

## QUALITY OF LIFE OF PATIENTS WITH STRESS URINARY INCONTINENCE TREATED WITH TWO SURGICAL METHODS: A RANDOMIZED CONTROLLED STUDY

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### ABSTRACT

**Introduction:** Static or stress urinary incontinence unquestionably in women has a significant negative impact on quality of life. Surgical treatment is the standard way of treating women with static stress incontinence, if the desired effect is not achieved with a conservative method of treatment.

**Objectives:** To compare the quality of life of a group of patients with stress urinary incontinence surgically treated with Hammock method with the group treated by Needle method, and to compare the results with the quality of life of a healthy population of women.

**Methods:** The study used the recommended questionnaire from the International Consultation on Incontinence, a short questionnaire ICIQ- SF. This questionnaire was used to collect data on symptomatology, frequency, amount of urine, and the impact on the quality of life before and after surgical treatment.

**Results:** A statistically significant difference ( $p < 0.05$ ) in improving the quality of life of patients operated on needle method was found, significantly higher after surgery. It was also found that there was a statistically significant difference ( $p < 0.05$ ) in improving the quality of life and in patients operated on by the Hammock method. Patients who underwent Needle surgery reported a better quality of life after surgery, compared to patients who underwent Hammock surgery. No statistically significant difference ( $p > 0.05$ ) was found between the postoperative quality of life of patients operated on the Needle method and people without incontinence difficulties.

**Conclusion:** The results of the research have shown that the Needle method is more effective in improving the quality of life of patients with stress urinary incontinence 6 months after surgery.

**Keywords:** stress incontinence, quality of life, surgical methods

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## INTRODUCTION

Urinary incontinence is a significant health and socioeconomic problem that is underestimated by both health professionals and patients. Every day in clinical work we meet patients who, due to fear of stigmatization and lack of information, ignore the symptoms of urinary incontinence for years, until the problems significantly impair the quality of their life (1). Stress urinary incontinence (SUI), defined by the International Association for Continence (ICS), is an involuntary runoff of urine when exercising, exercising and coughing or sneezing. Stress incontinence can occur at any age and today occurs in about 30% of women (2). When conservative and pharmacological treatment do not achieve a satisfactory result, surgical treatment is indicated. As there are numerous theories about the occurrence of stress urinary incontinence, so there are numerous methods of surgical treatment, relying on each of the hypothesized theories of occurrence. Currently, there is no standardized definition of the success of surgical treatment of stress urinary incontinence. Therefore, it seems very challenging to compare different procedures due to the high heterogeneity among the surgical methods used. It is strictly recommended to

use high-quality questionnaires, assessing both the patient's description of symptoms and their impact on the quality of life.( 3). The International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form- ICIQ-SF (3) is recommended. The European Association of Urology (EAU) recommends evaluating the symptoms described by patients, quality of life, objective outcomes, complications and health economic outcomes (4,5). There is no standardized definition of follow-up periods after surgical treatment, but it is believed that outcomes should be monitored for a period of 6 months or more. The aim of this study was to compare the quality of life of patients treated with two similar surgical methods .

## INTERVIEWEES AND PROCEDURES

The study was organized as a randomized controlled prospective study conducted at the Clinic for Gynecology and Obstetrics and the Department of Urology of the University Clinical Hospital (UCH) Mostar. I formed the groups in such a way that upon the arrival of the patient we distributed the operated into one group, and with a random sample using the age formed another group of women without symptoms. The time of the survey was from January 2016 to

December 2017. age. A total of 105 women were included in the study, of which 70 with diagnosed stress urinary incontinence who were recommended for surgical treatment. Patients of the study group were divided into two groups. One study group of 35 patients consisted of patients who were surgically treated with a technique based on the "Hammock" theory (6). The second study group consisted of 35 patients treated with suspension surgery using needles by Raz (7). After completing the surgical treatment, patients from both groups applied for a follow-up examination 6 months after the operation and on that occasion filled out the ICIQ SF questionnaire (8). The control group consisted of 35 women of a healthy population.

Criteria for inclusion in the study: age over 35, symptoms and signs of stress urinary incontinence, involuntary loss of urine without contraction of detrusors.

Exclusion criteria from the study: patients with neurogenic bladder, patients with suspected intrinsic sphincter deficiency (ISD), earlier gynecological or urological operations due to urinary incontinence, pelvic organ prolapse, pharmacological therapy for other diseased conditions.

All patients were diagnosed with stress urinary incontinence and were recommended surgical treatment. During

the preparation for surgical treatment, after signing the informed consent form, all subjects completed a modular questionnaire for the purpose of clinical assessment of symptoms and quality of life according to the recommendation of expert guides of the European Association of Urology-*guidelines* and the International Continence Society (ICS), *International Consultation on Incontinence Modular Questionnaire-ICIQ*, ICIQ – SF. The questionnaire serves to assess symptoms and quality of life before and after surgical treatment.

ICIQ - SF questionnaire is a questionnaire that evaluates the frequency of urinary incontinence, the amount of urine in incontinence, the overall impact on the quality of life, and self-diagnostic questions (8-10).

The ICIQ-SF questionnaire consists of 3 groups of questions, which are scored each for themselves, and are added to the total sum of the questionnaire points.

The first group of questions in the questionnaire refers to the frequency of urine escape and the maximum number of points for this group of questions is 5.

The second group of questions refers to the amount of urine when escaping, and the total number of points for this group of questions is 6.

The third group of questions relates to a subjective assessment of the quality of life

and the total number of points on the assessment of the quality of life for this group of questions is 10.

The total number of questionnaire points represents the sum of the points of all three groups of questions and is used for the overall assessment of the quality of life. The quality of life score is higher if the number of points is lower.

Postoperative follow-up - Six months after surgery to treat stress urinary incontinence, patients reported to a follow-up examination where they completed an ICIQ-SF questionnaire that was used to assess the quality of life after surgery and assess the improvement of symptoms and thus the outcome of treatment.

### Statistical data processing

Descriptive statistical methods were used to describe the frequency distribution of the investigated variables. All variables were tested for normal distribution by the Kolmogorov-Smirnov test. The mean values of continuous variables are expressed by the arithmetic mean and standard deviation for normally distributed variables. Nominal indicators are shown by the distribution of frequency by groups and share. The significance of the differences determined by statistical testing was expressed at the level  $p < 0.05$ . Originally

written database programs and statistical package Statistica for Windows 2010 (version 10.0, StatSoft Inc., Tulsa, OK) were used in the data processing.

## RESULTS

The average age of patients of the *Hammock* research group was 48.6 years.

Preoperative scoring related to the frequency of uncontrolled urination had an average scoring of 4.0, which would mean that most patients, as far as frequency is concerned, had involuntary or uncontrolled urinary escape several times a day. Scoring referring to the amount of urine that flowed uncontrollably, the average preoperative scoring, was 3.94, which would closely correspond to a moderate amount of urine escape. Scoring related to quality of life, i.e. how much these symptoms affected everyday life was an average of 9.82, and it is concluded that the symptoms had a significant negative impact on everyday life and that the problems they had significantly reduced their quality of life. The total preoperative questionnaire score was on average 17.85, which would correspond to the transition from severe to very severe symptoms in patients. Postoperative scoring shows a numerically significant recovery, so the scoring related to the frequency of uncontrolled urination averages 1.45. Such

scoring would correspond in a questionnaire on the frequency of uncontrolled urination once a week or less frequently. Postoperative scoring, which refers to the amount of uncontrolled urine output, is 2.34, and would refer to a smaller amount of urine. Skoring, which refers to the impact of uncontrolled urination on everyday postoperative life, averages 3.68, and is consistent with scoring on a scale from 0 to 10, some moderate negative impact on everyday life, i.e. what discomfort patients can cope well in relation to the impact they had before surgical treatment.

The total average postoperative score is 7.48 and in the scoring about the success of treatment is classified in the group of scores from 5 to 9 that would correspond to the successful result of treatment. The average age of the control group of 35 patients treated with the "needle" suspension method was 52.57 years. They were previously orally informed about the survey, after which they signed an informed consent form.

Preoperative single scoring of the frequency of uncontrolled urination for this group of patients preoperatively averages 3.4 and speaks of the frequency of involuntary urination between once a day and several times a day, somewhat closer to the frequency of once a day for sure. The

frequency of scoring the amount of uncontrolled urine uncontrolled is 4.45, varies between moderate and higher amounts of urine, but closer to a moderate amount uncontrollably muddles urine.

Skoring significantly affects everyday preoperative life, and the amount of 8.57 corresponds to a marked impact on everyday life on a scale from 0 to 10 corresponds to the number 9, which is close to an extremely negative impact on the daily life of patients. The total score of the preoperative questionnaire is an average of 17, corresponding to the gradation of symptoms, severe symptoms.

Postoperative scoring of completed questionnaires, frequency of uncontrolled urination postoperatively averages 0.3, says that uncontrolled urination never occurs. Scoring uncontrollably muddles the amount of urine postoperatively averages 0.68, would correspond to a negligible amount of urine to almost no negligence of urine. The scoring of the impact on everyday life postoperatively is 0.88, corresponding to the negligible impact on the daily life of patients. The postoperative total scoring of the questionnaire averages 1.91, corresponds to a scoring of 1 to 4, which speaks of the overall cure and success of treatment.

*Table 1. Arithmetic mean and standard deviation, and normality of distribution of quality of life results on two time occasions (before and after surgery) by two methods and in the control group (N=105).*

Method and time period	M	Sd	Flattened coefficient	Standard flattened error	Coefficient of asymmetry	Standard asymmetry error
Needle before surgery	17.00	3.03	2.05	0.77	-1.21	0.39
Needle after surgery	1.91	2.67	-1.33	0.77	0.77	0.39
Hammock before surgery	17.85	1.19	0.39	0.77	0.40	0.39
Hammock after surgery	7.49	2.87	0.39	0.77	-0.62	0.39
Healthy respondents	2.03	2.23	0.39	0.77	0.31	0.39

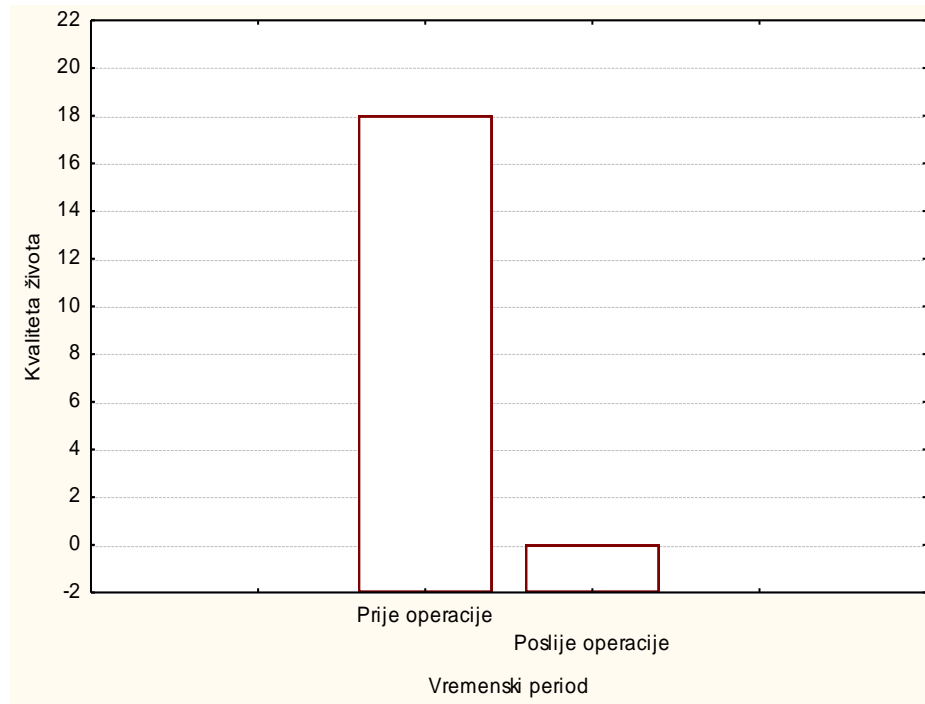
Normality distribution testing indicates that the results obtained by the test approximately follow the normal distribution, i.e. near the point of average.

This distribution allows the use of parametric statistical procedures in the processing of results.

*Table 2. Testing the significance of the difference in the quality of life of patients operated by the Needle method with respect to the time period (before and after surgery) with a t-test for dependent samples (N=35)*

	t	Df	P
Quality of life before and after needle surgery	26.60	34	0.000000*

\*significance at  $p < 0.05$  level



*Figure 1. Differences in the quality of life of patients operated on the Needle method with respect to the time period*

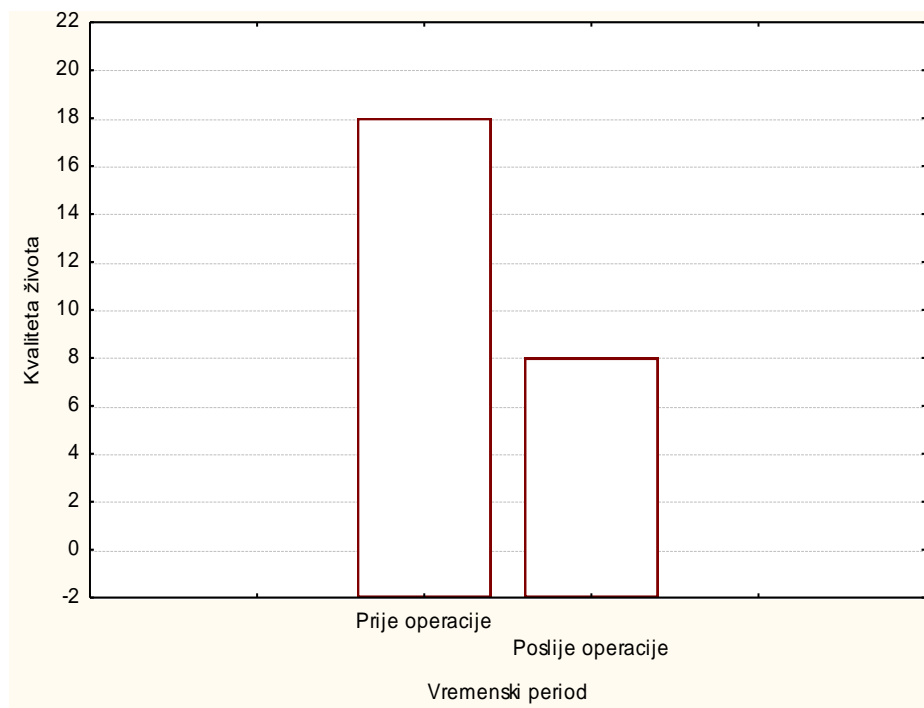
It was found that there is a statistically significant difference in the quality of life of patients operated on the Needle method with regard to the time period of filling out

the questionnaire (before or after surgery). The participants assessed the quality of life after surgery significantly higher than the period before the surgery.

*Table 3. Testing the significance of the difference in quality of life of patients operated by the Hammock method with respect to the time period (before and after surgery) by t-test for dependent samples (N=35)*

	T	Df	P
Quality of life before and after hammock surgery	22.18	34	0.000000*

\*significance at  $p < 0.05$  level



*Figure 2. Differences in the quality of life of patients operated by the Hammock method with respect to the time period*

It was found that there is a statistically significant difference in the quality of life of patients operated by the Hammock method with regard to the time period of filling out

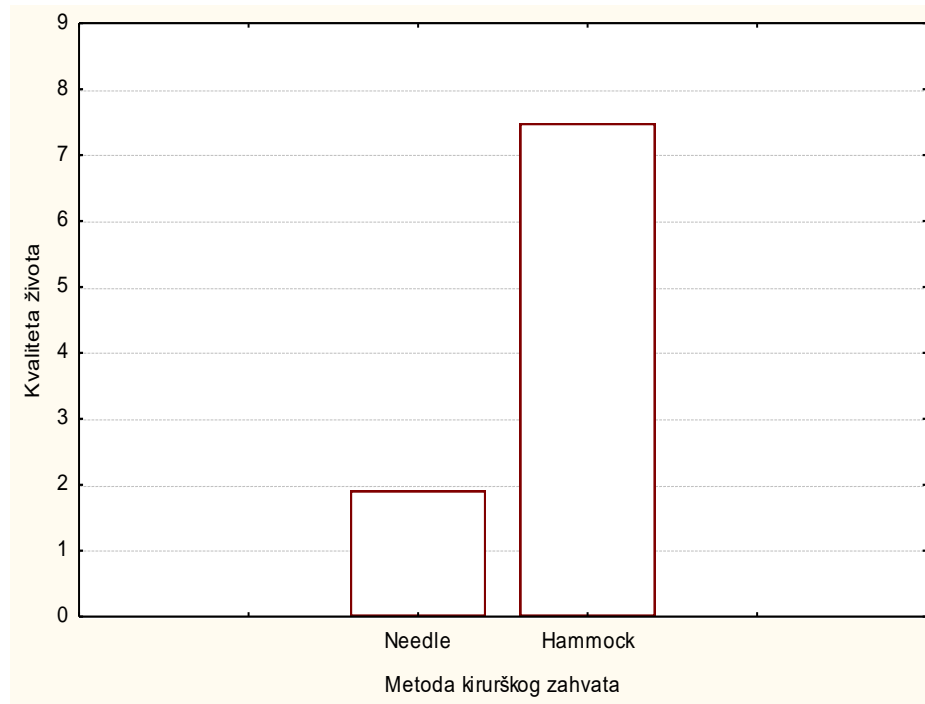
the questionnaire (before or after surgery). Subjects significantly higher assessment of the quality of life after surgery compared to the period before surgery.



*Table 4. Testing the significance of the difference in the quality of life of patients postoperative period of time in the function of different methods (Needle or Hammock) by t-test for independent samples (N=70)*

Quality of life after Needle surgery or Hammock method	T	Df	P
	-8.40	68	0.000000*

\*significance at  $p < 0.05$  level



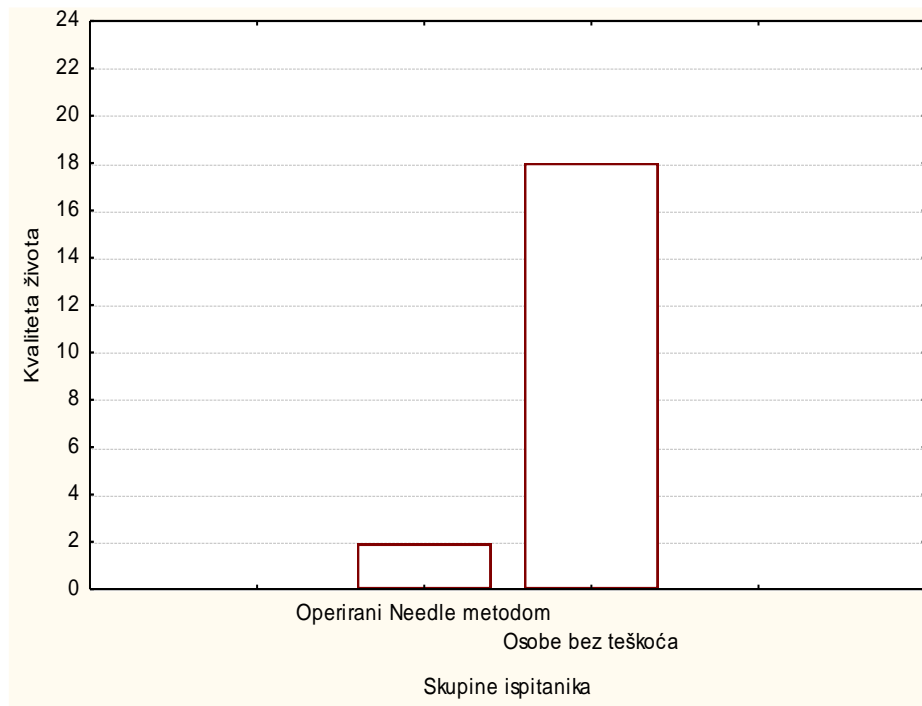
*Figure 3. Differences in the quality of life of patients in the postoperative period of time in the function of different methods*

There is a statistically significant difference in the quality of life of patients after surgery in the function of the method by which they were operated. Patients who underwent

Needle surgery reported a better quality of life after surgery compared to patients who underwent Hammock surgery.

*Table 5. Testing the significance of the difference in the quality of life of patients operated on the Needle method in the postoperative period of time and healthy individuals (N =70)*

	T	Df	P
Quality of life of patients after Needle surgery and healthy people	-0.19	68	0.846522



*Figure 4. Differences in quality of life of patients operated by Needle method in a percentage preative period of time without difficulty with incontinence*

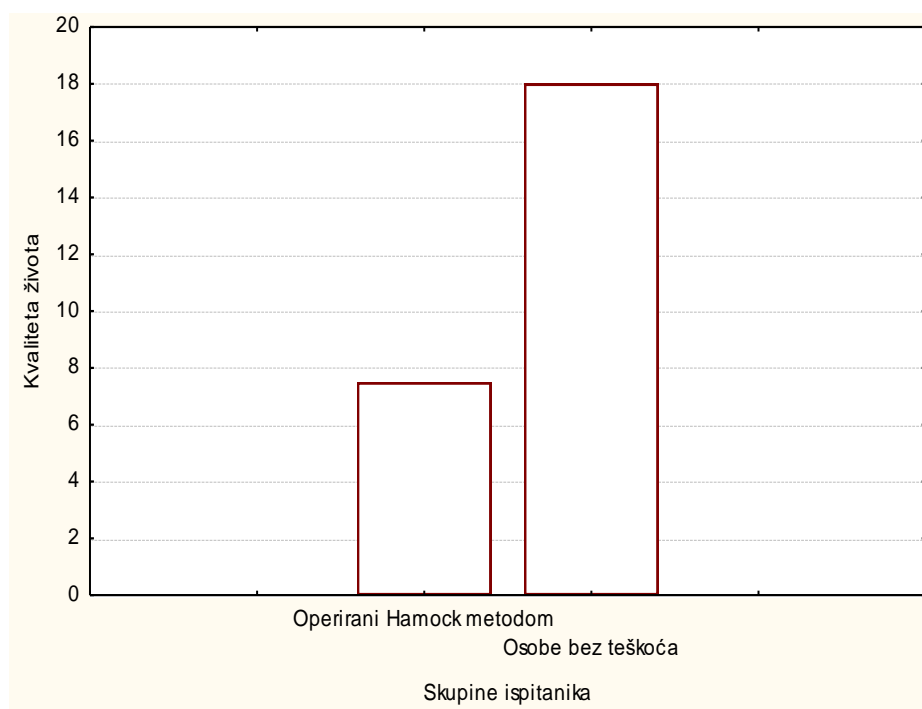
There was no statistically significant difference between the postoperative quality of life of patients operated on the

Needle method and healthy individuals. Thus, both groups of respondents give similar assessments of the quality of life.

*Table 6. Testing the significance of the difference in the quality of life of patients operated by the Hammock method in the postoperative period of time and people without difficulty with incontinence (N =70)*

	T	Df	P
Quality of life of patients after Hammock surgery and healthy people	8.88	68	0.000000*

\*significance at p<0.05 level



*Figure 5. Differences in the quality of life of patients operated on hammck in postoperative time and healthy individuals*

A statistically significant difference was found between the postoperative quality of life of patients operated on hammock method and healthy individuals. Patients operated on the Hammock method postoperatively reported a lower quality of life compared to healthy individuals.

## DISCUSSION

With this study, we found that patients operated on the Needle method after surgery reported a better quality of life compared to patients who underwent Hammock surgery. The average of the participants in this study is uniform and

there is no significant age difference compared to the study groups, and is similar to the age of the participants with the studies conducted so far.

Given that a very small number of publications reporting on medium and long-term outcomes of patients with Stress Urinary Incontinence, the analysis and discussion of the results of this study is limited. By analyzing the data obtained by the ICIQ -SF questionnaire, it was found that there was no significant difference between patients of the test and control groups due to the frequency of urinary escape, the amount of urine, and the degree of discomfort of patients due to urinary escape. This research has proven that the outcomes of treatment of patients treated with surgery "Hammock" and "Needle" suspension surgery, are not due to differences in health fitness of patients, which, since there are a whole range of methods for the treatment of stress urinary incontinence in women, an ideal surgical technique that would be effective, more economical, easy to learn and perform, with more durable effectiveness, minimally invasive and without long-term morbidity and functional the consequence, still does not exist (11, 12).

The analysis of the results confirms that there is a significant statistical difference in the overall score of the questionnaire as well

as in the quality of life due to the time period of filling out the questionnaire before and after the operation. For both groups of patients, those treated with the "Hammock" method and those with the "Needle" suspension method, it was characteristic that the subjects assessed the quality of their own life after surgery significantly higher compared to the period before the surgical procedure. By processing the results, it was also found that there is a statistically significant difference in the quality of life of patients after surgery in the function of the method by which they were operated (Hammock or Needle method). Analyses of the measures used in our study showed that ICIQ-UI SF showed high correlation coefficients with outcome measures.

This study found that the "Hammock" method also achieves a better quality of life, but still somewhat worse compared to a healthy population. This speaks in favor of successful treatment, which is in accordance with the set research criteria in scoring the success of treatment. Treatment results in both surgical methods show excellent short-term cure results, without severe complications. This fact is important to us, because it could draw a hypothesis for a long-term assessment of the results that would suggest that patients operated on "Needle" suspension surgery are likely to have better long-term treatment results, and

therefore a better quality of life than patients operated on the "Hammock" surgical method. There is currently an intensive debate at various professional levels about the use of meshes in transvaginal operations. The occurrence of unwanted allergic reactions to materials, changes in mesh positions after long-term monitoring, damage to the urethra, are mainly a topic of discussion whether to use nets at all in these procedures (13).

Limitations of this study could be the size of the sample of female subjects and short follow-up times. Also, a possible extension of the exclusion criteria would lead to a better analysis of the results. In addition, it should be noted that data on similar research on this topic are not available in Southeast Europe, which partly made it impossible to compare the results obtained more specifically. However, this study found that patients operated on the Needle method reported a better quality of life after surgery compared to patients who underwent Hammock surgery.

## CONCLUSION

Both groups of patients assessed significantly higher quality of life after surgical treatment. The analysis of the results did not reveal a statistically significant difference in the quality of life of

the control group of women and the group operated by the Needle suspension method. A group of patients operated on the Hammock method reported a lower quality of life compared to the control group of healthy women.

Comparing both groups of patients, it is concluded that a group of patients operated on the Needle method have a better quality of life compared to patients operated by the Hammock method, 6 months after surgery.

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## KVALITETA ŽIVOTA BOLESNIKA SA STRESNOM URINARNOM INKONTINENCIJOM LIJEČENA DVJEMA KIRURŠKIM METODAMA: RANDOMIZIRANOM KONTROLIRANOM STUDIJOM

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### SAŽETAK

Uvod: Statička ili stresna urinarna inkontinencija neupitno kod žena ima značajan negativan utjecaj na kvalitetu života. Kirurško liječenje je standardni način liječenja žena sa statičnom stresnom inkontinencijom, ako se željeni učinak ne postigne konzervativnom metodom liječenja.

Ciljevi: Usporediti kvalitetu života skupine bolesnika sa stresnom urinarnom inkontinencijom kirurški liječenom Hammock metodom s grupom liječenom iglom metodom, te usporediti rezultate s kvalitetom života zdrave populacije žena.

Metode: Studija je koristila preporučeni upitnik iz Međunarodnog savjetovanja o inkontinenciji, kratki upitnik ICIQ- SF. Ovaj upitnik korišten je za prikupljanje podataka o simptomatologiji, učestalosti, količini urina i utjecaju na kvalitetu života prije i nakon kirurškog liječenja.

Rezultati: Utvrđena je statistički značajna razlika ( $p < 0,05$ ) u poboljšanju kvalitete života pacijenata operiranih metodom igle, značajno veća nakon operacije. Također je utvrđeno da postoji statistički značajna razlika ( $p < 0,05$ ) u poboljšanju kvalitete života i u bolesnika operiranih Hammock metodom. Pacijenti koji su podvrgnuti operaciji igle izvijestili su o boljoj kvaliteti života nakon operacije, u usporedbi s pacijentima koji su podvrgnuti operaciji viseće mreže. Nije pronađena statistički značajna razlika ( $p > 0,05$ ) između postoperativne kvalitete života pacijenata operiranih metodom igle i osoba bez poteškoća s inkontinencijom.

Zaključak: Rezultati istraživanja pokazali su da je metoda igle učinkovitija u poboljšanju kvalitete života bolesnika sa stresnom urinarnom inkontinencijom 6 mjeseci nakon operacije.

**Ključne riječi:** stresna inkontinencija, kvaliteta života, kirurške metode

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