

A Randomised Two-way Comparison of Mastectomy Performed Using Harmonic Scalpel or Monopolar Diathermy

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ABSTRACT

The purpose of this study was to perform an overall evaluation and comparison of the success rate of modified radical mastectomy by harmonic scalpel and monopolar electrocauter. The prospective study included all of the patients that were planned for and mastectomized because of breast carcinoma during July 1st 2008 until December 21st 2008 at the Department of Surgery and Urology, University Hospital Mostar. Duration of the surgical procedure, intraoperative blood loss and operational drain secretion was measured and registered. Leukocyte number (Le), interleukin 6 (IL-6), C-reactive protein (CRP) and erythrocyte sedimentation rate was tested and registered out of peripheral venous blood before the operation, 4 hrs after it, as well as on the first, second and third day after the operation. Every patient was tested for postoperative pain intensity, amount of administered analgesics during hospital stay, number and types of postoperative complications; also the time needed for return to everyday activities was registered. 61 patients were included in the study. 31 patients were operated with the harmonic scalpel, and 30 of them with the monopolar electrocauter. There is no statistically significant difference between the operation time in the two groups: 78.50±17.50 minutes by harmonic scalpel and 82.50±18.50 minutes by electrocauter ($p=0.796$). The smaller amount of intraoperative blood loss is statistically significant in the group of patients mastectomized by harmonic scalpel 78±31 ml compared to 256±112 ml in the group mastectomized by electrocauter ($p<0.001$); as is the total operational drain secretion: patients mastectomized by harmonic scalpel 540±390 mL compared to 960±710 mL in patients mastectomized by electrocauter ($p<0.001$). There is no statistical difference in the number of leukocytes in blood after modified radical mastectomy using the harmonic scalpel or electrocauter ($p=0.957$), or in erythrocyte sedimentation rate ($p=0.114$), CRP ($p=0.071$) and IL-6 ($p=0.082$). The duration of postoperative hospital stay does not differ statistically between the two groups, nor does the postoperative pain intensity, amount of administered analgesics, number or types of postoperative complications, as well as the time needed for return to everyday activities. Therefore using the ultrasound harmonic scalpel in comparison to monopolar electrocauter brings certain advantages, which however do not contribute significantly to the total success rate of the operation.

Key words: harmonic scalpel, ultrasound knife, monopolar electrocauter, mastectomy

Introduction

Breast cancer is the most common carcinoma in the female population. It is the fifth leading cause of death from cancer in both sexes, yet it is the most common cause of death of women¹. The treatment of breast cancer is being conducted according to therapy protocol, depending on the histological type of tumor, degree of advancement of the malignant process and the general state of the organism. Several combinations of surgical therapy, radiotherapy, chemotherapy and hormonal immunotherapy are being used as ways of treatment².

However, in most patients therapy begins with a surgical procedure³. Today Halsted's radical mastectomy and other radical procedures with thoracotomy are being commonly replaced by more tissue saving operations⁴. Modified radical mastectomy is still the most common surgical treatment of breast cancer despite the surgeons' aspiration to preserve breast tissue⁵. Modified radical mastectomy performed by scalpel and monopolar electrocauter is followed by certain loss of blood and an operational morbidity in 35-50% of patients⁶. The most of

the morbidity is caused by extended axillary secretion caused by severed and thermally injured lymph pathways, as well as hematoma caused by sloppy electrocoagulation lymphostasis and hemostasis⁷. Lately, the ultrasound harmonic scalpel is being implemented as an adequate replacement for the electrocauter⁸. It uses high-frequency ultrasound waves which release kinetic energy within tissue cells, thus rupturing the cell membrane, denaturing proteins and forming coagula which cause lymphostasis and hemostasis. Its implementation in laparoscopic, cardiac and glandular surgery has achieved some encouraging results^{9,10}. Experimental studies on animals show that thermal tissue damage is smaller while using the ultrasound knife as opposed to the electrocauter^{11,12}. Therefore it is considered that implementing the harmonic scalpel in surgery leads to more efficient lymphostasis and hemostasis, causes less trauma and a lesser inflammatory tissue response when compared to monopolar electrocauter^{13,14}. This paper evaluates and compares the success rate of modified radical mastectomy performed by an ultrasound harmonic scalpel and a monopolar electrocauter.

Patients and Methods

This study was conducted during the period between July 1st 2008 and December 21st 2008 at the Department of Surgery and Urology of the University Hospital Mostar. The prospective study included patients that had been planned for and subjected to modified radical mastectomy during this period of time. Patients had been examined preoperatively (clinical examination, mammography, breast ultrasound, tumor markings, FNAB – Fine Needle Aspiration Biopsy) and diagnosed with breast carcinoma. Based on the examination results and advancement rate of the disease, modified radical mastectomy was advised as treatment by the surgical team. Breast carcinoma diagnosis was confirmed by biopsy intraoperatively and pathohistologically *ex tempore*.

Patients had been randomly classified in two groups. The first group had been subjected to modified radical mastectomy consisting of complete breast tissue removal up to the pectoral fascia, complete axillary dissection of the lymph nodes and placing of axillae suction drainage using the ultrasound (harmonic) knife (scalpel). Patients from the other group had been subjected to modified radical mastectomy with the use of the monopolar electrocauter.

The operation time had been measured and registered. Afterwards, intraoperative blood loss was measured and registered, in a way that the gauze used during operation for absorbing blood was weighed before and after the operation. Based on the weight difference, total amount of absorbed blood was calculated, that was actually the amount of blood lost during surgery. Secretion from drains was measured daily after the procedure. Drains were removed when secretion rate was under 30 mL *per* day, following the release of the patients. Samples of peripheral venous blood were tested before the procedure, 4 hrs after and during the first, second and third

postoperative day for leukocytes (Le), sedimentation of erythrocytes, interleukin 6 (IL-6) and C-reactive protein (CRP). Postoperative pain intensity was measured in every patient with a visual analog pain scale (VAS) after the procedure and during the first, second, third and fourth postoperative day. Pain intensity values according to VAS range from 0 to 100 mm, were evaluated for 0 being painless and 100 strongest pain sensation. The amount of analgesics administered during hospital stay was also measured. Postoperatively all of the patients received neodolpasse 250 mL solution (diclofenac sodium 750 mg, orphenadrin cytrate 30 mg), until the pain was arrested by oral administration of ibuprofen 200 mg pills on patient request after the first postoperative day. The number and type of postoperative complications were also registered. The time needed for return to everyday activities was also registered via telephone.

Information for both groups was compared. SPSS for Windows (version 13.0, SPSS Inc. Chicago, Illinois, USA) program was used for statistical analysis. Confidence interval (CI) was higher than 95%, statistically significant difference was observable within $p < 0.05$. The Mann Whitney U test was used for comparison of independent variables with the non-symmetrical distribution. Comparison of percentage stakes in discrete numeric or nominal categorical variables was conducted with the proportion difference χ^2 -test. Two-way variance analysis (repeated tests) was used for comparing multiple tests of the same type of information in two groups – modified radical mastectomy performed using the harmonic scalpel and electrocauter.

Results

During the period between July 1st 2008 and December 21st 2008, 61 patients were treated by modified radical mastectomy due to breast carcinoma at the Department of Surgery and Urology, University Hospital Mostar. 31 patients were operated using the ultrasound harmonic scalpel, while 30 were operated using the electrocauter. The average age of the patients was 62 ± 17 years. The youngest patient was 27, and the oldest 79 years old. Operations in which the harmonic scalpel was used lasted 78.50 ± 17.50 minutes on average, while the operations with the electrocauter lasted 82.50 ± 18.50 minutes. Statistically significant difference in operation time between the two groups does not exist (Mann-Whitney test = 165.00; $p = 0.796$). Smaller blood loss during surgery was statistically significant (Mann-Whitney test = 42.00, $p < 0.001$) in the group that had undergone mastectomy using the harmonic scalpel (78 ± 13 mL) in comparison to those who had the procedure done by electrocauter (256 ± 112 mL).

There was no statistically significant difference in the number of leukocytes after modified radical mastectomy with harmonic scalpel and electrocauter [$F = 0.03$; $p = 0.957$], although it was discretely smaller in the group operated with harmonic scalpel (Table 1). The number of leukocytes significantly grows in both groups ($7.006 \times 10^9/L$ be-

TABLE 1
LEUKOCYTE NUMBER (ARITHMETIC MEAN) IN PATIENTS BEFORE SURGERY, 4 HRS, 24 HRS, 48 HRS AND 72 HRS AFTER MODIFIED RADICAL MASTECTOMY BY HARMONIC SCALPEL AND ELECTROCAUTER

Modified radical mastectomy	Leukocyte number in patients $\times 10^9$				
	Before surgery	4hrs after surgery	24 hrs after surgery	48 hrs after surgery	72 hrs after surgery
Harmonic scalpel	6.81	18.27	12.72	8.90	7.69
Electrocauter	7.21	18.17	12.76	8.90	7.42

fore surgery) and reaches its maximal value 4hrs after surgery ($18.218 \times 10^9/L$) which has shown to be statistically significant (variance analysis $F=346.583$, $p<0.001$). After that, leukocyte count decreases gradually, so that 72 hrs after surgery it reaches its preoperational value. Postoperative leukocyte number movement dynamics is graphically shown in Figure 1.

Erythrocyte sedimentation rate of the test subjects after modified radical mastectomy with the harmonic scalpel and electrocauter does not differ statistically (variance analysis $F=4.82$; $p=0.114$), although it is discretely smaller in the group operated with the harmonic scalpel (Table 2). By measuring as early as 4 hrs after surgery (8.50 mm/h) both groups had shown statistically significant increase of erythrocyte sedimentation rate compared to preoperational values (7.95 mm/h). Erythrocyte sedimentation rate in both groups of patients had increased significantly 24 hrs after surgery (18.60 mm/h) and reached its maximal value 48 hrs after surgery (31.56 mm/h) (variance analysis $F=1786.589$, $p<0.001$). After that, erythrocyte sedimentation rate decreases gradually. Postoperative leukocyte number movement dy-

namics in blood samples of the patients is graphically shown in Figure 2. Levels of CRP in the blood of the patients after modified radical mastectomy with harmonic scalpel and electrocauter do not differ (variance analysis $F=2.67$; $p=0.071$), although they are discretely smaller in the group that was operated with the harmonic scalpel (Table 3).

Testing as early as 4 hrs after surgery both groups show a statistically significant increase in the levels of CRP (5.97 mg/L) compared to preoperative values (3.24 mg/L). Levels of CRP in both groups of patients statistically increase rapidly after operation (58.74 mg/L), continue to grow even 48 hrs after surgery (96.37 mg/L) and 72 hrs after surgery reach its maximal values (112.74 mg/L) (variance analysis $F=5281.001$, $p<0.001$). Postoperative CRP level movement dynamics is graphically shown in Figure 3.

Levels of IL-6 in the blood of the patients treated with modified radical mastectomy using the harmonic scalpel and electrocauter did not differ ($F=3.84$; $p=0.082$), although they were discretely smaller in the group operated with the harmonic scalpel (Table 4). Testing as early

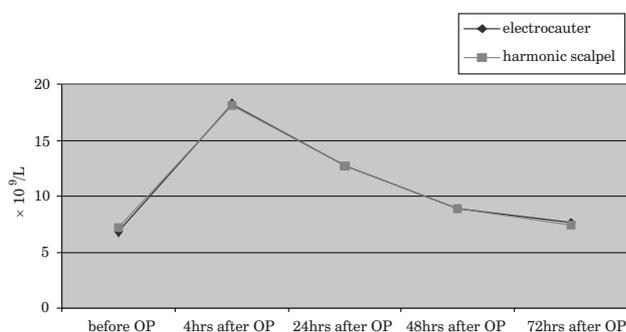


Fig. 1. Leukocyte number movement dynamics (arithmetic mean) in patients after modified radical mastectomy by harmonic scalpel and electrocauter.

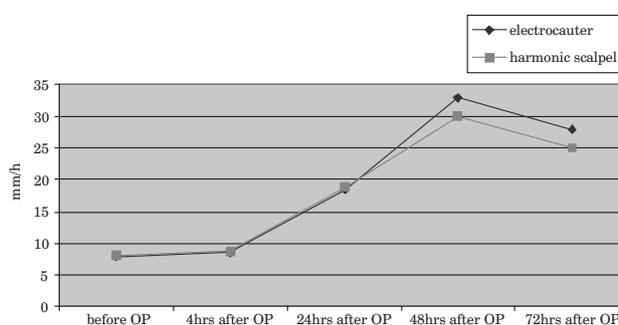


Fig. 2. Erythrocyte sedimentation movement dynamics (arithmetic mean) in patients after modified radical mastectomy by harmonic scalpel and electrocauter.

TABLE 2
ERYTHROCYTE SEDIMENTATION RATE (ARITHMETIC MEAN) IN PATIENTS BEFORE OPERATION, AND 4 HRS, 24 HRS, 48 HRS AND 72 HRS AFTER MODIFIED RADICAL MASTECTOMY BY HARMONIC SCALPEL AND ELECTROCAUTER

Modified radical mastectomy	Erythrocyte sedimentation rate in patients mm/hr				
	Before surgery	4 hrs after surgery	24 hrs after surgery	48 hrs after surgery	72 hrs after surgery
Harmonic scalpel	7.88	8.40	18.45	33.00	28.00
Electrocauter	8.03	8.60	18.75	30.13	25.05

TABLE 3
C-REACTIVE PROTEIN LEVELS (ARITHMETIC MEAN) IN PATIENTS BEFORE SURGERY, AND 4 HRS, 24 HRS, 48 HRS AND 72 HRS AFTER MODIFIED RADICAL MASTECTOMY BY HARMONIC SCALPEL AND ELECTROCAUTER

Modified radical mastectomy	C reactive protein (CRP) level in patients mg/L				
	Before surgery	4hrs after surgery	24 hrs after surgery	48 hrs after surgery	72hrs after surgery
Harmonic scalpel	3.30	6.00	56.70	93.83	109.70
Electrocauter	3.18	5.95	60.78	98.93	115.78

as 4 hrs after surgery both groups show a statistically significant increase of IL-6 levels (61.05 pg/mL) compared to preoperational values (21.14 pg/mL). IL-6 levels in blood of both groups of patients statistically grow rapidly 24 hrs after surgery (72.59 pg/mL), continue to grow even 48 hrs after surgery (86.27 pg/mL) and decrease gradually 72 hrs after surgery (79.61 pg/mL) variance analysis $F=5281.001, p<0.001$). Postoperative IL-6 level in the patients blood movement dynamics is graphically shown in Figure 4.

Smaller total drain secretion was statistically significant in the group of patients mastectomized with harmonic scalpel (540±390 mL) compared to the group mastectomized with the electrocauter (960±710 mL), (Mann-

Whitney test=45.00, $p<0.001$). The length of postoperative hospital stay in the test subjects did not show any statistically significant difference. In the group of patients mastectomized with harmonic scalpel it was 7±5 days compared to 7.5±5.0 days in the group mastectomized with electrocauter (Mann-Whitney test= 169.50, $p=0.897$). Postoperative pain intensity was measured with a visual analog scale after surgery and during the first five days every day, and graphically presented for modified radical mastectomies with harmonic scalpel and electrocauter (Figure 5).

Postoperative pain intensity of patients who had undergone modified radical mastectomy with harmonic scalpel and electrocauter did not differ statistically (Mann-Whitney U=273.50; $p=0.122$). The amount of administered analgesics (ibuprofen 200 mg pills) used to relieve postoperative pain during hospitalization had not shown statistically significantly difference in both groups. In the group mastectomized using the harmonic scalpel it was 1800±400 mg compared to 2000±400 mg in the group mastectomized using the electrocauter (Mann-Whitney test=198.50; $p=0.763$). No general complications occurred during the operations. The frequency of postoperative complications after modified radical mastectomy is shown in Table 5. The frequency of different kinds of complications was calculated by modified radical mastectomy with harmonic scalpel and electrocauter in accordance to the number of test subjects. Frequency of postoperative complications for patients who had undergone modified radical mastectomy did not differ statistically

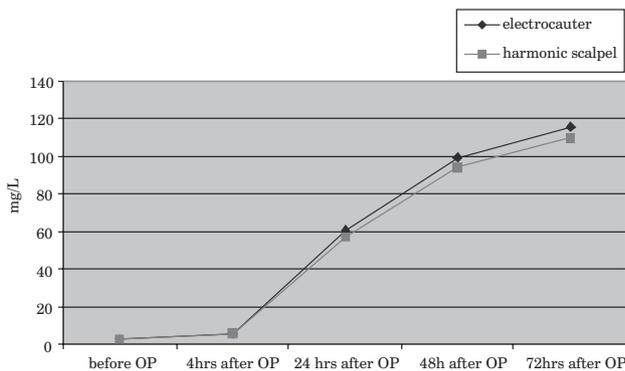


Fig. 3. C-reactive protein movement dynamics (arithmetic mean) in patients after modified radical mastectomy by harmonic scalpel and electrocauter.

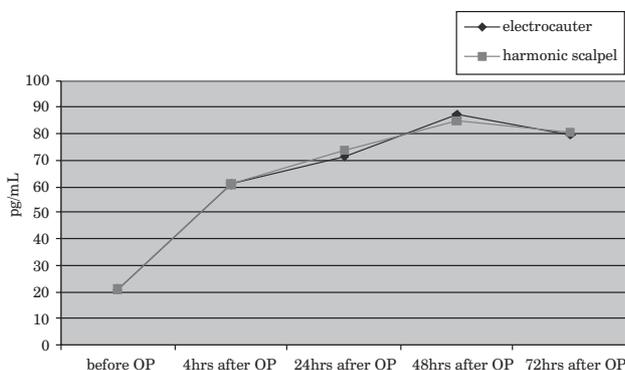


Fig. 4. IL-6 level movement dynamics (arithmetic mean) in patients after modified radical mastectomy by harmonic scalpel and electrocauter

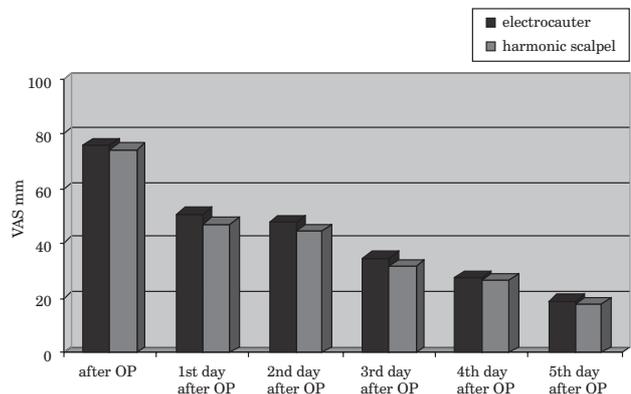


Fig. 5. Postoperational pain intensity (arithmetic mean) after surgery, and the first, second, third, fourth and fifth postoperational day (vas) after modified radical mastectomy by harmonic scalpel and electrocauter.

TABLE 4
IL-6 LEVEL IN PATIENTS BEFORE SURGERY, AND 4 HRS, 24 HRS, 48 HRS AND 72 HRS AFTER MODIFIED RADICAL MASTECTOMY BY HARMONIC SCALPEL AND ELECTROCAUTER

Modified radical mastectomy	IL-6 level in patients pg/mL				
	Before surgery	4 hrs after surgery	24 hrs after surgery	48 hrs after surgery	72hrs after surgery
Harmonic scalpel	21.18	60.95	73.68	84.83	80.42
Electrocauter	21.10	61.10	71.50	87.12	79.20

TABLE 5
POSTOPERATIVE COMPLICATIONS (NUMBER, TYPE AND %) OF MODIFIED RADICAL MASTECTOMY BY HARMONIC SCALPEL AND MONOPOLAR ELECTROCAUTER

Postoperative complications	Harmonic scalpel	Monopolar electrocauter	Total
Wound infection	2 (6.45%)	2 (6.67%)	4 (6.56%)
Seroma	3 (9.68%)	4 (13.34%)	7 (11.48%)
Wound dehiscence	0 (%)	1 (3.33%)	1 (1.64%)
Total	5 (16.13%)	7 (23.34%)	12 (19.68%)

depending on the application of either harmonic scalpel or electrocauter ($\chi^2=1.32$; $p=0.713$).

Recovery period from the modified radical mastectomy with harmonic scalpel and monopolar electrocauter to the return to everyday activities (harmonic scalpel: median 11.00 days, interquartile range 2.00; monopolar electrocauter: median 12.00 days, interquartile range 2.00) don't differ statistically (Mann-Whitney U=681.00; $p=0.085$; Figure 6).

Discussion

In surgery, the success of a certain kind of procedure can be evaluated based on its safety, efficiency, complications and recurrences, cost and its relation to efficiency, surgical technique and acceptance from the patients¹⁵. Acceptance from the patients is determined by postoperative pain, need for analgesics, length of hospital stay, and recovery rate which are, as well as complications, determined by tissue trauma level and organism stress caused by operation¹⁶. The level of the mentioned tissue

trauma and organism stress can be evaluated by the inflammatory response of the organism^{16,17}.

The initial or acute phase of the inflammatory response which starts even during surgery is also the most important. In fact, its intensity is proportional to the degree of trauma caused by the surgical procedure¹⁷. The acute phase of the inflammatory response includes release of different pro-inflammatory cytokines as IL-1 β , IL-6 and TNF- α , and also acute phase proteins such as CRP, serum amyloid A or haptoglobin^{16,18}. Accelerated erythrocyte sedimentation rate is also observed during the acute phase of inflammatory response, as is the increase in leukocyte number¹⁹.

Although modified radical mastectomy is a more exempting procedure compared to almost forgotten Halsted mastectomy, it also implies a great resection surface, a thorough axillary lymphadenectomy and formation of large skin grafts and subskin tissue, therefore an extensive surgical tissue trauma⁶. The application of surgical equipment and techniques that enable the performing of modified radical mastectomy in a less invasive manner signifies a great contribution for patients treated with these procedures daily.

The monopolar electrocauter converts electric energy directly into high-temperature heat and this maximal tissue heating is used for cutting and coagulation. The contact of the instrument and tissue creates a temperature as high as 500°C and smoke that contains organic chemicals that may have a toxic effect^{20,21}. Recent studies^{22,23} have shown that monopolar electrocauterization causes intensive thermal tissue trauma, which results in subskin vascular plexus damage^{24,25} and finally a faulty blood vessel and lymph duct occlusion, which leads to morbidity increase.

The ultrasound harmonic scalpel uses ultrasound energy frequency of 55,5 KHz and vibration amplitude from 60 do 80 μm ²⁶. That produces a minimal warm-up

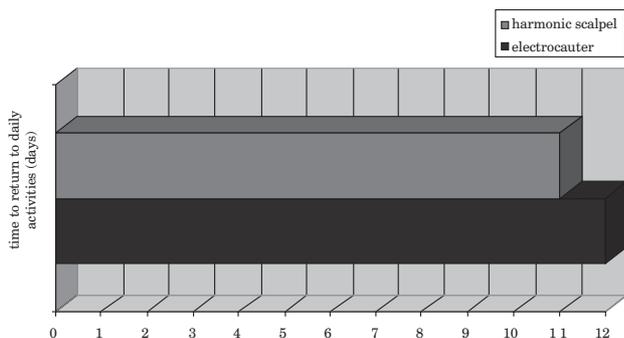


Fig. 6. Return time to everyday activities (median) after modified radical mastectomy by harmonic scalpel and electrocauter.

effect on the tip of the knife blade, so that the heat transferring from the knife to the tissue reaches 80°C maximum. The vibration produced by the ultrasound harmonic knife cause kinetic energy release within tissue cells because of the oscillation of water molecules. This results in cell membrane rupture and cell protein denaturation, which forms the coagulum and clogs blood vessels and lymph ducts²⁷. Using the ultrasound harmonic scalpel, electric energy does not reach the tissue, and it possesses safety mechanisms that prevent ultrasound vibration occurrence in unaimed tissue^{12,27}. This achieves better homeostasis than using the electrocauter²⁸, which is confirmed by measuring the level of intraoperative blood loss and postoperative drainage content. Statistically, intraoperative blood loss and postoperative secretion was significantly smaller in patients treated with the ultrasound harmonic scalpel.

Even next to the forementioned advantages of technology implemented in the ultrasound harmonic scalpel, research did not show statistically significant differences in the length of postoperative hospital recovery between the two groups. The reason probably lies in the fact that we released patients after removing operational drains, after reaching 30 mL/day secretion. This is a relatively small level and practically represents total homeostasis, and it makes the total length of postoperative treatment relatively long. This level was chosen to avoid possible postoperative complications. If the criteria for removing operational drains were set to a higher level, and considering the demonstrated statistically significantly smaller total secretion in the group mastectomized with ultrasound harmonic scalpel, it would be realistic to expect significant differences in postoperative hospital stay between patients mastectomized with ultrasound harmonic scalpel and those mastectomized with monopolar electrocauter.

Postoperative pain is one of the basic elements of patients accepting a new operational method, therefore measuring its intensity is one of the inevitable parameters in grading the success rate of a new method. Postoperative pain intensity is measured directly, using one of the constructed scales, or indirectly, measuring the amount of analgesics administered for pain treatment²⁹. Our research includes direct and indirect pain intensity measuring. For direct measuring of postoperative pain intensity we used the visual analog pain scale (VAS) because of its adequate sensitivity³⁰. There were no statistically significant differences between postoperative pain intensity and analgesic consumption in the two groups in our research.

The number and type of postoperative complications do not statistically differ between the tested groups. The most frequently occurring postoperative complication is seroma collection. However, its appearance in both tested groups is relatively rare and consistent to the results of new research³¹. The reason of rare seroma appearance in our research lies in the fact that operational drains were removed after reaching almost total homeostasis. Infection of postoperative wounds incidence was also low,

which matches earlier studies conducted at the same Clinic³².

We have not determined statistically significant differences in the total recovery rate between two groups of patients. Namely, although mastectomy is a mutilating operational procedure, it does not compromise the locomotor system greatly and with that the ability of motion, or other organ systems³³. Lymphatic drainage disorder in the upper extremity is a side-effect of modified radical mastectomy, and it's caused by extensive subaxillar lymphadenectomy, leading to possible functional disorders of the upper extremity³⁴.

The time elapsed until the patients returned to work was not considered relevant in this study. Namely, after the surgical treatment, every patient goes through multiple oncology protocols, which are not the same for every patient and those protocols compromise their work ability in different ways³⁵.

This study also tried to show the level of tissue trauma and organism stress caused by modified radical mastectomy using ultrasound harmonic scalpel and monopolar electrocauter by evaluating acute phase inflammatory response intensity. Respecting the laboratory features of the institution in which the research was conducted, we analyzed erythrocyte sedimentation rate, leukocyte number, serum level of CRP and IL-6 (which enables objective determination of surgical trauma) to evaluate acute phase inflammatory response intensity^{16,36}.

Activation of the inflammatory response mechanism as its response to tissue trauma caused by surgical procedure is conditioned by releasing a great number of mediators – cytokines. One of the most important is IL-6 which regulates the liver component of the acute phase of inflammatory response, which results in protein synthesis³⁷. Acute phase inflammatory response protein synthesis is a recognizable organism response to tissue trauma³⁸. CRP is the key protein of acute phase inflammatory response whose level consistently increases, and it is extremely suitable for screening purposes³⁶. There is a statistically significant increase in CRP levels as early as 4-12 hrs after the procedure, and it reaches its maximal values 24-72 hrs after the procedure³⁸. This matches the results we got in our research. Increased CRP serum levels are maintained for about 2 weeks after the surgical procedure¹⁸.

Cytokine response to tissue trauma caused by surgical treatment has been intensively studied³⁹. The primary mediator of this response is considered to be IL-6. Serum IL-6 levels are early and sensitive marks of tissue trauma and their levels increases proportionally to the tissue trauma caused by surgical trauma¹⁸. It was determined that increase in IL-6 levels is connected to the occurrence of surgical complications, operation time, and blood loss during surgery⁴⁰. It was also determined that a correlation exists between the highest CRP serum levels and postoperative IL-6⁴¹, which was also confirmed by our research. Namely, there is a statistically significant increase in IL-6 levels as early as 4 hrs after surgery, and it reaches its maximal values after 48 hrs.

Immunosuppression is also a determined side-effect of surgical tissue trauma and organism stress. It is not defined only through cytokine activation, but more importantly, through the cell component of the system immune response⁴². Although the number of leukocytes in peripheral blood after the procedure is not the main characteristic of acute phase inflammatory response, recent researches show statistically significant increase in leukocyte number in the peripheral blood after classical surgery procedures⁴³. Our research shows a statistically significant increase in the number of leukocytes in peripheral blood in both patient groups as early as 4 hrs after surgery. After that the level of leukocytes in the peripheral blood decreases gradually.

The conducted research shows that modified radical mastectomy leads to significant surgical tissue trauma, leads to intensive acute inflammatory response, implies a certain blood loss during surgery, and leads to significant postoperative secretion through operational drains. Post-

operative pain can be suppressed by oral analgesics, the number and types of complications are acceptably small, recovery and return to everyday activities, taking into consideration the mutilating character of the operation, are relatively short.

Statistically significant differences in measured parameters: operation time, inflammatory response, post-operative pain intensity, analgesics consumption, number and types of complications, length of hospital stay and time needed for return to everyday activities between the two groups of patients were not determined. The smaller amount of drainage content, and intra-operative blood loss in the group operated with the ultrasound harmonic scalpel has been statistically significant.

Therefore, using the ultrasound harmonic scalpel in comparison to the monopolar electrocauter brings certain advantages, which however do not contribute significantly to the total success rate of the operation.

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RANDOMIZIRANA DVOSMJERNA USPOREDBA MASTEKTOMIJE S ULTRAZVUČNIM NOŽEM I MONOPOLARNIM ELEKTROKAUTEROM

SAŽETAK

Cilj ovog rada je sveobuhvatna evaluacija i usporedba uspješnost modificirane radikalne mastektomije uz uporabu ultrazvučnog noža i monopolarnog elektrokautilera. U prospektivnu studiju su uključene sve pacijentice kojima je zbog karcinoma dojke planirana i učinjena modificirana radikalna mastektomija u razdoblju od 01.07.2008. godine do 31.12.2008. godine na klinici za Kirurške bolesti i urologiju KB Mostar. Mjerene su i registrirane dužine trajanja operacija, intraoperacijski gubitci krvi, te sekrecija na operacijske drenove. Iz uzoraka periferne venske krvi prije operacije, 4h nakon operacije, te prvi, drugi i treći poslijeoperacijski dan su mjerene i registrirane vrijednosti leukocita (Le), sedimentacije eritrocita, interleukina 6 (IL-6) i C-reaktivnog proteina (CRP). Svakom pacijentu je mjereno i intenzitet poslijeoperacijske boli, količina analgetika administrirana pacijentima za vrijeme boravka u bolnici, broj i vrsta poslijeoperacijskih komplikacija, a registrirano je i vrijeme nakon operacije kada su se pacijentice mogle vratiti svakodnevnim aktivnostima. U navedenom razdoblju u studiju je uključena ukupno 61 pacijentica. Uz primjenu ultrazvučnog noža je operirana 31 pacijentica, a uz primjenu elektrokautilera njih 30. Statistički značajne razlike u trajanju operacije između dvije skupine nema: $78,50 \pm 17,50$ minuta s ultrazvučnim nožem i $82,50 \pm 18,50$ minuta s elektrokautilerom (Mann-Whitney test = 165,000, $p = 0,796$)., Količina krvi izgubljene za vrijeme operacije je statistički značajno manja u skupini pacijentica mastektomiranih uporabom ultrazvučnog noža 78 ± 31 ml u odnosu na 256 ± 112 ml kod skupine mastektomiranih uporabom električnog noža (Mann-Whitney test = 42,000, $p < 0,001$), kao i ukupna sekrecija na operacijske drenove; u skupini pacijentica mastektomiranih uporabom ultrazvučnog noža 540 ± 390 ml u odnosu na 960 ± 710 ml kod skupine mastektomiranih uporabom elektrokautilera (Mann-Whitney test = 45,000, $p < 0,001$). Statistički broj leukocita u krvi ispitanika nakon modificirane radikalne mastektomije s ultrazvučnim nožem i elektrokautilerom se ne razlikuje ($F = 0,003$; $p = 0,957$), kao ni sedimentacija eritrocita (analiza varijance $F = 4,823$; $p = 0,114$), CRP ($F = 2,672$; $p = 0,071$) i IL-6 ($F = 3,841$; $p = 0,082$). Dužina poslijeoperacijskog boravka u bolnici kod ispitivanih skupina nije pokazala statistički značajnih razlika, kao ni intenzitet poslijeoperacijske boli i količina administriranih analgetika, te vrsta i broj poslijeoperacijskih komplikacija, odnosno vrijeme do povratka svakodnevnim aktivnostima. Dakle, uporaba ultrazvučnog harmoničnog noža u odnosu na monopolarni elektrokautiler pri modificiranoj radikalnoj mastektomiji donosi izvjesne prednosti, koje međutim ne doprinose značajnije ukupnoj uspješnosti operacije.