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LAPAROSCOPIC RESECTIONS WITH TRANSANAL SPECIMEN EXTRACTION IN RECTAL CANCER SURGERY (a systematic review and meta-analysis)

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INTRODUCTION: the NOSES technique allows one to remove specimen without incisions on the anterior abdominal wall and is accompanied by fewer complications by reducing the incidence of wound infections. The results of these surgeries on colorectal tumors are presented in a limited number of heterogeneous studies, which necessitates obtaining objective data using meta-analysis.
AIM: to compare the immediate and long-term outcomes of two methods for surgical treatment of colorectal cancer.
MATERIALS AND METHODS: a systematic review was carried out in accordance with PRISMA practice and recommendations.
RESULTS: nine comparative studies were selected for the period from 2014 to 2019.
1,693 patients were included in the meta-analysis: in 765 (45%), the tumor specimen was removed transanally (NOSES group) and in 928 (55%) it was removed via minilaparotomy (LA group). The tumor size in the NOSES group was 0.5 cm smaller (OR=0.5, CI95% 0.2-0.8, p=0.0004) than in the LA group. In regards to the other parameters the groups had no publication bias. The surgery duration when comparing NOSES with LA was comparable (p =0.11). The VAS pain was on average 2 points (OR=1.8, CI95% 1.2-2.4, p<0.00001) more pronounced in the LA group. The postoperative hospital stay was less in the group with transanal specimen removal (OR=0.8, CI95% 0.4-1.3, p=0.0003). The chance of developing postoperative complications in the NOSES group was (OR=0.5, CI95% 0.4-0.8, p=0.0004) with a rate of 62/765 (8%) cases, compared with the control group - 130/931 (14%). The chance of developing wound infection was higher in the LA group (OR=0.2, CI95% 0.1-0.3, p<0.00001). There were no differences in the incidence of anastomotic leakage (p=0.97).
There were also no differences in the five-year overall (p=0.74) and cancer-specific survival (p=0.76).
CONCLUSION: using NOSES techniques creates better conditions for the patients' recovery due to the low incidence of postoperative complications due to the absence of wound infection and is a safe manipulation. However, the presence of publication biases requires a careful interpretation of the data obtained.

[Key words: rectal cancer, colorectal surgery, oncology, laparoscopic surgery. metaanalysis]

CONFLICTS OF INTERESTS: The authors declare no conflicts of interest.

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INTRODUCTION

The introduction of laparoscopic techniques in rectal cancer surgery has significantly reduced the number of postoperative complications, enhanced recovery, and improved the cosmetic effect [1-4]. However, the minilaparotomy required to extract the surgical specimen is complicated by infection in 10.3-22.7% of cases, and is the main cause of postoperative pain, as well as the source of postoperative hernias [5-7].

In 1993, laparoscopic colon resection was proposed using the NOSES (Natural orifice specific extraction surgery), with the specimen removed through natural openings without incisions on the anterior abdominal wall [8].

The main factors hindering the widespread use of this technique are: the duration and complexity of surgery, as well as the prevalence of the tumor process and the size of the primary tumor [9].

The reproducibility of these surgeries and patient safety, including cancer, remain the subject of discussion.

In this regard, it is interesting to analyze the world literature to assess the effectiveness and safety of laparoscopic resections with transanal specimen removal using the NOSES method in the rectal cancer surgeries, in comparison with traditional, laparoscopically-assisted surgeries.

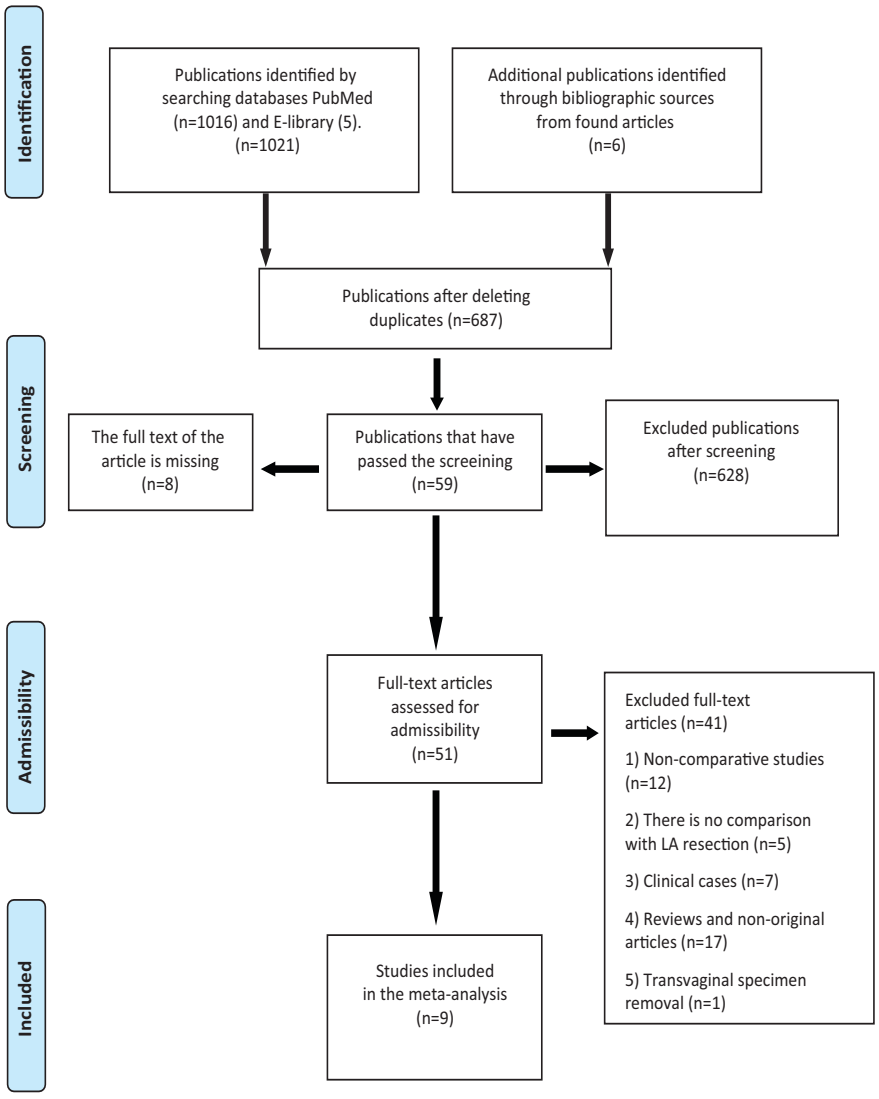

Figure 1. *PRISMA-article search chart*

MATERIALS AND METHODS

The systematic review and meta-analysis were performed in accordance with the recommendations of "The preferred reporting items for systematic reviews and meta-analyses" (PRISMA) [10].

Search for Publications

The search for original studies for analysis was carried out in the Medline and E-library by key words: "colorectal cancer", "colorectal surgery", "rectal cancer", "colorectal disease", "NOTES", "NOSES", "natural orifice specimen extraction", "transanal specimen extraction", and "hybrid natural orifice transluminal endoscopic surgery".

The meta-analysis included comparative studies in Russian and English without restrictions on the date or status of publication, in which laparoscopic resections using the NOSES method (with transanal specimen removal) were compared with laparoscopically-assisted resections, where the macro-specimen was removed from the abdominal cavity by minilaparotomy.

The studies in which the tumor was removed transvaginally were excluded from the search, since when compared with the transanal method, this could significantly distort the results.

Animal studies were also excluded.

In addition, a literature search was performed on the bibliographic data of selected studies in order to identify unfound articles during the initial search.

Inclusion and Exclusion Criteria

The criteria for inclusion in the study were patients

Table 1. *Characteristics and quality of research*

№	Author	Year	Period	Country	Type	Quality score	N			Gender	
							Overall	NOSES	LA	NOSES	LA
1	Yi Ding et al.	2019	January 2015 - September 2017	China	prospective randomized	9	86	43	43	25 \18	22 \21
2	Hoi-Loi Ng et al.	2018	September 2013 - June 2016	China	retro	7	73	35	38	20\15	22\16
3	Hu et al.	2019	June 2015 – 2018	China	retro	8	52	26	26	17\9	15\11
4	Liu et al.	2019	January 2015 - December 2017	China, Russia	retro	8	768	356	412	192\164	235\177
5	Park et al.	2018	January 2006 - November 2012	Korea	retro	8	276	138	138	32\106	41\97
6	Wang et al.	2019	January 2011 - September 2013	China	retro	8	67	30	37	19\11	20\17
7	Hisada et al.	2014	2011 - 2012	Japan	retro	7	70	20	50	12\8	н\д
8	Xingmao et al.	2014	May 2012 - July 2013	China	retro	8	197	65	132	32\33	57\75
9	Zhou et al.	2019	January 2017 - January 2018	China	retro	8	104	52	52	27\25	27\25

with rectal adenocarcinoma T1-T3 according to preoperative computed tomography (CT).
The criteria for exclusion from the meta-analysis were early cancer removed by transanal endomicrosurgery (TEM), recurrent, locally advanced and metastatic tumors, and transvaginal specimen removal.

Data Acquisition
The following data was found from studies: author, year of publication, study design, study quality, number of patients in groups (laparoscopic with transanal specimen removal and laparoscopically-assisted resections), characteristics of groups, postoperative complications, pain on a visual analog scale (VAS), general and cancer-specific 5-year survival, satisfaction with cosmetic results.

Statistical Analysis
The statistical analysis for direct comparison of the methods was performed using the Review Manager 5.3 software. The total value of dichotomous data was described as the odds ratio (OR) with a 95% coincidence interval (CI). OR was calculated using the Peto method if one of the values of the two-field table was 0. The continuous data was described using a non-standardized weighted average with a 95% CI. The statistical heterogeneity among the studies was assessed using the χ^2 test. Significant heterogeneity was considered at $p<0.1$ and $I^2>50\%$.

Research Quality
The quality of the included studies was evaluated according to the Newcastle-Ottawa Score (NOS). With a level of 7 out of 9 stars, the study was considered high-quality (Table 1).

RESULTS

After compiling the query, 1,016 articles were found in the PubMed database and 5 articles in the E-library. Additionally, 6 articles were identified from the bibliographiclists of the found articles.
At the next stage of the search, duplicates and articles that do not fit the research objectives were excluded. Further, a critical analysis of the found sources was carried out, as a result of which 9 full-text studies that fit the meta-analysis objectives were selected (Fig.1).
Eight studies were retrospective by design and one was prospective randomized, published between 2014 and 2019.
A total of 1,693 patients were included in the meta - analysis, of whom 765 (45.0%) had the specimen with the tumor removed transanally (NOSES group) and 928 (55.0%) - via minilaparotomy (LA group).

The results were analyzed in the following order: the study of publications for the presence of heterogeneity in groups by preoperative indicators, the analysis of intraoperative indicators, immediate and long-term results (Fig.2).

PREOPERATIVE INDICATORS

Studies on gender, age, body mass index, neoadjuvant treatment, cavitary surgery history, tumor site and distance of the tumor from the anal edge, and stage T did not have publication shifts.
The only significant factor (p=0.0004) when comparing NOSES and LA was the tumor size (Table 2).
The data on the tumor size is presented in 7 publications, including 893 patients, of whom NOSES - 383, LA - 490 (Fig.3). The average tumor size in the NOSES group was 0.5 cm smaller (CI 95% 0.2-0.8, p=0.0004) than in the

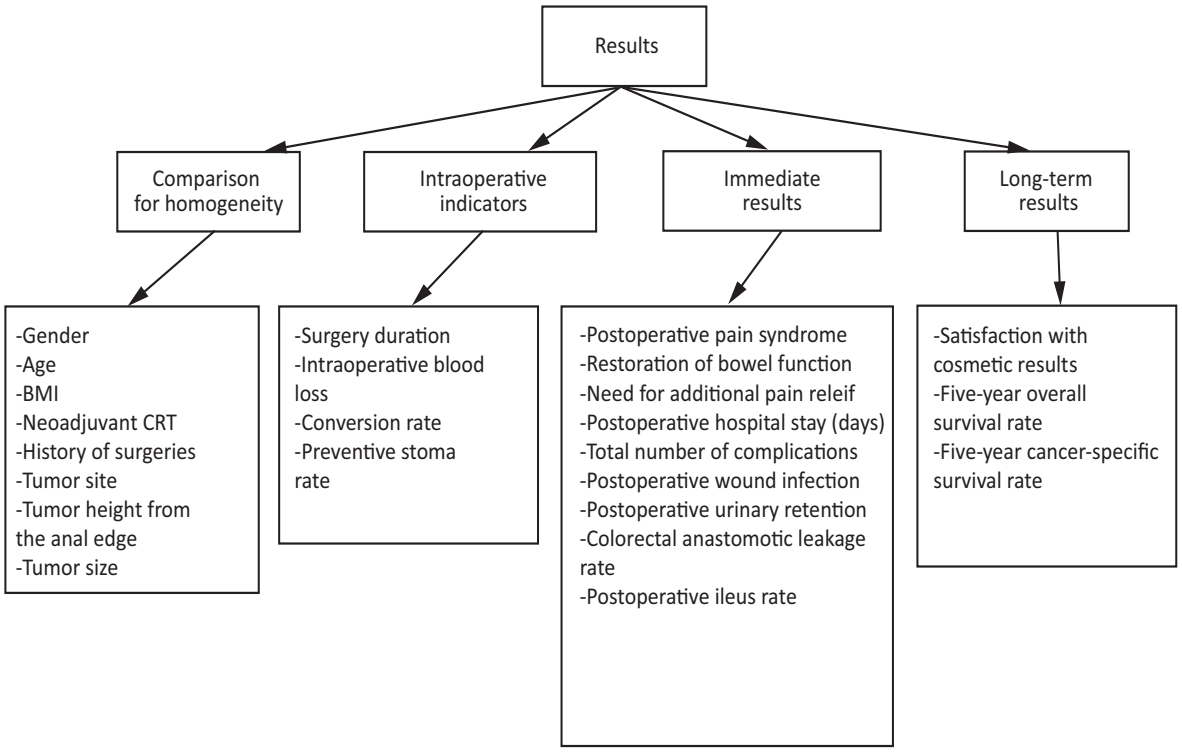

Figure 2. *Block diagram description of the results*

LA group. The existing heterogeneity demonstrates the fact that when using the approach with transanal specimen removal, patients with small tumors were selected.

INTRAOPERATIVE INDICATORS

1. The operation time in minutes when comparing NOSES with LA was comparable (p=0.11).
The data is presented in 8 studies involving 925 patients: 409 – NOSES and 516 – LA (Fig.4).
2. The data on the volume of intraoperative blood loss is available in 8 publications, including 925 patients: 409 - NOSES group and 516 - LA group (Fig. 5).
The intraoperative blood loss was 18 ml less (CI 95% 10-27, p<0.0001) in the NOSES group.
Despite the existing heterogeneity, the difference in the volume of blood loss is negligible and has no clinical significance.
3. The data on the conversion rate is presented in 2 studies involving 1,044 patients, of whom 494 were in the NOSES group and 550 were in the LA group (Fig.6). In the NOSES group, the conversion was taken as a conversion to both open surgery and laparoscopic surgery with minilaparotomy. When comparing NOSES with LA group, there were no differences in its rate (p=0.93).

Таблица 2. *Сравнение групп на однородность по предоперационным параметрам*
Table 2. *Comparison of groups for homogeneity by preoperative parameters*

Parameter	NOSES vs LA
Age	OR=0.27, CI 95%1-1.6, p=0.69
Gender	OR=1.04, CI 95%0.8-1.3, p=0.69
BMI	OR=0.03, CI 95% 0.3 -0.4, p=0.88
Neoadjuvant CRT	OR=1.30, CI 95% 0.7-2.2, p=0.36
History of surgeries	OR=1.35, CI 95% 0.7-2.5, p=0.34
Tumor site	OR=0.83, CI 95% 0.5-1.2, p=0.34
Tumor height from the anal edge	OR=0.09, CI 95% 0.3-0.4, p=0.63
Tumor size	OR=0.54, CI 95% 0.2-0.8, p=0.0004
cT3	OR=1.35, CI 95% 0.8-2.1, p=0.21

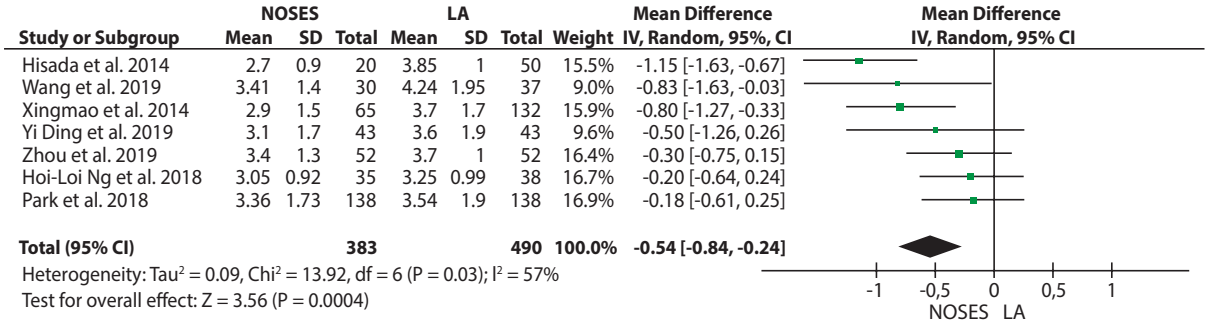

Figure 3. *Comparison of groups for homogeneity in tumor size*

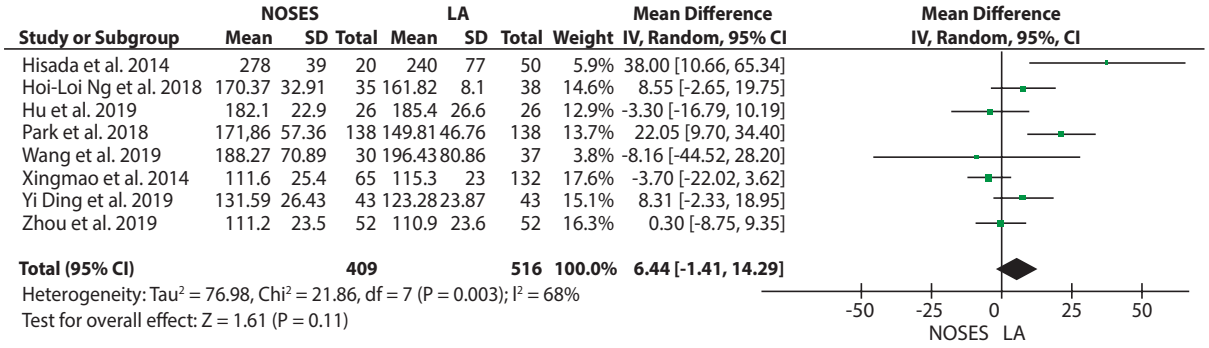

Figure 4. *Surgery duration when comparing NOSES with LA*

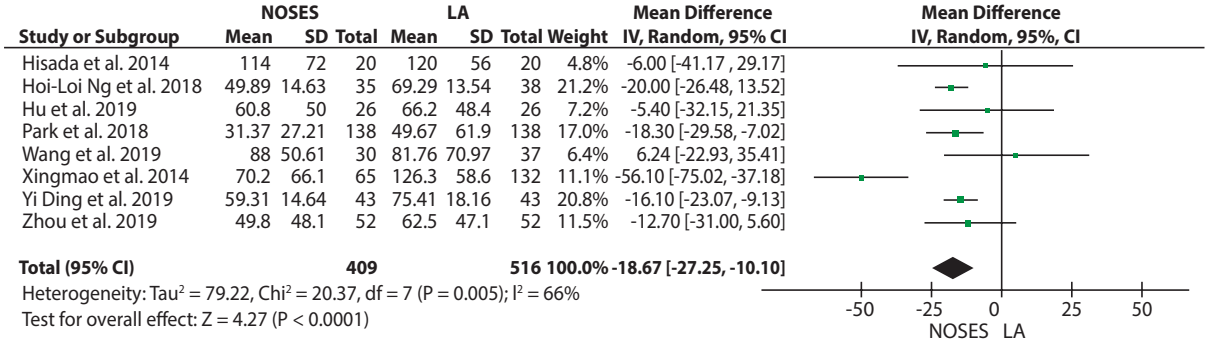

Figure 5. *Intraoperative blood loss when comparing NOSES with LA*

4. The preventive stoma rate is presented in 2 studies involving 1,044 patients, of whom 494 – NOSES, 550 - LA (Fig.7). In the NOSES group a diversion stoma was formed in 13 patients out of 494 (3.0%), and in the LA group - in 24 out of 550 (4.0%); the differences were not significant (p=0.13).

IMMEDIATE RESULTS

1. The data on postoperative pain is available in 4 studies involving 453 patients: 186 - NOSES and 253 - LA (Fig.8). The pain intensity was assessed on the 1st day after surgery by VAS (where 0 points – no pain, and

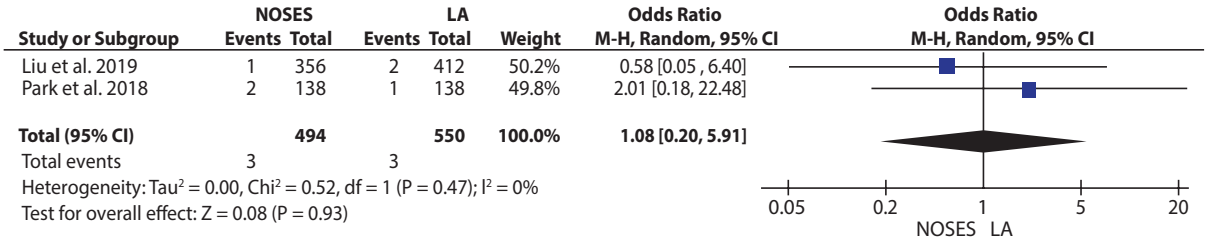

Figure 6. *Conversion rate when comparing NOSES with LA*

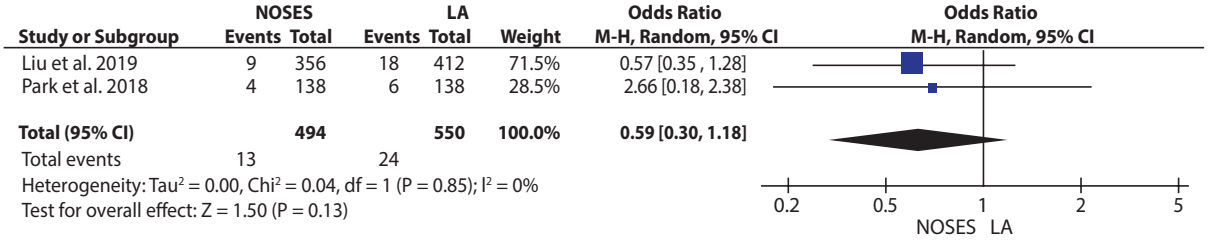

Figure 7. *Preventive stoma rate when comparing NOSES with LA*

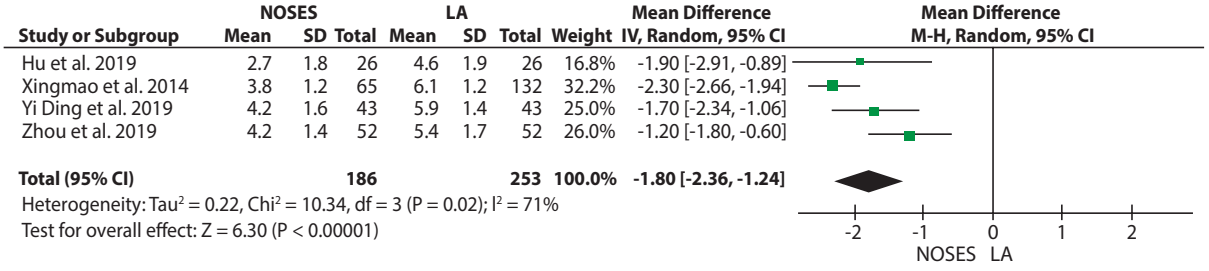

Figure 8. *Pain intensity when comparing NOSES with LA*

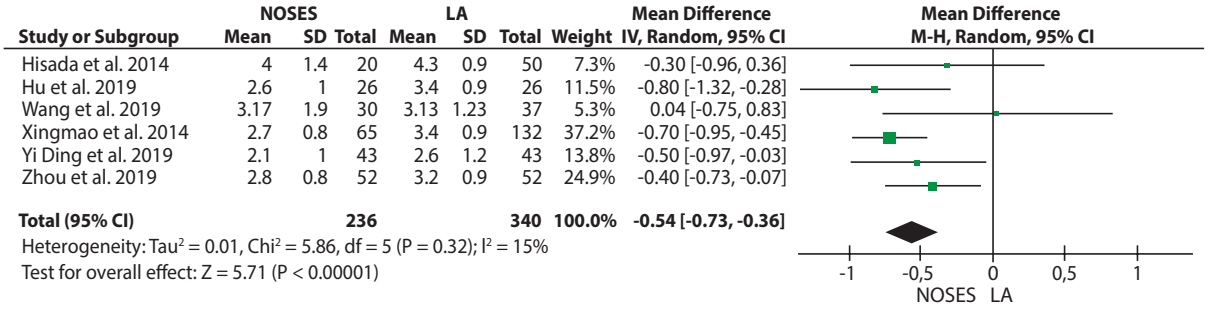

Figure 9. *Recovery of bowel function when comparing NOSES with LA*

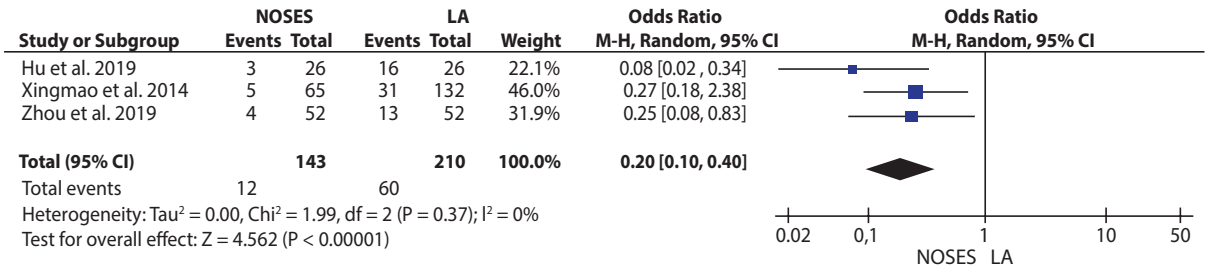

Figure 10. *Need for additional pain relief when comparing NOSES with LA*

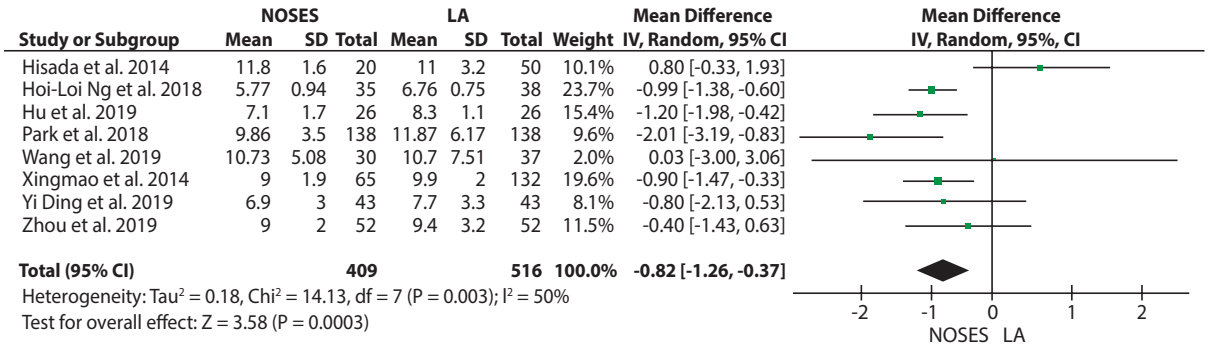

Figure 11. *Duration of a postoperative hospital stay when comparing NOSES with LA*

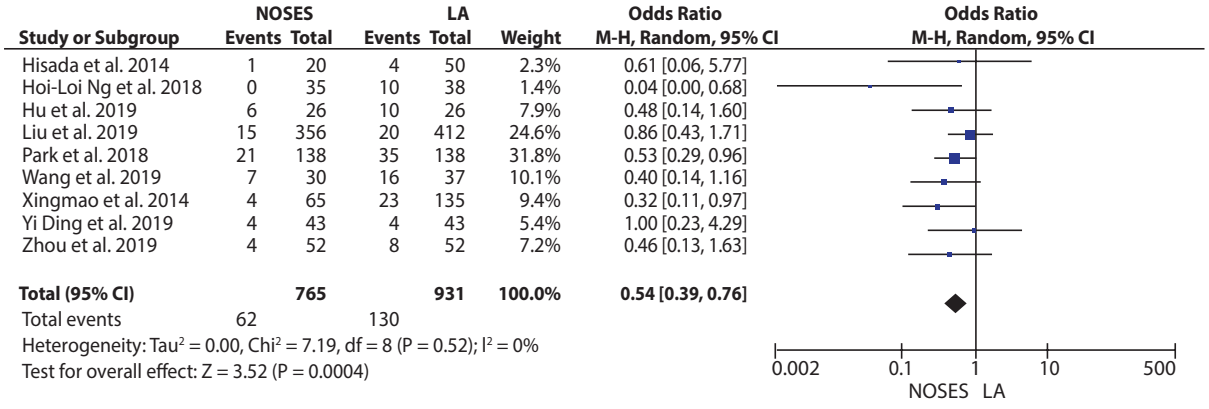

Figure 12. *Postoperative complications rate when comparing NOSES with LA*

10 points - maximum pain). The VAS pain was 2 points higher (CI 95% 1.2 -2.4, p<0.00001) in the control group.

2. The timing of restoration of bowel function is presented in 6 studies involving 576 patients: 236-NOSES and 340 - LA (Fig.9). The following criteria were used to normalize bowel function: the ability to eat enterally and/or the beginning of stool or gas discharge. In the NOSES group, GI function was restored at an earlier time (OR=0.5, CI 95% 0.4-0.8, p<0.00001). In general, the recovery period did not exceed 4 days for the both groups.

3. The need for additional pain relief is presented in 3 studies involving 353 patients: 143 - NOSES and 210 - LA (Fig.10). In the control group, it was required by 12/143 (8%) patients, and in the NOSES

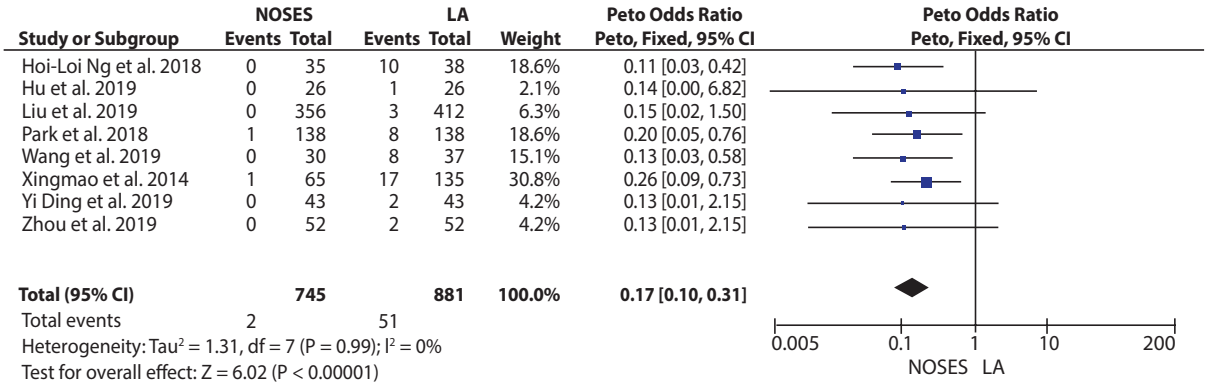

Figure 13. *Postoperative wound infection rate when comparing NOSES with LA*

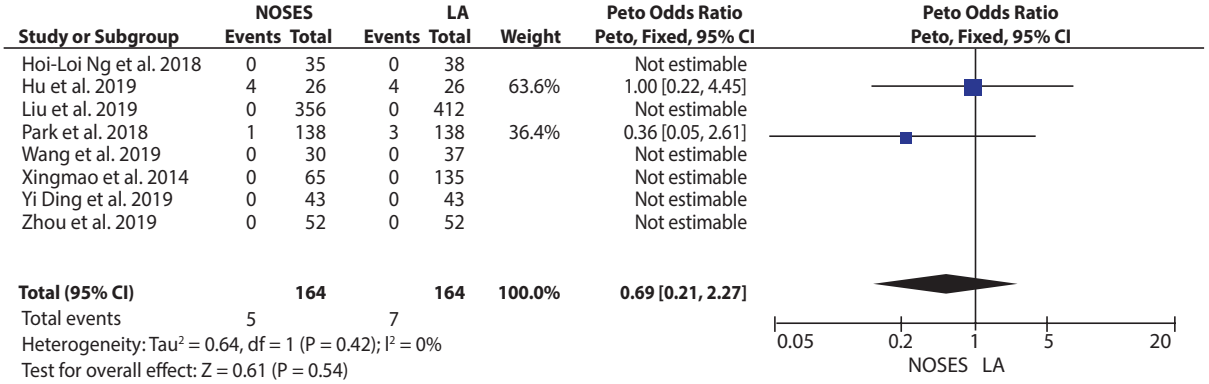

Figure 14. *Postoperative urinary retention rate when comparing NOSES with LA*

group - 60/210 (29%). The differences are significant (p<0.0001).

4. The postoperative hospital stay was presented in 8 studies, the total number of the patients included was 925: NOSES group - 409, LA group - 516 (Fig.11). The postoperative hospital stay wasless in the group with the transanal specimen removal (OR=0.8, CI 95% 0.4-1.3, p=0.0003).

5. The total number of postoperative complications is presented in 9 studies involving 1,696 patients: 765 in the NOSES group and 931 in the LA group (Figure 12).

The chance of developing postoperative complications was lower in the NOSES group (OR=0.5, CI 95% 0.4-0.8, p=0.0004) with the rate of 62/765 (8%) cases, compared to the control group – 130/931 (14%).

6. The postoperative wound infection rate was separately calculated: in the NOSES group it was 2/745 (0.3%), in the LA group – 51/881 (6%). Thus, the chance of developing wound infection was higher in the control group (OR=0.2, CI 95% 0.1-0.3, p<0.00001). The data is presented in 8 publications, including 1,626 patients: 745 – NOSES and 881 – LA (Fig. 13).

7. Postoperative urinary retention was observed in 2 studies involving 328 patients: 164 - NOSES group and 164 - LA group (Fig.14). In the group with transanal removal of the specimen the postoperative urinary retention rate was 5/164 (3%) cases and 7/164 (4%) in the control group. There was no significant difference between the groups (p=0.54).

8. When comparing the groups depending on the incidence of colorectal anastomotic leakage, no significant differences were found (p = 0.97). Data is presented in 8 studies, including 1,620 patients: 730 in the NOSES group and 890 in the LA group (Fig.15). The incidence of failure in the group with transanal specimen removal was 29 per 730 (4%) cases, and in the control group - 37 per 890 (4%).

9. The incidence of postoperative ileus in the NOSES group was 3/658 (0.5%), and in the LA group - 10/777 (1.3%), with no significant differences obtained. The data is presented in 5 publications, including 1,431 patients (654 - NOSES group and 777 - LA group) (Fig.16).

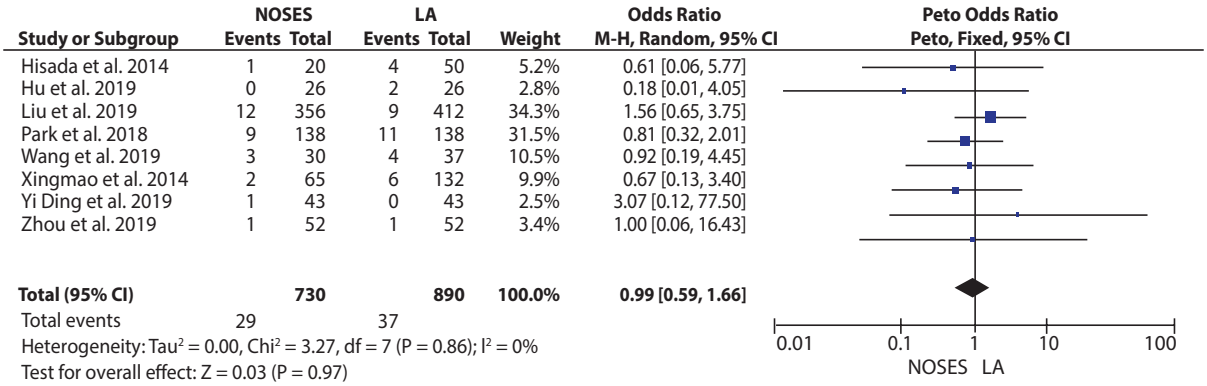

Figure 15. *Colorectal anastomotic leakage rate when comparing NOSES with LA*

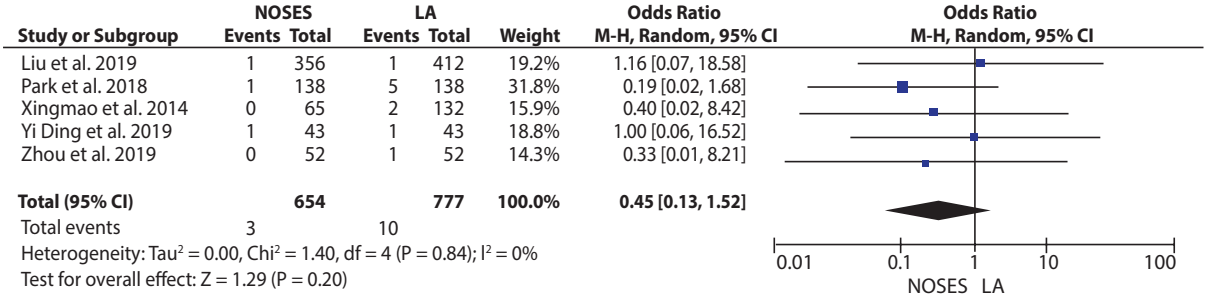

Figure 16. *The incidence of postoperative ileus when comparing NOSES with LA*

LONG-TERM RESULTS

1. Two studies tracked satisfaction with cosmetic results 2 months after surgery.

In the presented articles, the assessment was made by a survey method on a ten-point scale, where 0 points - complete dissatisfaction, and 10 points - maximum satisfaction with cosmetic results.

A total of 138 patients were included (69 in each group), and with transanal specimen removal, the patients rated the cosmetic results on average 3 points higher (CI 95% 0.1-6, p <0.04) than in the control group (Fig.17).

2. When analyzing oncological results, five-year overall survival was analyzed in 2 studies, including 380 patients (190 in each group) (Fig.18). There was no significant difference between the two groups (p = 0.74).

3. Five-year cancer-specific survival was followed in 2 studies including 380 patients (190 in each group) (Fig.19).

When comparing the groups, no significant difference was found (p=0.76).

DISCUSSION

At the end of the last century, the successful results of the first laparoscopic colectomy with transanal specimen removal using the NOSES technique were published (Franklin M.E. et al, 1993) [8]. Since then, NOSES surgeries have become an attractive alternative to traditional laparoscopic procedures, since the absence of a laparotomic incision minimizes the likelihood of wound infection, is accompanied by less pronounced postoperative pain and short recovery [9]. At the same time, the technique has a number oflimitations in the form of tumor size andlocation. The transvaginal method can successfully remove large tumors of any site, which was clearly demonstrated in their study by Yagci M.A. et al. in 2017, removing a 9.0 cm diameter caecum tumor [11]. On the contrary, with the transanal technique, according to the literature, the maximum permissible size of the removed tumor does not exceed 6.5 cm [12]. In addition, with transanal resection of colon tumors, the risk of conversions is 13.3 times higher than with resection of rectal tumors, as evidenced by a retrospective study of 72 patients by Karagul et al. in 2015 [13].

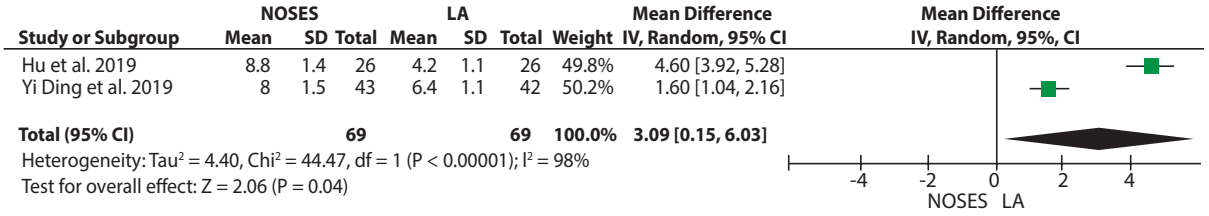

Figure 17. *Satisfaction with cosmetic results when comparing NOSES with LA*

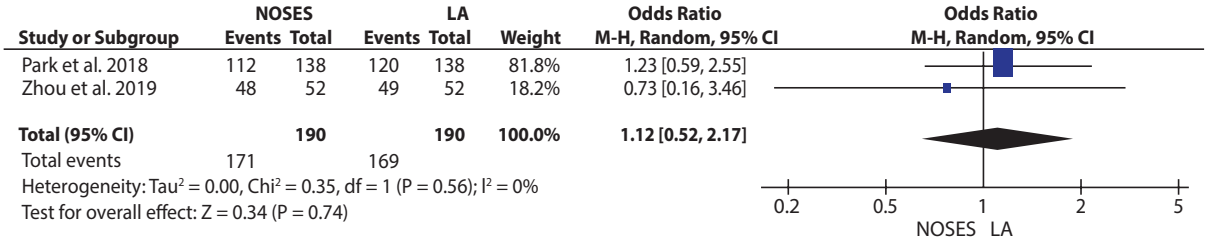

Figure 18. *Five-year overall survival when comparing NOSES with LA*

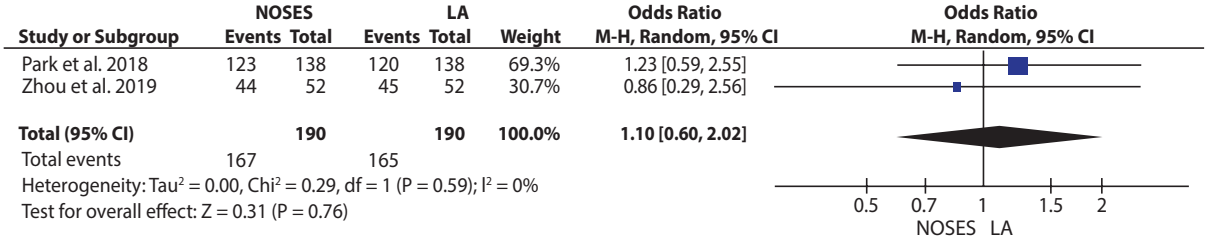

Figure 19. *Five-year cancer-specific survival when comparing NOSES with LA*

However, the technical complexity of surgeries, together with the need to use special equipment, determine the very limited number of published studies comparing the results of NOSES with traditional laparoscopic surgeries. It should also be noted that the available studies do not fully meet the requirements of modern evidence-based medicine, since 8 out of 9 studies are retrospective [14-21], and only one is prospective randomized [22].

In order to obtain objective immediate and long-term results of laparoscopic resections with transanal specimen removal, we initiated a meta-analysis. In order to exclude the likelihood of systematic selection errors, it was decided not to include the studies in which transvaginal removal was performed in the analysis.

Safety is the most important and assessed criterion. The incidence and structure of postoperative complications are the cornerstone of all new treatment approaches, especially in surgery, where the cost of an error is the life and health of the patient. When analyzing the metadata, the NOSES group showed a lower chance of complications (OR = 0.5, CI 95% 0.4-0.8, p = 0.0004) compared to the control group: the total number of complications in NOSES and LA is 8% and 14%, respectively.

It is also logical that in patients who underwent removal of the surgical specimen through laparotomy, postoperative wound infection prevails 6%, in contrast to surgeries using the NOSES technique - 0.3% (OR = 0.2, CI 95% 0.1-0.3, p < 0.00001).

It is important to emphasize that the groups did not differ in the anastomotic leakage rate, since its formation is generally standardized and does not depend on the method of removing the surgical specimen. The factor of proximal stoma could indirectly affect the incidence of clinically significant anastomotic leakage. In this regard, the preventive stoma rate was analyzed in the presented studies, but no significant

differences were found (p = 0.13). Thus, in the NOSES group the preventive stoma was donein 13/494 (3%), and in the LA group - in 24/550 (4%). However, the results obtained do not allow one to objectively judge the influence of this factor on the incidence of failure, since the data is presented in the limited number of studies.

The safety of NOSES surgeries is confirmed by the results in 139 patients in the first and most complete world registry of NOSES surgeries - GERMANNOTES REGISTRY (GNR). Thus, according to GNR, the mortality is comparable or even lower after NOSES surgery compared to LA, which, in turn, is associated with a lower incidence of postoperative complications [23].

The low incidence of postoperative complications is not the only advantage of NOSES. The data of the presented meta-analysis shows that the average hospital stay in the NOSES group was also less than in the LA group (OR = 0.8, CI 95% 0.4-1.3, p = 0.0003). The recent research data demonstrates that with a laparoscopic approach, internal organs can avoid contact with the environment and not be contaminated with conditional pathogenic flora [24]. Moreover, NOSES avoids injury to the anterior abdominal wall by a laparotomic incision and is accompanied by a lower risk of vascular and nerve injury [25], which directly affects the severity of pain, which is less intensive in the NOSES group (p<0.00001).

The latter factor can, by increasing the tone of the sympathetic nervous system, indirectly affect the likelihood of developing postoperative ileus [26]. In our meta-analysis, there is a trend for alower incidence of postoperative ileus in the NOSES group and although differences were not achieved (p=0.2), in the group with transanal excision, the restoration of normal restored bowel function was noted earlier (OR=0.5, CI 95% 0.4 0.8, p <0.00001), which also indirectly confirms the proposed theory.

These three factors probably explain the short recovery in patients after surgery. It is encouraging that there is no difference in the incidence of postoperative urinary retention, which could adversely affect the duration of recovery, due to the risk of injury to the pelvic nerve plexuses during transanal manipulations. When comparing NOSES with laparoscopic resections, significant differences were not obtained (p=0.54).

When assessing the long-term results, an important factor is the likelihood of implantation metastases during transanal specimen removal. Dissemination of tumor cells can be avoided by using special sterile extraction containers [27].

Some researchers prefer to use wound protectors for this purpose [28–30]. As a result, when comparing NOSES with the control group, the meta-analysis found no difference in overall and cancer-specific 5-year survival (p = 0.74 and 0.76, respectively). Franklin, M.E. et al. in 2013 conducted a retrospective study on a sample of 179 patients and demonstrated similar data: the two-year disease-free survival rate in patients after laparoscopic resections with transanal specimen removal was 95% [31], which is not inferior to 93.4% of cancer-specific survival in patients after traditional laparoscopic procedures [32].

However, significant factors affecting long-term results are not the methods of extracting the surgical specimen, but factors directly related to the tumor process – the size of the neoplasm, the stage of the disease, as well as the quality of the removed surgical specimen.

It is important to note the obvious advantage of NOSES surgeries when analyzing patient satisfaction with cosmetic results (p<0.04).

The data obtained requires careful interpretation. When analyzing the studies for homogeneity, it was found that the NOSES group consciously selected patients with tumors that were 5 mm smaller (CI95% 0.2-0.8, p=0.0004), i.e. there was a systematic selection bias. Therefore, in order to obtain objective data, it is necessary to conduct randomized studies that allow leveling systematic errors.

CONCLUSION

The meta-analysis of the literature data showed that the use of NOSES techniques looks like a promising approach in rectal cancer surgery, and creates better conditions for the patient recovery due to the low postoperative morbidity rate due to the absence of wound infection. However, the presence of publication biases requires careful interpretation of the data obtained.

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