cao et al. presented a meta-analysis in the Open Medicine, which compared RARP, LRP and ORP. In addition to oncological results, operation time, intraoperative blood loss, frequency of blood transfusion, hospitalization time, catheterization and other complications were also assessed. The meta-analysis included 8522 patients from 11 studies (5051 in RARP/LRP group, 3471 in ORP group). It is noteworthy that in the subgroup of patients with PCa of stage ⩾pT3, the rate of positive margin was lower in RARP/LRP than in ORP group (41.4% [434/1049] vs. 50.1% [419/830], respectively). Taking this into account, there was no clinically significant difference in the rate of biochemical relapse after 3 (OR=0.74, 95% CI: 0.32–1.73, p=.49), 12 (OR=1.60, 95% CI: 0.41–6.15, p=0.50), and 24 months (OR=0.63, 95% CI: 0.38–1.06, p=0.08). Regarding

urinary continence, no significant advantages were found for any of methods [22].

The results of one of the key studies (LAPRO) comparing functional and oncological outcomes between ORP and RARP were published on April 16, 2018 in the European Urology [23]. Of the 2,625 participants, 1,847 were undergone to RARP and 778 to ORP. A pathological stage T3 was detected in 511 (28%) and 190 (24%) cases, respectively. As in many similar studies, the incidence of urinary continence disorders between groups was virtually the same and amounted to 19 and 16% in the RARP and ORP groups, respectively. There was no clinically significant difference in oncologic outcomes at 24 months. Biochemical relapse was found in 12.5% of patients after RARP and 13.1% after ORP.

Authors from the UAE presented a similar study in October 2020 with a follow-up of 19 months, which compared ORP and RARP [24]. They randomized men who underwent open or robotic procedure between 06/01/2013 and 10/01/2016. There were 211 men in RARP group, including 27 (21.6%) patients with stage pT3a, while ORP group involved 67 men, from whom 14 (23.7%) had stage pT3a. The results showed that RARP was superior in terms of mean hospital stay (4 days vs. 5 days), postoperative blood transfusion rate (2.4% vs. 10.2%), and severity of pain syndrome. In ORP group, the average amount of nonsteroidal anti-inflammatory drugs per patient was 52 mg, compared to 34 mg in RARP group. Oncologic outcomes were not significantly different. The rates of positive surgical margins were 28.8 and 24.8%, respectively. The biochemical recurrence rate was also similar (16.9% in ORP group vs. 13.6% in RARP group), as well as recurrence-free survival over 3 years (72.9% vs. 75.7%, respectively). When analyzing the results, should be mentioned that for all oncological outcome p was >0.05.

Wang Deng et al. carried out a study comparing RAR and LRP, which was published in Frontiers in Oncology in September 2021 [25]. The authors retrospectively analyzed the data of 231 patients who were treated in Nianchang University Hospital in China, including 126 men in RARP group and 105 in LRP group. Postoperative morphological study showed that stage pT3 was detected in 33 (26.2%) and 20 (19.0%) patients, respectively. Notably, the rate of positive surgical margins was slightly lower in RARP group (24.2% vs. 30.0%).

In February 2021, Zilberman et al. published the results of a small but essential study in the Israel Medical Association Journal, which assessed the oncological outcomes of patients with clinical stage T3 after RARP [26]. The study included 79 men who underwent RARP at Sheba Medical Center in Tel Aviv from 2010 to 2018. The PSA level, the biochemical relapse rate and the need for salvage treatment within 3-6 months were assessed. The average age of the patients was 64 years. The perioperative PSA level was 7.14 ng/ml, the average prostate volume was 53 cc. Downstaging to T2 stage was seen in 23 patients, while the rate of positive surgical margins was 42%. Median follow-up was 74 months. The overall 5-year disease-free survival rate was 61%, while cancer-specific survival rate was 92%.

The important work of Taiwanese colleagues led by Ching Wei Yang was published in Scientific Reports on July 12, 2021. The authors' goal was to retrospectively evaluate the rate of positive margins and biochemical recurrence after RARP in 419 patients who were treated from December 2010 to January 2018 at Taipei Veterans General Hospital [27]. According to the morphological study, 44.8% of patients had a stage pT3a and 11.8% stage pT3b. The rate of positive surgical margins in stage T3 was 43.6%, which is comparable to or better than the results with ORP demonstrated in most studies. In addition, this trial showed that the key factor in the development of biochemical relapse is the initial PSA level, rather than the presence of a positive surgical margin.

The Da Vinci® Surgical System has rapidly gained popularity around the world due to its 3D, 10x magnification view of the surgical field, as well as the increased flexibility, maneuverability and precision of movement achieved through the integration of EndoWrist® technology. Despite its technical and financial issues, robotic surgery is confidently replacing traditional open procedures for many diseases. In the early days of robotic surgery, critics warned the scientific community that the lack of tactile feedback, as well as the educational opportunities available at the time, would negatively impact oncology results. This has led to more careful selection of patients with PCa in routine practice as well as in clinical trials, which is why the majority of them are clinical stage T1-2. In this review, we presented comparative studies and meta-analyses, which focused on patients who were diagnosed with a stage pT3. Based on the results, it should be noted that there were no advantages of OPR or LRP in this subgroup. RARP seems to be better, or at least no worse, than other procedures in both oncologic and functional outcomes. However, two comparative studies and one review report a clinically significant benefit of RARP in the postoperative quality of life.

Thus, we can conclude that RARP is a safe and effective procedure for PCa of stage pT3 and, probably, the indications should be reviewed, expanding them to T3 tumors.

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