# Original Paper

# Clinical Assessment of the Advantages of Laparoscopic

# Cholecystectomy Compared to Standard Cholecystectomy

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### 1. History of Laparoscopy

First laparoscopic cholecystectomy was performed in 1987, and was made of two operative techniques: laparoscopy and cholecystectomy. Two classical surgical procedures were united with the discovery and application of miniature video-camera in the concept of minimally invasive surgery.

The significance of these discoveries in surgery can only be compared to implementation of asepsis, anesthesia and antibiotics.

### **History of Cholecystectomy**

Diseases of gallbladder represent one of the commonest indication for operative treatment in general surgery. This disease, old as the mankind itself, can be traced back to the antic times. Gallbladder stones was found in a mummy of a 21<sup>st</sup> Egyptian dynasty priest Amom, cca. 1000 BCE.

First cholecystectomy was performed by Fabricius in 1618, but it is not sure if it was performed on a live patient. First documented cholecystectomy was performed by an American surgeon, Bobs in 1897. Procedure was indicated due to the gallbladder hydrops and was performed in an apartment above the pharmacy.

15<sup>th</sup> of July 1892, Carl Langenbuch, 36 year old surgeon, did his first cholecystectomy in Lazarus hospital in Berlin. His 43 year old patient became addicted to morphine due to 16 years of repeated biliary colic. Patient was preoperatively prepared during the course of five days by washing – out the intestines, and was discharged from the hospital after six weeks. Langenbuch set the principle: gallbladder should be removed not because it contains stone, but because it creates it.

In America, first cholecystectomy was performed by Ohage in 1886. First choledochotomy was performed by Courvasier in 1890. The biggest name in billiar surgery of that time was Halsted, who unfortunately died from the consequences of choledocholithiasis.

First laparoscopic cholecystectomy was performed in 1986, by E. Muhe from Boblingen, Germany, and he published his procedure in an article Die erste cholecystectomy durch das laparoscop. The

article was published in a magazine called Langenbebeck's surgical archive. The article was unnoticed by his colleagues and he did not get any recognition. The glory came to Philip Mouret despite the fact that he did not publish his operation.

In 1987 in Lyon, Phillip Mouret performed his first laparoscopic cholecystectomy but he did not publish it. The procedure was performed in secrecy, without video camera, by using classical direct vision thru the telescope. The liver was retracted up and back, while he performed dissection in Calot's triangle. After ligation and resection of cystic artery and cystic duct, which was performed by laparoscopic technique, he then performed mini subcostal laparotomy, which he used to remove the gallbladder from its bed. The second operation was performed by Philip Mouret by using video camera and completely using laparoscopic technique.

#### Indications and Contraindications for Laparoscopic Cholecystectomy

Cholelithiasis is very common condition. Around 10% of USA population has stones in either gallbladder or biliary tract. In these patients, around 20% of them have some form of symptoms in the moment of diagnosis, but most of them (around 80%) remain asymptomatic during their entire life. European data shows that around 50% of the diagnosed patients remain asymptomatic. In Bosnia there is no exact data to show incidence and prevalence.

It is our opinion that every patient with the diagnosis of gallbladder stones should be offered an operation – cholecystectomy. We derive this conclusion from the next facts:

- Constant presence of gallbladder stones presents a risk factor for developing a gallbladder carcinoma (around 85% of gallbladder carcinoma has stones in it)
- The function of gallbladder which contains stones is disrupted, which leads to bad digestion of food, primarily fat.
- Stones, especially smaller ones represent a risk for developing an obstruction in biliary tract and acute pancreatitis.

These are the facts that should be discussed with every patient with gallbladder stones, if they are asymptomatic, and we consider operative treatment.

Contraindication for laparoscopic cholecystectomy can be relative and absolute. Today, the only absolute contraindication is surgeon's inexperience.

By relative contraindications, we consider:

Untreated choledocholithiasis

Pregnancy

Untreated cholangitis

Coagulation disorders

**Biliary** pancreatitis

Extreme obesity

Previous surgeries in upper abdomen

Generalized peritonitis

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Carcinosis of the peritoneum

Advanced or sever liver disease

#### **Technique of Laparoscopic Cholecystectomy**

Operating surgeon stands on the left side of the patient, next to him stands the first assistant who operates the camera. Across the operating surgeon stands the second assistant, and next to him stands the operating nurse (American positioning).

Other than this positioning, its also possible to use lithotomy position, when the operator stands in between the patients abducted legs.



Picture no.1: American Positioning

#### Conversion

By conversion we consider turning the laparoscopic cholecystectomy into an open procedure. The rate of conversion varies from 0,5-8% according to various series and has the tendency of going down if we observe the laparoscopic cholecystectomy since the beginning. The decision of conversion is made by the operating surgeon during the laparoscopic procedure, when he estimates that he won't be able to safely completes the procedure laparoscopically. Conversion shouldn't be considered as a failure by the surgeon, and he shouldn't prolong the decision to make an conversion. Conversion is made by transferring to open surgery and finishing the operation through an open midline or right subcostal incision.

#### Complications

### **General Complications of Laparoscopic Surgery**

**Respiratory** changes during the laparoscopic surgery are usually caused by pneumoperitoneum.

**Cardiovascular** changes during the laparoscopic procedure are usually consequences of pneumoperitoneum and of positioning the patient in a certain way.

**Gas embolism** – absorption of a small quantity of carbon-dioxide into the bloodstream from the peritoneal cavity, or from the accidental intravenous way during the insufflation process, usually does not represent a problem, because carbon-dioxide quickly dilutes into non toxic molecules. If a larger amount of carbon-dioxide gets to the bloodstream, it can be fatal. This outcome is very rare, and it occurs in about 1-4 cases / 65 000 laparoscopic procedures.

**Subcutaneous emphysema** occurs as a consequence of carbon-dioxide getting under the skin. It is usually small in area it affects, although there have been more severe cases.

**Nausea and vomiting** are common side effects after surgical procedures, and surgeons mostly attribute them to effects of anesthesia. As far as laparoscopic procedures are considered, nausea and vomiting occur in about 45% of the cases.

**Hypothermia** is relatively common, it occurs in about one third of the patients, if the laparoscopic procedure lasts more than two hours.

**Pain** after laparoscopic procedures is common, despite the common misinformation that laparoscopic procedures are painless. Up to 13% of the patients describe intense pain after the laparoscopic procedures.

#### Laparoscopy Specific Complications

Complications that occur during and after laparoscopic procedures, and are directly linked with the laparoscopic technique, are considered specific complications. They can be intraoperative and postoperative. Postoperative complications can be early or late complications.

Intraoperative complications

1. Complications caused by Veres needle – these complications have incidence of about 1 patient in 500-1000 cases. If the needle doesn't enter the peritoneal cavity, and injection of the gas is started, this leads to subcutaneous emphysema. During the application of the needle, vascular structure can be punctured, thus leading to bleeding, unless the needle is inserted into the avascular zone. Far more dangerous can be complications associated with the needle in the peritoneal cavity. Veres needle can perforate bowel or blood vessel, and since the diameter of the needle is small, the place of the perforation can remain unseen, heal spontaneously and doesn't require additional treatment. Large blood vessels lesions (i.e. aorta, v. cava, iliac veins or arteries) are rare, but can be fatal, unless prompt conversion and hemostasis is made. The best prevention is careful insertion of the Veres needle.

2. Trocar injuries. In the most common technique, first trocar placement after the pneumoperitoneum is achieved, is done by "blind" technique and is related to vascular elements or bowel injuries.

3. Thermal injuries. Harmonic scalpel is a specially constructed, so thermal injuries are rare. The

most common thermal injuries are related to cautery use. Electrocautery can cause thermal injuries of the bowel, which if not recognized during the procedure, can lead to serious and sometimes fatal injuries. Tissue injury can be consequence of instrument isolation damage. Direct electric current lesion often remains undetected, because the contact between the electrode and the metal laparoscope is outside the field of vision. Other than these injuries, who can remain undetected, sometimes there are injuries that can be instantly seen, such as direct cautery injuries of the tissue. It is not uncommon that during the tissue preparation, the tip of the cautery "hops" on adjacent structures (liver, diaphragm, stomach, bowel...) and damages them. These lesions are usually minimal, but need careful observation and potentially, treatment.

4. Complication during the cholecystectomy – these complications can occur in any phase of the laparoscopic procedure, and are usually consequence of bad technique or bad judgment of the operating surgeon. During the gallbladder fundus retraction, and manipulation by forceps, injury can be made to the wall of the gallbladder, which leads to perforation with leakage of the bile and stones. Perforation can be made with the use of cautery, also by accident. The most dreaded injuries in gallbladder surgery, open or laparoscopic, are bile duct injuries. These injuries can happen even to the most experienced surgeons, and the causes are numerous. Bleeding and bile leakage, during or more commonly after the procedure, can be consequence of clips falling of the blood vessel or bile duct, bleeding from the gallbladder bed, or leakage from an aberrant bile duct in the bed of the gallbladder. Sometimes the bleeding can be from the place of the port, and it happens shortly after the port removal. It is vital that this injury is recognized early and adequately treated.

Postoperative complications

Early postoperative complications happen in 48 hours after the surgery.

Pain after the laparoscopic procedure is usually not intense nor long-lasting. This pain usually stops shortly after the surgery.

Every noticed bleeding should be examined. It is important to identify the place and the source of the bleeding, and take adequate measures in its controlling. Bleeding from the gallbladder bed usually spontaneously stops, and does not require surgical treatment in most cases. Massive bleeding in postoperative period, with deterioration in patient's condition, requires urgent surgical intervention – laparoscopically or open surgery hemostasis.

Bile leakage can be consequence of clips failure or falling of the stump of cystic duct, leakage from accessory duct in gallbladder bed, or it can be from bile duct injury.

Serious infections after laparoscopic cholecystectomy are considered rare complications.

Pancreatitis is also a very rare complication and has a very high morbidity and mortality, so it requires intensive care treatment.

Late postoperative complications are those which are presented at least a month after the laparoscopic operation, and are not rare.

Abscess – stone dissemination from the gallbladder in the peritoneal cavity, during the procedure is not uncommon.

Malignant cell dissemination – Gallbladder removal in which the carcinoma is discovered during the histopathological examination very rarely leads to dissemination, if done laparoscopically.

In 2% of the patients undiagnosed bile duct stones remain, whether it is done laparoscopically or with open technique.

Very rare complications – these are usually bizarre. Japanese surgeons have published a metal clips migration in bile duct, that later on caused choledocholithiasis. It took him a year post op to cause that. The prevention of complications is the most important thing. One study showed that the biggest percentage of complications is in the first 15 cases that a surgeon performs. Like in any other procedure, it is vital to maintain good technique and protocols, and do not improvise.

### 2. Goals of the Paper

In treating of this problem there are two different ways; laparoscopic and open procedure – cholecystectomy. The possibility of achieving an uniform conclusion is highly unlikely, due to the fact that different hospitals have different economical potentials in educating their surgeons and getting the required equipment, as well as economical potential of the patients and their personal understanding of the problem.

The high incidence of this pathology, different approach in surgical care and financial potential of the patients highlight not only health care importance, but also economical importance, so this paper will represent a path to better understanding and treatment of this pathology.

Our own experience in treating gallbladder disease, oblige us to critically analyze the cases and give a prospective study in incidence and ways of treatment of these diseases.

Laparoscopic cholecystectomy becomes a gold standard in treatment of cholelithiasis and complete assessment of its value depends on analyzes of intraoperative complications. By assessing these complications, we can direct the further development of this method in terms of patient safety.

By analyzing intraoperative complications and reaching the conclusion, we can evaluate the safety and functionality of the equipment, we can suggest the ways of further development, which in turn has huge medical as well as financial importance.

By broadening the indications, i.e. removing the acute cholecystitis as a relative contraindication, the philosophy of gallbladder stones treatment is changed dramatically, and the benefits of the laparoscopic approach can be enjoyed by a wider number of patients.

### **General Goal**

To determine if there is a difference in the ways of treatment and effects between standard and laparoscopic cholecystectomy?

Specific goals

To determine if there are differences in medical parameters between open and laparoscopic cholecystectomy?

To determine if there are differences in economical parameters between open and laparoscopic cholecystectomy?

By following the previous, we have set the specific goals of this paper:

- 1. To determine the length of the operative procedure in laparoscopic and open cholecystectomy?
- 2. To determine the length of the hospitalization in both methods
- 3. To determine the number of the postoperative complications in both methods
- 4. To determine the mortality in both methods
- 5. To determine the length of postoperative pain in both methods
- 6. To determine the length of the recoalescence in both methods
- 7. To determine the financial effects of patient treatment in both methods
- 8. To determine the financial effects of treatment for the hospital and society in both methods If we put all of this together, we need to do an cost-benefit analysis:

The safety and trust of the patients in our work, brings our hospital bigger financial gain.

#### 3. Hypothesis

After the listed goals of research, we have made the hypothesis. Null hypothesis

0H There is no difference in the ways and effect of treatment in between laparoscopic and open procedure

Alternative hypothesis

aH There is a difference in the ways and effect of treatment in between laparoscopic and open procedure

There are differences in medical and economical parameters in between laparoscopic and open cholecystectomy. Laparoscopic cholecystectomy is a superior method from both the medical and economical point of view.

Considering the previous statement, we have se the special, working hypothesis: Working hypothesis

1H The length of operative time in laparoscopic and open cholecystectomy do not differ.

2H The length of hospitalization in laparoscopic and open cholecystectomy do not differ.

3H The number of postoperative complications in laparoscopic and open cholecystectomy do not differ.

4H The mortality in laparoscopic and standard cholecystectomy do not differ.

5H The length of pain after laparoscopic and open cholecystectomy do not differ.

6H The recoalescence after laparoscopic and open cholecystectomy do not differ.

7H The financial effects of treatment for patients in laparoscopic and open cholecystectomy do not differ.

8H The financial effects of treatment for hospital and society in laparoscopic and open cholecystectomy do not differ.

The success of this research will confirm or reject the thesis, that laparoscopic cholecystectomy is a method of choice in treatment of gallbladder stones.

#### 4. Materials and Methods

This paper represents randomized, prospective, clinical study of patients in Clinic for general and abdominal surgery, University clinical center Banja Luka.

During the study, open and laparoscopic cholecystectomies were performed in our Clinic, and evaluation has encompassed the work of all the surgeons in the clinic. The main sample of the study make patients (180) operated on because of gallbladder stones. The patients will be divided into 2 study groups: group S (study group) will be made of 90 patients operated on by open procedure, and group L (control group) will be made of 90 patients operated on by laparoscopic procedure. The data and surgical procedures will be shown in text, graphs, and open and laparoscopic procedure will be shown in video.

Study is planned and realized in 4 parts:

A. Entry protocol – patients were, with their consent, randomly allocated according to study criteria and including and excluding criteria. According to method used for operation, they were divided into group S, and group L, and they were given study protocols.

B. Hospital part of the study – in this part patients were operated on, treated, discharged from the hospital and followed up, and all the important data were noted in individual papers.

C. Ambulant part of the study – in this part the patients were followed up in an office setting, from the moment of discharge until the end point of the study (return to normal activities, at least 3-6 months post-op). After the last check-up (at least 3-6 months post-op) the individual paper was closed for every patient, and was sent for further analysis. This was done after checking the excluding criteria and achieving adequate number (90) for both groups.

D. Data analysis and presentation – this was done after concluding the ambulant part of the study for the last followed patient.

Entry protocol

Including criteria was:

1. Agreeing to operative treatment of gallbladder stones

2. Signing the consent form on the study information leaflet

3. Not having a malignant disease

Excluding criteria was:

- 1. Those who were treated without operation
- 2. Those who had active concomitant disease
- 3. Those who died during the study

- 4. Those who decided to leave the study
- 5. Those who were reoperated on during the study, regardless the cause
- 6. Those who had malignant disease, diagnosed during or after the operation

Hospital part of the study

Admission to the hospital – patients were admitted to the hospital according to surgeon indications. The selection of the patients for the study was selective in regard with entry level criteria – inclusion criteria. After being included in the study, and allocation to group L or S, each patient was given an individual protocol of the study in which all the important data for the study was tracked.

History and physical exam

For this study we used the following data from the exam an history: name and surname, date and place of birth, phone and address, occupation, habits. From this data we extracted the next variables:

- 1. Sex,
- 2. Age,
- 3. Decades of life,
- 4. diabetes,
- 5. obesity,
- 6. chronic respiratory disease,
- 7. smoking y/n,

8. preoperatively set number of smoked cigarettes (pack x year),

- 9. blood leukocytes,
- 10. blood glucose levels,
- 11. blood protein levels,
- 12. blood hemoglobin levels,
- 13. blood hematocrit,

14. Operation time – for expressing in numeric values, we used statistical parameters median value, minimum, maximum +- standard deviation, T test, distribution, frequency and trend.

15. Operation time longer than 100 minutes – according to data from the operation list regarding the procedure time, procedure that took more than 100 minutes were coded with Y, and procedures shorter than 100 minutes were coded with an N. We used  $\chi^2$  test.

16. ASA score – tests were done with the  $\chi^2$  test and the markings were – 1 ASA I 2 ASA II 3 ASA III 4 ASA IV 5 ASA V

17. Injuries during trocar insertion – or during opening of the abdomen. We wrote down the number, type and quality of the injuries. We described it and potential testing for non-homogenous results was done using the  $\chi^2$  test.

18. Intraoperative injuries - We wrote down the number, type and quality of the injuries. We described it and potential testing for non-homogenous results was done using the  $\chi^2$  test.

19. Abdominal drain placement - patients that had drain were coded with Y, and patients who

did not have drain were coded with N. Testing were done using  $\chi^2$  test.

20. Histopathological findings – according to the findings of the acute inflammation of the gallbladder was coded with **acute**, and HP findings of the chronic inflammation was coded **chronic**. The testing was done using  $\chi^2$  test.

21. Conversion – the number, types and reasons of conversion were noted. We described it and potential testing for non-homogenous results was done using the  $\chi^2$  test.

22. Postoperative complications - We described it and potential testing for non-homogenous results was done using the  $\chi^2$  test.

23. Lethal outcome – where the lethal outcome occurred, it was coded with Y, and where the lethal outcome did not happen, it was coded with N. The testing was done using the  $\chi^2$  test.

24. Pain syndrome duration - for expressing in numeric values, we used statistical parameters median value, minimum, maximum +- standard deviation, T test, distribution, frequency and trend.

25. Postoperative usage of antibiotics - for expressing in numeric values, we used statistical parameters median value, minimum, maximum +- standard deviation, T test, distribution, frequency and trend.

26. Postoperative cough – The presence of cough was coded with Y, and absence was coded with N. The testing was done using the  $\chi^2$  test. We noted the number of patients with cough and the number of days it lasted. For expressing in numeric values, we used statistical parameters median value, minimum, maximum +- standard deviation, T test, distribution, frequency and trend.

27. Postoperative nausea and vomiting – the intensity of nausea was subjectively evaluated by patients, and was given a score of one for light nausea, two for medium nausea, and three for heavy nausea with vomiting urges. The occurrence of vomiting was given a score of four. The point was given during 12-hour intervals. The maximum day of follow up was 4. The presence of postoperative nausea was coded with Y, and absence was coded with N. The testing was done using the  $\chi^2$  test.

28. The length of the hospitalization – the number of days spent in hospital. for expressing in numeric values, we used statistical parameters median value, minimum, maximum +- standard deviation, T test, distribution, frequency and trend.

Postoperative treatment and testing during hospital stay was done in a standard fashion, as in any other patient with this kind of pathology. Physical exams were done every day, laboratory tests and additional testing were done according to clinical indications and complications. The start of enteral feeding and ambulation of the patient was done in according to clinical findings. The patients were discharged from the hospital when deemed capable, and follow up of the patients was done by a single surgeon and in ordinance with the protocol.

The office part of the study

29. The recoalescence – was determined by the number of days spent in recovering, i.e. the last day after which the patients returned to work or resumed usual activities. It was the end point of the study.

30. Cost-benefit analysis – after the study was finished, it gathered different economical data: The cost of operation, the cost per day of patients with health insurance and those with no health insurance, the cost of sick days. This data was used and they were subjected to statistical and mathematical analysis.

#### 5. Statistical Analysis and Presentation of Data

After finishing the series, the data charts and individual forms for remaining patients were closed and were forwarded to statistical analysis and presentation. Before the statistical analysis there were 90 patients in the group S, and 90 patients in the group L.

All the results were inserted into data base (numerical values – were coded in number, and descriptive values were coded in yes or no, or differently according to methodology) and statistically analyzed. The statistical methods were used: median value (x bar) +/- standard deviation (+/- SD), minimal value (min), maximal value (max), percentage (%), frequency, distribution, trends, Student T test,  $\chi^2$  test with Yates correction for small samples where needed) with accepted statistical significance of 0,05 or p<0.05. Where the results or data were incomparable the results were shown descriptively. The results were shown in numbers, tables, graphs and charts.

### 6. Results

The results of treatment will be shown in this study according to statistical analysis of observed parameters, more precisely by analysis of the observed goals and working hypothesis.

After finishing the study and completing the documentation of the 186 patients that were encompassed by this study, the following results were shown. Four patients did not finish the study in standard group (S). One patient died, from reasons not directly linked to the operation, one patient left the study, one patient was re-operated on, and one patient was lost in the follow up period due to migration. Two patients did not finish the study in the laparoscopy group (L). One patient left the study during the follow up period, and one other was lost during the follow up period duo to migration. To achieve adequate number of patient, the next four patients were included in the research of standard group (S), as well as next two patients in the laparoscopy group (L). After completing the groups and meeting the inclusion criteria of the research, the both groups had the same number of the patients. Standard group had 90 patients, laparoscopy group had 90 patients. The results were shown according to parameters observed.

### 6.1 Gender Structure

In group S we had 90 patients (table no.1 graph no. 1a, 1b, 1c.) 21 (23,3%) male, and 69 (76,7%) female. In group L we had 90 patients: 22 (24,4%) male and 68 (75,6%) female.

	Male	Female	Total
Group S	21 (23.3%)	69 (76.7%)	90 (100%)
Group L	22 (24.4%)	68 (75.6%)	90 (100%)
	$\chi^2 = 0.03$	<b>p</b> = <b>0.861</b>	180

### Table 1. Genderstructure

Of the total number 21 males and 69 females were operated on using standard method, and 22 males and 68 females were operated on using laparoscopic method. There was no statistical significance (p=0,861) in correlation of gender and method of operative treatment.



Of the total number of patients, there were more females than males. From graph No. 1a we can see the total numbers. The ratio of females to males is 3,18:1. The females were statistically significant more operated on than females, 3,18 times more.

In the group S there were more females than males (graph no.1b). The ratio of operated females 69 (76,7%) to 21 operated males (23,3%) is 3,29:1. The females were statistically significant more operated on than males, 3,29 times more.



In the L group females were more operated on than males (graph No.1c). The ratio of operated females 68 (75,6%) and operated males 22 (24,4%) is 3,09:1. The females were more operated on statistically significant, 3,09 times more than males.



Of the total sample, both group S and L, there was equal but statistically significant more females than males (3,18; 2,29; 3,09) in average 3,2 times more.

# 6.2 Age Structure

The average age (table 2, graph no. 2) in the group S was  $54,22 \pm 20.51$  (Min 17, Max 90). The average age in the group L was  $46,67 \pm 14.53$  (Min 23, Max 80).

	X min	X max	X bar	$\pm$ SD	
Group S	17	90	54.22	20.51	
Group L	23	80	46.67	14.53	
	t = 2.711	df = 178	<b>p</b> = <b>0.008</b>	p<0.01	

Table 2. Age	Structure
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There is statistically significant difference (t= 2,849 df=178 p = 0,008 p<0,01) between groups S and L in regard to age of the patients. The patients from the group S who were operated using standard method are statistically significantly (p=0,008) older than the patients in the group L who were operated on using laparoscopic method.



### 6.3 Age Structure by Decades

The average age in the group S was 54,22 years, and the average age in the group L was 46,67 years.

		0							
Years	do 20	21 - 30	31 - 40	41 - 50	51 - 60	61 - 70	71 - 80	81 - 90	Σ
Group S	1	7	10	16	24	20	11	1	90
Group L	0	13	20	24	18	11	4	0	90
Σ	1	20	30	40	42	31	15	1	180

**Table 3. Distribution According to Decades** 

In the table 3 and in graph No. 3 we can see the distribution of operated patients according to decades of life in group S and in group L, and also in the whole sample. Most patients who were operated on in the group S was in sixth and seventh decade of life, and most patients in the group L who were operated on was in fourth and fifth decade of life. Of the total number of patients, most of them were in fifth and sixth decade of life.



# 6.4 Diabetes

In group **S** there were 6 patients with diabetes, and in group **L** there were 12 patients with diabetes (Table 4, Graph no. 4).

# Table 4. Diabetes

	YES	NO	In total
Group S	6	84	90 (100%)
Group L	12	78	90 (100%)
	$\chi^2 = 2.22$	p = 0.136	180

There is no statistically significant difference ( $\chi^2 = 2.22$ , df = 1, p = 0.136, p > 0.01) between groups S and L in relation to diabetes. Although it can be seen from the data that there were twice as many diabetics in group L, in the sample there is no statistical significance (p=0.136) in the connection between diabetes and the method of surgical treatment.



### 6.5 OBESITY

There were 14 obese patients in group S, and 23 obese patients in group L (Table 5, Graph no. 5).

	YES	NO	In total	
Group S	14	76	90 (100%)	
Group L	23	67	90 (100%)	
	$\chi^2 = 2.76$	p = 0.0969	180	

### Table 5. Obesity

There is no statistically significant difference ( $\chi^2 = 2.76$ , df = 1, p=0.0969, p>0.01) between groups S and L in relation to obesity. Although it can be seen from the data that there were almost twice as many

obese people as in group L, in the sample there is no statistical significance (p=0.0969) in the connection between obesity and the method of operative treatment.



# 6.6 Chronic Respiratory Disease

In group **S** there were 8 patients with chronic respiratory disease, and in group L there were 6 patients with chronic respiratory disease (Table 6, Graph no. 6).

Table 6. Chro	nic Respi	catory Disease
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	YES	NO	In total
Group S	8	82	90 (100%)
Group L	6	84	90 (100%)
	$\chi^2 = 0.31$	p = 0.5778	180

There is no statistically significant difference ( $\chi^2 = 0.31$ , df = 1, p=0.5778, p>0.01) between group S and group L in relation to chronic respiratory disease. In the sample, there is no statistical significance (p=0.5778) in the connection between chronic respiratory disease and the method of operative treatment.



# 6.7 Preoperative Smoking

In group **S**, 15 patients smoked preoperatively, and in group **L**, 21 patients smoked preoperatively (Table 7, Graph no. 7).

Tabl	e 7.	Preope	rative	Smol	king
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	YES	NO	In total
Group S	15	75	90 (100%)
Group L	21	69	90 (100%)
	$\chi^2 = 1.25$	<b>p</b> = <b>0.2636</b>	180

There is no statistically significant difference ( $\chi^2 = 1.25$ , df = 1, p=0.2636, p>0.01) between group S and group L in relation to smoking. In the sample, there is no statistical significance (p=0.2636) between smoking and the method of operative treatment.



6.8 Numerically Determined Smoking Preoperatively

The numerically determined amount of smoking preoperatively, pack x years of smoking, (Table 8 and Graph no. 8) was in group **S**, (n=15), 23.5  $\pm$  21.31 packs x years (Min 1.5, Max 60). Numerically determined amount of smoking preoperatively, pack x years of smoking, was in group **L**, (n=21), 32.71  $\pm$  24.76 pack x years (Min 1, Max 72).

**Table 8. Numerical Smoking Preoperatively** 

	X min	X max	X bar	±SD
Group S, n = 15	1.5	60	23.5	21.31
Group L, n = 21	1	72	32.71	24.76
	t = 1.193	df = 34 $p = 0.2$	252 p>0.05	

There is no statistically significant difference (t = 1.193, df=34, p=0.252, p>0.05) in the average number of numerically determined smoking preoperatively (p>0.05) between group S and group L. In the sample, there is no statistical significance (p=0.252) in the connection between the amount of smoking and the method of operative treatment.



# 6.9 Leucocytes in the Blood $(10^9/l)$

The values of leukocytes in the blood (Table 9 and Graph no. 9) were in group S 8.83  $\pm 2.95 \ 10^{9}$ /l (Min 6.00, Max 14.0). The values of leukocytes in the blood were in group L 9.6  $\pm 2.83 \ 10^{9}$ /l (Min 6.40, Max 12.0).

Table	9.	Leukocytes
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	X min	X max	X bar	±SD
Group S	6	14	8.83	2.95
Group S	6.4	12	9.6	2.83
	t = 1.7637	df = 178	p< 0.10	p> 0.05

There is no statistically significant difference (t=1.7637, df=178, p<0.10, p>0.05) in the average number of leukocytes in the blood (p>0.05) between group S and group L. Patients from group L have higher values, but this is not statistically significant. The probability threshold is between p=0.10 and p=0.05.



# 6.10 Blood Sugar (mmol/l)

Blood sugar values (Table 10 and Graph no. 10) were in group S 6.12  $\pm$  2.58 mmol/l (Min 3.20, Max 15.2). In group L, blood sugar was 5.85  $\pm$  2.68 mmol/l (Min 3.40, Max 14.3).

	X min	X max	X bar	±SD
Group S	3.2	15.2	6.12	2.58
Group L	3.4	14.3	5.85	2.68
	t = 0.6937	df = 178 p>0.05		

## **Table 10. Blood Sugar**

There is no statistically significant difference (t=0.6937, df=178, p>0.05) in the average value of blood sugar (p>0.05) between group S and group L. In the sample, there is no statistical significance in the connection between the average value of blood sugar and the method of operative treatment.



### 6.11 Proteins in the Blood (g/l)

Blood protein values (Table 11 and Graph no. 11) were in group **S** 62.0  $\pm$  4.27 g/l (Min 56, Max 70). In group **L**, the protein values in the blood were 62.2  $\pm$  4.29 g/l (Min 56, Max 70).

Table 11.	Proteins	in the	Blood
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	X min	X max	X bar	±SD
Group S	56	70	62	4.27
Group L	56	68	62.2	4.29
	t = 0.3134	df = 178	p>0.05	

There is no statistically significant difference (t=0.3134, df=178, p>0.05) in the average blood protein value (p>0.05) between group S and group L. In the sample, there is no statistical significance of the association between the average blood protein value and the method of operative treatment.



### 6.12 Hemoglobin (g/l)

Hemoglobin values in the blood (Table 12 and Graph no. 12) were in group S 132.3  $\pm$ 17.6 g/l (Min 99, Max 158). In group L, hemoglobin values in the blood were 135.5  $\pm$  13.8 g/l (Min 100, Max 161).

	X min	X max	X bar	±SD
Group S	98	158	132.3	17.6
Group L	100	161	135.5	13.8
	t = 1.357	df = 178 p>0.05		

#### Table 12. Hemoglobin in the Blood

There is no statistically significant difference (t=1.357, df=178, p>0.05) in the average value of hemoglobin in the blood (p>0.05) between group S and group L. There is no statistical significance in the sample when it comes to the connection between the average value of hemoglobin in the blood and the method of operative treatment.



# 6.13 Hematocrit (u %)

The hematocrit values in the blood (Table 13 and Graph no. 13) were in group S 41.2  $\pm$ 4.24 % (Min 26, Max 49). In group L hematocrit was 42.0  $\pm$ 3.86 % (Min 35, Max 53).

	X min	X max	X bar	±SD
Group S	26	49	41.2	4.24
Group L	35	53	42	3.86
	t = 1.3236	df = 178 p>0.05	5	

# Table 13. Hematocrit

There is no statistically significant difference (t=1.3236, df=178, p>0.05) in the average value of hematocrit in blood (p>0.05) between group S and group L. There is no statistically significant connection in the sample between the average value of hematocrit in blood and the method of operative treatment.



### 6.14 Duration of Operation

The average duration of surgery in patients (Table 14, graph no. 14) in group S was 70.22  $\pm$ 28.52 (Min 40, Max 120) minutes. The average duration of the operative procedure in patients in group L was 53.83  $\pm$ 19.56 (Min 30, Max 95) minutes.

	X min	X max	X bar	±SD
Group S	40	120	70.22	28.52
Group L	30	95	53.83	19.56
	t = 4.502	df = 178	<b>p</b> = <b>0.001 p</b> < <b>0.00</b>	)1

### Table 14. Duration of Operation

There is a statistically very significant difference (t=4.502, df=178, p=0.001, p<0.001) in the average duration of surgery for patients (p<0.001) between group S and group L. Average duration of surgery for patients in group S, 70.22  $\pm$  28.52 minutes, is statistically significantly longer (p<0.001) than in patients in group L where the duration was 53.83  $\pm$  19.56 minutes.



Table 14A shows the comparative distribution of the duration of the operation in 10-minute intervals for group **S** and group **L**. From Table 14A, it can be seen that the largest number of operated patients (n = 72 = 80%) in group S was in intervals of 50 to 80 minutes. It can also be seen from the graph-trend that the largest number of operated patients (n = 74 = 82.2%) in group L was in intervals of 40 to 60 minutes.

minutes	31-40	41-50	51-60	61-70	71-80	81-90	91-100	101-110	111-120	Σ
<b>GROUP S</b>	0	2	21	32	19	7	4	3	2	90
<b>GROUP</b> L	1	37	37	9	3	2	1	0	0	90

Table 14A. Distribution of the Duration of the Operation

The following graph no. **14A** shows a linear trend in 5-minute intervals that compares the duration of surgery in group **S** and group **L**. It can be seen that most patients in group **S** were operated on in time intervals of 55 to 85 minutes, and that most patients in group **L** were operated in time intervals of 45 to 65 minutes.



# 6.15 Operation Longer than 100 Minutes

In group **S** there were 5 patients in whom the operation lasted longer than 100 minutes, and in group L there were no patients in whom the operation lasted longer than 100 minutes (Table 15, Graph no. 15).

	YES	NO	In total
Group S	5	85	90 (100%)
Group L	0	90	90 (100%)
	$\chi^2 = 5.14$	<b>p</b> = <b>0.0233</b>	180

Table 15. Operation Longer than 100 Min

There is a statistically significant difference ( $\chi^2 = 5.14$ , df=1, p=0.0233, p<0.05) between group S and group L in relation to the duration of the operation longer than 100 minutes. There is statistical significance in the sample (p=0.0233), and operations last over 100 minutes more often with the standard method of operative treatment.



# 6.16 ASA Criteria

ASA criteria were determined according to the decision of the anesthesiologist and entered from the medical history of the patients in the individual sheets. Testing was done with  $\chi^2$  by the homogeneity test, and it is coded as an attributive feature with labels 1, 2, 3, 4, 5.

### Table 16. ASA Criteria

	ASA 1	ASA 2	ASA 3	ASA 4	ASA 5	Σ	
Group S	14	50	24	2	0	90	
Group L	23	57	10	0	0	90	
$\gamma^2 = 9.412$	df = 3 p<0.	05					



The distribution of ASA criteria of patients in our sample is shown in Table 16 and in Chart no. 16. In group **S** there were 14 **ASA1**, 50 **ASA2**, 24 **ASA3**, 2 **ASA4** and 0 **ASA5** operated patients. In group **L**, there were 23 **ASA1**, 57 **ASA2**, 10 **ASA3**, 0 **ASA4** and 0 **ASA5** operated patients.

To test this feature, we applied the slightly more complicated  $\chi^2$  test, i.e.  $\chi^2$  homogeneity test, because there is no ordinary 2 x 2 contingency table, but a 5 x 2 contingency table, and when **ASA5**, which has a value of 0 in both groups, is removed, a 4 x 2 contingency table remains. This  $\chi^2$  homogeneity test tests the null hypothesis that all the samples in the table belong to the same set, and for the level of confidence we set the probability of p = 0.05, with df = 3 i.e. three degrees of freedom. After testing, the following result was obtained:  $\chi^2$  test=9.412 >  $\chi^2$  (df=3 and p=0.05)=7.815,  $\rightarrow$  p<0.05. As well as  $\chi^2$  test=9.412 <  $\chi^2$  (df=3 and p=0.01)=11.341  $\rightarrow$  p>0.01. We reject this null hypothesis and conclude that these samples do not belong to the same (homogeneous) group, but are statistically significantly different because  $\chi^2$  test = 9.412 > 7.815, for df=3 and p=0.05. The certainty of the conclusion comes to the level of **p=0.03**. There is high statistical significance.

6.17 Injuries during Opening - Installation of the Trocar

	YES	NO	In total
Group S	0	90	90 (100%)
Group L	3	87	90 (100%)
	$\chi^2 = 1.36$	<b>p</b> = <b>0.2443</b>	180

Table 17. Injuries in the First Stage of the Operation

Operational work can be divided into three stages. During the first stage, during the opening, there were no injuries in group **S**. During the first stage, during the creation of the pneumoperitoneum and the introduction of the trocar, 2 subcutaneous emphysema occurred during the creation of the pneumoperitoneum with the Veress needle and 1 injury to the blood vessel of the abdominal wall in group **L**. During the introduction of the working port under the xiphoid, in one patient, a blood vessel of the abdominal wall was injured. The intensity of the injury was such that it required surgical care, i.e. the placement of stitches during the operation itself, so that the operation could be completed laparoscopically. During the introduction of the trocar, there was no injury to the blood vessels of the abdomen, nor were there any injuries of the intra-abdominal organs made.

There is no statistically significant difference ( $\chi^2 = 1.36$ , df = 1, p=0.244, p>0.05) between groups S and L in relation to injuries in the first stage of surgery. Although it can be seen from the data that there were 3 injuries in group L, in the sample there is no statistically significant (p=0.244) connection between the injury in the first stage of the operation and the method of operative treatment.

6.18 Intraoperative Injuries

	YES	NO	In total
Group S	0	90	90 (100%)
Group L	2	88	90 (100%)
	$\chi^2 = 0.51$	p = 0.477	180

Table 18. Injuries in the Second Stage of the Operation

Operative work can be divided into three stages. During the second stage, during intra - abdominal work, there were no injuries in group S. During the second stage, 2 injuries occurred in group L, an injury to the duodenum with an electrohook and an injury - a section of the choledochus. The injury of the duodenum was recognized and of such intensity that it required surgical care, that is, the placement of a suture, and a conversion was performed. Injury of the choledochus was also recognized, and conversion and hepaticojejunal anastomosis were performed.

There is no statistically significant difference ( $\chi^2 = 0.51$ , df = 1, p=0.477, p>0.05) between groups S and L in relation to injuries in the second stage of the operation. Although it can be seen from the data that there were 2 injuries in group L, in the sample there is no statistical significance (p=0.477) between the injury in the second stage of the operation and the method of operative treatment.

#### 6.19 Closing Injuries

Operative work can be divided into three stages. During the third stage, during the closure, there were no injuries in group S and group L.

Statistical work in a 2 x 2 contingency table, where two results are 0, cannot be evaluated, so p=1.00 or there is no statistical difference.

## 6.20 Abdominal Drainage

In group **S** there were 82 patients in whom an abdominal drain was placed, and in group **L** there were 35 patients in whom an abdominal drain was placed (Table **19**, Graph no. **17**).

	YES	NO	In total
Group S	82	8	90 (100%)
Group L	35	55	90 (100%)
	$\chi^2 = 53.94$	p = 0.0000	180

Table	19.	Abdominal	Drainage
Labic	1/1	nouommu	Dramage

There is no statistically significant difference ( $\chi^2 = 53.94$ , df=1, p=0.0000) between group S and group L in relation to abdominal drain placement. There is statistical significance in the sample (p=0.0000) and the abdominal drain is placed statistically significantly more often with the standard method of operative treatment.



# 6.21 PH Finding

In group **S** there were 22 patients with acute inflammation of the gallbladder, and in group **L** there were 9 patients with acute inflammation of the gallbladder (Table 20, Graph no. 18).

	ACUTE INFLAMMATION	CHRONIC INFLAMMATION	In total
Group S	22	68	90 (100%)
Group L	9	81	90 (100%)
	$\chi^2 = 6.59$	<b>p</b> = 0.0103	180

## Table 20. Pathohistological Findings

There is no statistically significant difference ( $\chi^2$  =6.59, df=1, p=0.0103) between group S and group L in relation to pathohistological findings. There is statistical significance in the sample (p=0.0103), and acute inflammation of the gallbladder occurs statistically significantly more often with the use of standard method of surgical treatment.



### 6.22 Conversion

Conversion as a parameter cannot be followed in both groups. As part of the operative treatment method, conversion exists only in group L. Due to its importance, it must be mentioned, and the statistical comparison is not possible. Operative work can be divided into three stages. During the second stage, during intra-abdominal work, 2 injuries occurred in group L, an injury to the duodenum with an electrohook and an injury - a section of the choledochus. Both of these injuries required conversion for proper and timely treatment. The injury of the duodenum was recognized and of such intensity that it required surgical care, that is, the placement of a suture, and a conversion was performed. Injury of the choledochus was also recognized, and conversion and hepaticojejunal anastomosis were performed.

In this study, conversion was performed in 2 out of 90 patients, 2.22%.

#### 6.23 Postoperative Complications

Postoperative complications that occurred were rare. As they can only be compared to the same kind, we will list them here. In group **S**, there were 4 surgical wound infections and 3 seromas. In group **L**, there was 1 biloma and 1 intra-abdominal abscess. We tried to statistically compare these two groups, although we collected attributive features that are not the same and can hardly be compared.

In group **S** there were 7 patients who developed postoperative complications, and in group **L** there were 2 patients who developed postoperative complications (Table 21).

	YES	NO	In total
Group S	7	83	90 (100%)
Group L	2	88	90 (100%)
	$\chi^2 = 1.87$	p = 0.171	180

#### **Table 21. Postoperative Complications**

There is no statistically significant difference ( $\chi^2 = 1.87$ , df=1, p=0.171) between group S and group L in relation to postoperative complications. There is no statistical significance in the sample (p=0.171), and postoperative complications occur statistically similarly in both methods of operative treatment.

If we were to test each attributive feature separately, which has a frequency of occurrence of 0,1,3 or 4, we would get statistically the same results, i.e. that there is no statistical difference.

### 6.24 Death Outcome

In group  $\mathbf{L}$ , 1 death occurred, while in group  $\mathbf{S}$  there were no cases of death (Table 21, Graph no. 19).

Table 21	l. Mortalit	y
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	YES	NO	In total
Group S	0	90	90 (100%)
Group L	1	89	90 (100%)
	$\chi^2 = 1.01$	p = 0.316	180

There is no statistically significant difference ( $\chi^2 = 1.01$ , df=1, p = 0.316) between group S and group L in relation to death. In the sample, there is no statistically significant (p = 0.316) correlation between the death outcome and the method of operative treatment.



### 6.25 Duration of the Pain Syndrome

The average duration of the pain syndrome in patients (Table 22, graph no. 20) in group S was 10.37  $\pm$  2.85 (Min 7, Max 14) days. The average duration of the pain syndrome in patients in group L was 3.01  $\pm$  1.38 (Min 1, Max 5) days.

of the day	X min	X max	X bar	±SD
Group S	7	14	10.37	2.85
Group L	1	5	3.01	1.38
	t = 22.05	df = 178	<b>p</b> = <b>0.001</b>	p<0.001

There is no statistically significant difference (t=22.05, df=178, p=0.001, p<0.001) in the average duration of pain syndrome in patients (p<0.001) between group S and group L. The average duration of pain syndrome in patients in group S,  $10.37 \pm 2.85$  days, is statistically significantly longer (p<0.001) than in patients in group L where it was  $3.01 \pm 1.38$  days.



On Table 23, and on Chart no. 21, the trend of pain syndrome in group S and in group L is shown.

Table 23.	Trend in	<b>Duration</b> of	f Pain S	vndrome
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DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14
GROUP S	0	0	0	0	0	0	4	7	10	26	24	13	5	1
GROUP L	6	14	<b>48</b>	17	5	0	0	0	0	0	0	0	0	0

From Table 23, and especially from Chart no. 21, it can be seen that the pain syndrome in group **S** lasted from 7 to 14 days. The pain syndrome in group **L** lasted from 1 to 5 days. The most common duration of pain syndrome (Mod) in group **S** was 10 days, and in group **L** it was 3 days. The duration of the pain syndrome was statistically significantly shorter in group **L**.



## 6.26 Postoperative Use of Antibiotics

Antibiotics were not routinely administered during this study. In group S, antibiotics were used in 26 patients, and in group L, antibiotics were used in 14 patients (Table 24, Graph no. 22).

	YES	NO	In total
Group S	26	64	90 (100%)
Group L	14	76	90 (100%)
	$\chi^2 = 3.89$	<b>p</b> = <b>0.0486</b>	180

There is no statistically significant difference ( $\chi^2 = 3.89$ , df=1, p=0.0486) between group S and group L in relation to the use of antibiotics. There is statistical significance in the sample (p=0.0486) and antibiotics were applied statistically significantly more often with the standard method of operative treatment.



### 6.27 Cough Postoperatively

In group **S**, 25 patients developed a cough postoperatively, while in group **L**, 14 patients developed a cough postoperatively (Table 25, Graph no. 23).

	YES	NO	In total
Group S	25	65	90 (100%)
Group L	14	76	90 (100%)
p=.0704	$\chi^2 = 3.96$	<b>p</b> = <b>0.0466</b>	180

#### Table 25. Cough

There is no statistically significant difference ( $\chi^2 = 3.96$ , df=1, p = 0.0466) between group S and group L in relation to the occurrence of cough. In the sample, there is a statistical significance (p=0.0466) of the association between cough and the method of operative treatment. Cough occurs statistically significantly more often in group S. This result is at the limit of statistical significance, because if Yates' correction is taken into account, the result is p= .0704, which is not statistically significant.



The average duration of cough postoperatively in patients (Table 26, Graph no. 24) in group **S** (n=25) was 2.0  $\pm$  1.25 (Min 1, Max 4) days. The average duration of cough postoperatively in patients in group **L** (n=14) was 1.33  $\pm$ 0.5 (Min 1, Max 3) days.

Tabl	e 26.	Cough
		~~~ <u>_</u>

	X min	X max	X bar	±SD	
Group S, n= 25	1	4	2	1.25	
Group L, n=14	1	3	1.33	0.5	
	t = 2.3635	df = 37	p< 0.05		

There is a statistically significant difference (t=2.3635, df=378, p<0.05) in the average duration of cough postoperatively (p<0.05) between group S and group L. The average duration of cough in patients in group S,  $2 \pm 1.25$  days, is statistically significantly longer (p<0.05) than in patients in group L where it was 1.33 ±0.5 days.



6.28 Postoperative Nausea and Vomiting

In group **S**, 58 patients got postoperative nausea and vomiting (PONV), while in group **L** 27 patients got PONV (Table 27, Graph no. 25).

	YES	NO	In total
Group S	58	32	90 (100%)
Group L	27	63	90 (100%)
	$\chi^2 = 21.42$	p = 0.0000	180

# Table 27. PONV

There is a statistically significant difference ( $\chi^2 = 21.42$ , df=1, p = 0.0000) between group S and group L in relation to the occurrence of PONV. In the sample, there is a statistical significance (p=0.0000) of the connection between PONV and the method of operative treatment. PONV occurs statistically significantly more often in group S.



The average duration of postoperative nausea and vomiting (PONV), measured in 12-hour intervals, in patients (Table 28, Graph no. 26) in group **S** was  $1.25 \pm 0.75$  (Min 0.5, Max 4) days. The average duration of PONV in patients in group **L** was  $0.66 \pm 0.3$  (Min 0.5, Max 1.5) days.

### Table 28. PONV

	X min	X ma	x X bar	±SD
Group S, n= 58	0.5	4	1.25	0.75
Group L, n=27	0.5	1.5	0.66	0.3
	t = 5.1683	df = 83	p< 0.001	

There is a statistically significant difference (t=5.1683, df=83, p<0.001, p<0.001) average duration of PONV in patients (p<0.001) between group S and group L. The average duration of PONV in patients in group S, 1.25  $\pm$  0.75 days, is statistically significantly longer (p<0.001) than in patients in group L, where was 0.66  $\pm$  0.3 days.

6.29 Length of Hospitalisation

The length of hospitalisation in group **S** was  $6,244 \pm 3.89$  (Min 2, Max 24) days. In group L, the length of hospitalisation was  $3,433 \pm 2,366$  (Min 1, Max 11) days (Table 29, Graph no. 27).

	X min	X max	X bar	±SD	
Group S	2	24	6.244	3.89	
Group L	1	11	3.433	2.366	
	t = 5.8570	df = 178	p< 0.001		

 Table 29. Hospitalization

There is a statistically significant difference (t=5.8570, df=178, p<0.001, p<0.001) average duration of hospitalisation of patients (p<0.001) between group S and group L. The average duration of hospitalisation for patients in group S, 6,244  $\pm$  3.89 days, is statistically significantly longer (p<0.001) than for patients in group L, where it was 3,433  $\pm$ 2,366 days.



The complex Table 30 (Table 30 - S, and Table 30 - L.) shows the total hospitalisation by groups and by the number of days spent in the hospital per group. The total number of days spent in hospital in group S was 562 days, and in group L it was 309 days.

T	TABLE No. 30 - S				
Day	n	Day x n			
1	0	0			
2	1	2			
3	9	27			
4	12	48			
5	16	80			
6	28	168			
7	13	91			
8	2	16			
9	1	9			
10	1	10			
11	2	22			
12	0	0			
13	1	13			
14	0	0			
15	1	15			
16	0	0			
17	1	17			
18	0	0			
19	0	0			
20	1	20			
21	0	0			
22	0	0			
23	0	0			
24	1	24			
Σ	90	562			

TABLE No. 30 - L				
day	n	Day x n		
1	13	13		
2	25	50		
3	26	78		
4	6	24		
5	5	25		
6	4	24		
7	4	28		
8	2	16		
9	1	9		
10	2	20		
11	2	22		
Σ	90	309		

### 6.30 Length (Speed) of Recovery

The length of convalescence in group **S** was  $35,789 \pm 4,555$  (Min 25, Max 48) days. In group **L**, the length of convalescence was  $18,089 \pm 2,993$  (Min 14, Max 28) days (Table 31, Graph no. 28).

### Table 31. Recovery

	X min	X max	X bar	±SD
Group S	25	48	35.789	4.555
Group L	14	28	18.089	2.993
	t = 30.808	df = 178	p< 0.001	

There is a statistically significant difference (t=30.808, df=178, p<0.001, p<0.001) average duration of patient convalescence (p<0.001) between group S and group L. The average duration of convalescence in patients in group S, 30,789  $\pm$  4,555 days, is statistically significantly longer (p<0.001) than in patients in group L, where it was 18,089  $\pm$ 2,993 days.



The complex table 32 (table 32 - S, and table 32 - L.) shows the total recovery by groups and by the number of lost working days per group. The total number of lost working days in group S was 3221 days, and in group L it was 1628 working days.

1	TABLE No. 32- S				
Days	n	days x n			
25	1	25			
26	1	26			
27	2	54			
28	1	28			
29	2	58			
30	2	60			
31	4	124			
32	5	160			
33	9	297			
34	10	340			
35	10	350			
36	7	252			
37	7	259			
38	6	228			
39	5	195			
40	4	160			
41	3	123			
42	3	126			
43	3	129			
44	2	88			
45	1	45			
46	1	46			
47	0	0			
48	1	48			
Σ	90	3221			

1	TABLE No. 32- L				
days	n	Days x n			
14	6	84			
15	10	150			
16	12	192			
17	14	238			
18	22	396			
19	5	95			
20	5	100			
21	4	84			
22	3	66			
23	3	69			
24	2	48			
25	1	25			
26	1	26			
27	1	27			
28	1	28			
Σ	90	1628			

#### 6.31 Cost Benefit Analysis

The results of this treatment would not be complete without a financial-economic analysis. This analysis is completely different from the point of view of the hospital, i.e. fund and on the other hand the patient personally. Results, parameters, prices and estimates currently valid in our hospital, fund and social and private sector are shown.

### Costs of Treatment for the Hospital and the Fund

Assumptions are the following data taken:

- the price of a standard cholecystectomy operation on the basis of 8 days of treatment is
   1920 BAM, and without hospital days is 1280 BAM.
- 2. the price of a laparoscopic cholecystectomy operation based on 3 days of treatment is 900 BAM, and without days in the hospital is 660 BAM.

	Standard cholecystectomy	Laparoscopic cholecystectomy
Medicines and material	200 BAM	200 BAM
Anesthesia	250 BAM	160 BAM
Operative intervention	830 BAM	300 BAM
Hospital treatment	80 BAM x 8 dana =640 BAM	80 BAM x 3 dana =240 BAM
IN TOTAL	1920 BAM	900 BAM

Table 33. Treatment Prices	for S	Standard and La	paroscopic Ch	olecystectomy
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The following data are also required:

1. self-paying patient, one hospital day is 80 BAM for both methods.

2. the patient with the instruction pays a co-payment of 8 BAM for each hospital day with both methods.

3. she patient's sick leave is paid for up to 4 months by the organization in which he is employed, and over 4 months by the fund, for both methods.

4. sick leave is 70% of salary, so the work organization loses 70% per month during sick leave, because the sick person does not work, and the sick person receives 30% less per month than his regular salary as long as he does not work.

5. the Gettinge (1999) sterilisation apparatus costs about 67,000 BAM, and is used for both methods.

6. specific sterilisation in laparoscopy can be ignored.

7. Dr äger anesthesia machine (1995) costs about 20,000 BAM, and is used for both methods.

8. a set of instruments for standard abdominal surgery costs around 12,000 BAM and must be present for both methods.

9. laparoscopic apparatus R. Wolf (2002) costs about 60,000 BAM and is used only for the laparoscopic method.

10. average salaries in the civil service are as follows: the lowest is about 170 BAM, the average is about 450 BAM, and the highest (managers 1450 BAM and directors 3500 BAM).

11. average salaries in the private sector are as follows: the lowest is around 250 BAM, the average is around 650 BAM and the highest is around 1800 BAM. It is normal for owners of private companies to have incomes greater than 5,000 BAM per month.

We will assume two hypothetically same hospitals where about 300 cholecystectomies are performed annually. The first operates exclusively standard, and the second exclusively laparoscopically. Let's assume that the basic equipment and instruments and drugs are the same, that they operate the same, that they have all other parameters the same. The only difference is that the other hospital had to spend 60,000 BAM for the purchase of laparoscopic equipment.

In the standard group, annual basic hospital costs are 1,280 BAM x 300 operations plus 300 patients x 6,244 average days of hospitalization x 80 BAM. (384,000 + 149,856) = 533,856 KM.

In the laparoscopic group, annual basic hospital costs are 660 BAM x 300 operations plus 300 patients x 3,433 average days of hospitalization x 80 BAM. (198,000 + 82,392) = 280,392 KM.

The difference between these total prices is the annual financial benefit of the laparoscopic method (about 534,000 - about 281,000 is about 253,000 KM). This difference only based on the annual estimate of 300 operations allows for the purchase of laparoscopic equipment and earnings.

Losses for state-owned enterprises are based on the same estimate of 300 cholecystectomy operations per year in the previous two hypothetical hospitals.

In a hospital with a standard operating method, the loss of a state-owned enterprise with an average salary of 450 BAM per month is 70% of 15 BAM per day, which is 10.5 BAM per day. Hospitalisation and convalescence of the standard method is 6,244 + 35,789 days = about 42 days. Doctors prescribe additional sick leave for another 10 to 15 days, so it can be assumed that the total absence is about 55 days. 10.5 BAM per day x 55 days x 300 patients = 173,250 BAM per year.

In a hospital with a laparoscopic operative method, the loss of a state enterprise with an average salary of 450 BAM per month is 70% of 15 BAM per day, which is 10.5 BAM per day. Hospitalisation and recovery of the laparoscopic method is 3,433 + 18,089 days = about 21.5 days. Doctors prescribe an additional sick leave of about 10 to 15 days, so it can be assumed that the total absence is about 33 days. 10.5 BAM per day x 33 days x 300 patients = 103,950 BAM per year.

The difference between these two results is that 69,300 more sick leave payments are paid per year, ie about 70,000 BAM with the standard method. If 2.5 times the value of the lowest average wages were used in the calculation, the total benefit for laparoscopy would be around 28,000 BAM. If the calculation used 5 times the value of the highest average salaries, the total benefit for laparoscopy would be around 350,000 BAM. One can accept with high statistical certainty the calculation for the average salary in the civil service as complete and accurate, and claim that the laparoscopic method is more favorable for state enterprises on an annual basis by about 70,000 BAM. The state and state-owned enterprises should stimulate the purchase of laparoscopic equipment, maintenance of equipment and instruments, as well as favor the laparoscopic method due to its lower costs.

Losses to private companies are based on the same estimate of 300 cholecystectomies per year in the previous two hypothetical hospitals.

In a hospital with a standard operating method, the loss of a private company with an average salary of 650 BAM per month is 70% of 21.7 BAM per day, which is 15.2 BAM per day. Hospitalisation and convalescence of the standard method is 6,244 + 35,789 days = about 42 days. Doctors prescribe additional sick leave for another 10 to 15 days, so it can be assumed that the total absence is about 55 days. 15.2 BAM per day x 55 days x 300 patients = 250,800 BAM per year. For each patient, the loss of a private company is 836 BAM.

In a hospital with a laparoscopic operative method, the loss of a private company with an average salary of 650 BAM per month is 70% of 21.7 BAM per day, which is 15.2 BAM per day.

Hospitalisation and recovery of the laparoscopic method is 3,433 + 18,089 days = about 21.5 days. Doctors prescribe additional sick leave for another 10 to 15 days, so it can be assumed that the total absence is about 33 days. 15.2 BAM per day x 33 days x 300 patients = 150,480 BAM per year. For each patient, the loss of a private company is 502 BAM.

The difference between these two results is that approximately 100,000 BAM more is paid annually for sick leave with the standard method. If the calculation used 2.5 times the value of the lowest average wages, the total benefit for laparoscopy would be around 40,000 BAM. If the calculation used 5 times the value of the highest average salaries, the total benefit for laparoscopy would be around 500,000 BAM. One can accept with high statistical certainty the calculation for the average salary in the civil service as complete and accurate, and claim that the laparoscopic method is more favorable for private companies on an annual basis by about 100,000 BAM. Private companies should stimulate the purchase of laparoscopic equipment, maintenance of equipment and instruments, and favor the laparoscopic method is 22 days x the value of one day's sick leave. Payment for laparoscopy is 485 BAM and divided by 22 is 22 BAM per sick day value. The salary should be at least 22 x 30 x 1.42 = 937 BAM in order for the private company to pay the costs of the laparoscopy so that the worker can return to work sooner.

### 7. Discussion

Gallbladder calculus is the most common indication for gallbladder surgery.

In the entire sample, 21 (23.3%) men and 69 (76.7%) women were operated on using the standard method, and 22 (24.4%) men and 68 (75.6%) women were operated laparoscopically. In the sample, there is no statistical significance (p=0.861) between gender and method of operative treatment. In the entire sample, more women were operated than men. The ratio of operated 137 women (76.1%) and operated 43 men (23.9%) is 3.18:1. Women were operated statistically more significantly, 3.18 times more than men. In the group of patients who were operated using the standard method, there were 21 men and 69 women, and women were operated statistically significantly, 3.29 times more than men. There were 22 men and 68 women in the group operated by the laparoscopic method, and women were operated statistically more significantly, 3.09 times more than men. All these data of ours fit in with all the world literature data on the frequency of this disease depending on gender. Gallbladder disease with calculus is more common in women and the ratio is about 4:1. This fact proves that female patients are much more common in biliary pathology and that this disease occurs much more often in women 1, 3, 4, 7, 8, 13, 91, 92, 93, 100, 101, 104, 108, 109, 110, 111, 112, 114, 115, 118, 119.

In the entire sample, the largest number of operated patients belong to the 5th and 6th decades of life. The distribution of operated patients by decade of life shows that the largest number of operated patients in group S was in the 6th and 7th decade of life, and in group L the largest number of operated patients was in the 4th and 5th decade of life. The average age of patients who were operated on by the

standard method was  $54.22 \pm 20.51$  (Min 17, Max 90) years, and  $46.67 \pm 14.53$  years (Min 23, Max 80) in patients operated by the laparoscopic method. These two groups are approximately similar in age when they were operated, but there is still a statistical difference. There is a statistically significant difference ( $\mathbf{t} = 2,849$ ,  $\mathbf{df} = 178$ ,  $\mathbf{p} = 0.008$ ,  $\mathbf{p} < 0.01$ ) between groups S and L in relation to the age of the patient. Patients from group S are statistically significantly older ( $\mathbf{p}=0.008$ ) opting for standard gallbladder surgery, and patients from group L are statistically significantly younger ( $\mathbf{p}=0.008$ ) opting for laparoscopic gallbladder surgery. Similar data are presented by foreign authors 1, 3, 4, 7, 8, 13, 91, 92, 93, 100, 101, 104, 108, 109, 110, 111, 112, 114, 115, 118, 119...

In the entire sample, 18 diabetics and 162 non-diabetics were operated on. In the entire sample, significantly more non-diabetics were operated. There were 10% diabetics. Non-diabetics were operated statistically more significantly, 10 times more than diabetics.

There were 6 diabetics in the group of patients operated by the standard method, and 12 diabetics in the group operated by the laparoscopic method. There is no statistically significant difference ( $\chi^2 = 2.22$ , df = 1, p=0.136, p>0.01) between groups S and L in relation to diabetes. Although it can be seen from the data that group L had twice as many diabetics, in the sample there is no statistical significance (p=0.136) of the connection between diabetes and the method of operative treatment. All these data of ours fit in with all the world literature data on the frequency of this disease in the general population, but also in biliary diseases. Gallbladder disease with diabetes occurs in 10% of patients, and these facts prove that patients with diabetes more often decide to undergo the laparoscopic method, but also that surgeons more often recommend the laparoscopic method for diabetes in biliary pathology 1, 3, 4, 7, 8, 13, 91, 92, 93, 100, 101, 103, 104, 108, 109, 110, 111, 112, 114, 115, 118, 119, 139, 141...

In the entire sample, 37 obese and 143 normally fed patients were operated. In the entire sample, significantly more normally fed patients were operated, about 4 times more than obese patients. There were 14 obese patients in the group of patients operated by the standard method, and 23 obese patients in the group operated by the laparoscopic method. There is no statistically significant difference ( $\chi^2 = 2.76$ , df = 1, p=0.0969, p>0.01) between groups S and L in relation to obesity. Although it can be seen from the data that there were almost twice as many obese people in group L, there is no statistical significance (p=0.0969) of the association between obesity and the method of surgical treatment in the sample. All these data of ours fit in with all the world literature data on the frequency of this condition in the general population, and these facts prove that obese patients more often decide to undergo the laparoscopic method, but also that surgeons more often recommend the laparoscopic method in obese patients with biliary pathology 1, 3, 4, 7, 8, 13, 91, 92, 93, 100, 101, 103, 104, 108, 109, 110, 111, 112, 114, 115, 118, 119, 139, 141...

In the entire sample, 14 patients with chronic respiratory disease and 166 patients without chronic respiratory disease were operated. In the entire sample, significantly more patients without chronic respiratory disease were operated, about 11 times more than patients with chronic respiratory disease. There were 8 patients with chronic respiratory disease in the group of patients operated by the standard

method, and 6 patients with chronic respiratory disease in the group operated by the laparoscopic method. There is no statistically significant difference ( $\chi^2 = 0.31$ , df = 1, p=0.5778, p>0.01) between group S and group L in relation to chronic respiratory disease. In the sample, there is no statistical significance (p=0.5778) of the connection between chronic respiratory disease and the method of operative treatment. All these data of ours fit into all world literature data 1, 3, 4, 74, 75, 78, 80, 91, 92, 93, 108, 109, 110, 111, 112, 118, 119, 120, 122, 139, 141, 142, 144, 146, 147, 148...

In the entire sample, 36 smoking patients and 144 non-smoking patients were operated. In the entire sample, significantly more non-smoking patients were operated, about 4 times more than smoking patients. In the group of patients operated on by the standard method, there were 15 smoking patients, and in the group operated by the laparoscopic method, there were 21 smoking patients. There is no statistically significant difference ( $\chi^2 = 1.25$ , df = 1, p=0.2636, p>0.01) between group S and group L in relation to smoking. In the sample, there is no statistical significance (p=0.2636) between smoking and the method of operative treatment. The amount of smoking preoperatively in both groups of patients was numerically determined as a function of the product of two variables, i.e. the number of packs smoked on average and the number of years of smoking, expressed numerically as "pack x years of smoking". In the group of patients who were operated using the standard method, there were 15 patients who were smokers. Numerically determined amount of smoking preoperatively, pack x years of smoking, was in group S, n=15, 23.5  $\pm$  21.31 pack x years (Min 1.5, Max 60). There were 21 patients who were smokers in the group operated by the laparoscopic method. Numerically determined amount of smoking preoperatively, pack x years of smoking, was in group L, n=21, 32.71  $\pm$  24.76 pack x years (Min 1, Max 72). There is no statistically significant difference (t = 1.193, df=34, **p=0.252**, **p>0.05**) of the average number of numerically determined smoking preoperatively (**p>0.05**) between group S and group L. In the sample there is no statistical significance (p=0.252) of the association of the amount smoking and operative treatment methods. All these data of ours fit into all world literature data 1, 3, 4, 74, 75, 78, 80, 91, 92, 93, 108, 109, 110, 111, 112, 118, 119, 120, 122, 139, 141, 142, 144, 146, 147, 148...

The values of leukocytes in the blood were in group S  $8.83 \pm 2.95$  109/l (Min 6.00, Max 14.0). The values of leukocytes in the blood were in group L 9.6  $\pm 2.83$  109/l (Min 6.40, Max 12.0). There is no statistically significant difference (t=1.7637, df=178, p<0.10, p>0.05) in the average number of leukocytes in the blood (p>0.05) between group S and group L. Patients from group L have higher values, but this is not statistically significant.

Blood sugar values in group S were 6.12  $\pm 2.58$  mmol/l (Min 3.20, Max 15.2). In group L, blood sugar was 5.85  $\pm 2.68$  mmol/l (Min 3.40, Max 14.3). There is no statistically significant difference (t=0.6937, df=178, p>0.05) in the average value of blood sugar (p>0.05) between group S and group L. In the sample, there is no statistical significance of the connection between the average value of blood sugar and the method of operative treatment.

Blood protein values in group S were  $62.0 \pm 4.27$  g/l (Min 56, Max 70). In group L, the protein values

in the blood were 62.2  $\pm$  4.29 g/l (Min 56, Max 70). There is no statistically significant difference (t=0.3134, df=178, p>0.05) in the average value of protein in the blood (p>0.05) between group S and group L.

There is no statistical significance in the sample between the average value of protein in the blood and the method of operative treatment.

Blood hemoglobin values in group S were 132.3  $\pm$ 17.6 g/l (Min 99, Max 158). In group L, hemoglobin values in the blood were 135.5  $\pm$  13.8 g/l (Min 100, Max 161). There is no statistically significant difference (t=1.357, df=178, p>0.05) in the average value of hemoglobin in the blood (p>0.05) between group S and group L. There is no statistical significance in the sample between the average value of hemoglobin in the blood and the method of operative treatment.

The hematocrit values in the blood were  $41.2 \pm 4.24$  % (Min 26, Max 49) in group S. In group L hematocrit was  $42.0 \pm 3.86$  % (Min 35, Max 53). There is no statistically significant difference (t=1.3236, df=178, p>0.05) in the average value of hematocrit in blood (p>0.05) between group S and group L. There is no statistical significance in the connection in the sample between the average value of hematocrit in blood and the method of operative treatment.

In many works where laparoscopy research was done, laboratory parameters were not found to be significant. In the same way, all these data of ours fit into all world literature data 1, 3, 4, 7, 8, 13, 91, 92, 93, 100, 101, 103, 104, 108, 109, 110, 111, 112, 114, 115, 118, 119, 139, 141...

The average duration of the operative procedure in patients operated on by the standard method was 70.22  $\pm$  28.52 (Min 40, Max 120) minutes, and the average duration of the operative procedure in patients operated on by the laparoscopic method was  $53.83 \pm 19.56$  (Min 30, Max 95) minutes. There is a statistically very significant difference (t=4.502, df=178, p=0.001, p<0.001) in the average duration of surgery for patients (p<0.001) between group S and group L. Average duration of surgery for patients in group S, 70.22  $\pm$  28.52 minutes, is statistically significantly longer (p<0.001) than in patients in group L where it was  $53.83 \pm 19.56$  minutes. A comparative analysis of the distribution of the duration of the operation in 10-minute intervals for both groups shows that the largest number of operated patients (n = 72 = 80%) in group S was in intervals of 50 to 80 minutes. It can also be seen that the largest number of operated patients (n = 74 = 82.2%) in group L was in intervals of 40 to 60 minutes. A comparative analysis of the distribution of the duration of the operation in 5-minute intervals for both groups shows that the largest number of operated patients in group S was in intervals of 55 to 85 minutes. It can also be seen that the largest number of operated patients in group L was in intervals of 45 to 65 minutes. Although the duration analysis is more precise in smaller time intervals, all these results show that the duration of the operative procedure is significantly shorter with the laparoscopic method. The duration of the laparoscopic operation is significantly shorter than the duration of the standard operation. This indicates that the standard surgical procedure for the surgeon is more difficult, more demanding and takes longer 1, 3, 4, 7, 8, 13, 91, 92, 93, 100, 101, 103, 104, 108, 109, 110, 111, 112, 114, 115, 118, 119, 139, 141...

In the entire sample, 5 patients were operated for longer than 100 minutes. In the group of patients who were operated by the standard method, there were 5 patients who were operated for longer than 100 minutes, and in the group who were operated by the laparoscopic method, there were no patients who were operated for longer than 100 minutes. There is a statistically significant difference ( $\chi^2 = 5.14$ , df=1, p=0.0233, p<0.05) between group S and group L in relation to the duration of the operation longer than 100 minutes. There is statistical significance in the sample (p=0.0233), and operations last over 100 minutes more often with the standard method of operative treatment. All these data of ours fit into all the world literature data on the difficulty of operating with these methods, that laparoscopic surgery is faster 1, 3, 4, 7, 8, 13, 91, 92, 93, 100, 101, 103, 104, 108, 109, 110, 111, 112, 114, 115, 118, 119, 139, 141...

ASA criteria were determined according to the decision of the anesthesiologist and entered from the medical history of patients in individual sheets. The distribution of ASA criteria of patients in our sample was as follows: in group S there were 14 ASA1, 50 ASA2, 24 ASA3, and 2 ASA4 operated patients, and in group L there were 23 ASA1, 57 ASA2, and 10 ASA3 operated patients. These samples do not belong to the same (homogeneous) group but differ statistically significantly because  $\chi^2$  test = 9.412 > 7.815, for df=3 and p=0.05. There is high statistical significance. All these data of ours fit into all the world literature data on the distribution of patients according to ASA criteria 66, 68, 69, 70, 71, 72...

Operative work can be divided into three stages. During the first stage, during the opening, there were no injuries in group **S**. During the first stage, during the creation of the pneumoperitoneum and the introduction of the trocar in group **L**, 2 subcutaneous emphysema occurred during the creation of the pneumoperitoneum with the Veress needle and 1 injury to the blood vessel of the abdominal wall. During the introduction of the working port under the xiphoid, in one patient, a blood vessel of the abdominal wall was injured. The injury was of such intensity that it required surgical care, i.e. the placement of stitches during the operation itself, so that the operation could be completed laparoscopically. During the introduction of the trocar, there was no injury of blood vessels of the abdomen, nor was there any injury to the intra-abdominal organs. There is no statistically significant difference ( $\chi^2 = 1.36$ , df = 1, p=0.244, p>0.05) between groups **S** and **L** in relation to injuries in the first stage of surgery. Although it can be seen from the data that there were 3 injuries in group **L**, in the sample there is no statistical significance (**p=0.244**) between the injury in the first stage of the operation and the method of operative treatment. Similar data are presented by other authors 131, 132, 152, 154, 155, 157, 159, 166, 167, 168, 178, 182, 183, 193.

During the second stage, during intra-abdominal work, there were no injuries in group S. During the second stage, 2 injuries occurred in group L, an injury of the duodenum with an electrohook and an injury - a section of the choledochus. The injury to the duodenum was recognized and of such intensity that it required surgical care, that is, the placement of a suture, and a conversion was performed. Injury of the choledochus was also recognized, and conversion and hepaticojejunal anastomosis were

performed. There is no statistically significant difference ( $\chi^2 = 0.51$ , df = 1, p=0.477, p>0.05) between groups S and L in relation to injuries in the second stage of the operation. Although it can be seen from the data that there were 2 injuries in group L, in the sample there is no statistical significance (p=0.477) between the injury in the second stage of the operation and the method of operative treatment. Injuries of biliary and other elements during laparoscopic work are more frequent than with the standard method and in all world reports, and the intensity of injuries in our country of several % fits in with the world literature. This fact indicates the training of the surgical team that performed the operations 131, 132, 152, 154, 155, 157, 159, 166, 167, 168, 178, 182, 183, 193...

During the third stage, during the closure, there were no injuries in group S and group L. Statistical work in a 2 x 2 contingency table, where two results are 0, cannot be evaluated, so p=1.00 or there is no statistical difference.

In the entire sample, 117 patients were operated, where an abdominal drain was placed. In the entire sample, significantly more patients were operated on with abdominal drainage, about 2 times more than without abdominal drainage. In the group of patients operated by the standard method, there were 82 patients with abdominal drainage, and in the group operated by the laparoscopic method, there were 35 patients with abdominal drainage. There is a statistically significant difference ( $\chi^2 = 53.94$ , df=1, **p=0.0000**) between group **S** and group **L** in relation to abdominal drain placement. There is statistical significance in the sample (**p=0.0000**) and the abdominal drain is placed statistically significantly more often with the standard method of operative treatment. All these data of ours fit in with all the world literature data on the frequency of placing an abdominal drain. Surgeons more often decide to place an abdominal drain with the standard method than with the laparoscopic method, but the laparoscopic method rightfully bears the name of minimally invasive 1, 3, 4, 7, 8, 13, 91, 92, 93, 100, 101, 103, 104, 108...

In the entire sample, 31 patients with acute inflammation of the gallbladder were operated. In the whole sample, significantly fewer patients with acute inflammation of the gallbladder were operated, about 6 times less than with chronic inflammation of the gallbladder. In the group of patients operated by the standard method, there were 22 patients with acute inflammation of the gallbladder, and in the group operated by the laparoscopic method, there were 9 patients with acute inflammation of the gallbladder.

There is a statistically significant difference ( $\chi^2 = 6.59$ , df=1, p=0.0103) between group S and group L in relation to pathohistological findings. There is statistical significance in the sample (p=0.0103), and acute inflammation of the gallbladder occurs statistically significantly more often with the standard method of surgical treatment. All these data of ours fit in with all the world literature data on the frequency of acute and chronic inflammation of the gallbladder and methods of operative treatment 1, 3, 4, 91, 92, 93, 103, 104, 108, 109, 112, 114, 115, 118, 119, 125, 139, 141...

Conversion as a parameter cannot be sent to both groups. As part of the operative treatment method, conversion exists only in group L. Due to its importance, it must be mentioned, and statistical

comparison is not possible. Operational work can be divided into three stages. During the second stage, during intra-abdominal work, 2 injuries occurred in group L, an injury of the duodenum with an electrohook and an injury - a section of the choledochus. Both of these injuries required conversion for proper and timely treatment. The injury to the duodenum was recognized and of such intensity that it required surgical care, that is, the placement of a suture, and a conversion was performed. Injury to the choledochus was also recognized, and conversion and hepaticojejunal anastomosis were performed. In this study, conversion occurred in 2 out of 90 patients, 2.22% 1, 3, 4, 91, 92, 93, 100, 101, 119, 131, 132, 139, 141...

Postoperative complications that occurred were rare. As they can only be compared to those of the same kind, we will only list them here. In group **S**, there were 4 surgical wound infections and 3 seromas. In the postoperative period, wound infection occurred in patients who were operated for acute inflammation of the gallbladder, while there was no wound infection in the laparoscopic method. In group **L**, there was 1 biloma and 1 intra-abdominal abscess. In patients who underwent laparoscopic surgery for acute inflammation of the gallbladder, bile leakage into the drain occurred in two cases. They later developed a biloma and an intra-abdominal abscess. We tried to statistically compare these two groups, although we collected attributive features that are not the same and can hardly be compared. There were 7 patients with complications in the group of patients operated by the standard method, and 2 patients with complications in the group operated by the laparoscopic method. There is no statistically significant difference ( $\chi^2 = 1.87$ , df=1, p=0.171) between group **S** and group **L** in relation to postoperative complications. There is no statistical significance in the sample (p=0.171), and postoperative complications occur statistically similarly with both methods of operative treatment 131, 132, 152, 154, 157, 159, 166, 167, 168, 178, 182, 183, 193...

There was 1 fatal outcome in the group of patients who were operated using the standard method, and there was no fatal outcome in the group who were operated using the laparoscopic method.

There is no statistically significant difference ( $\chi^2 = 1.01$ , df=1, p = 0.316) between group S and group L in relation to death. In the sample, there is no statistical significance (p=0.316) between the death outcome and the method of operative treatment. These data of ours fit in with all the world literature data on the frequency of death in biliary surgery 125, 131, 132, 152, 154, 155...

In the entire sample, the average duration of the pain syndrome in all patients is 6.50 days. The average duration of the pain syndrome in patients who were operated using the standard method was

10.37  $\pm$  2.85 (Min 7, Max 14) days. The average duration of pain syndrome in patients operated laparoscopically was 3.01  $\pm$  1.38 (Min 1, Max 5) days. The pain syndrome in group S lasted from 7 to 14 days. The pain syndrome in group L lasted from 1 to 5 days. The duration of the pain syndrome was statistically significantly shorter in group L. There is a statistically significant difference (t=22.05, df=178, p=0.001, p<0.001) in the average duration of the patient's pain syndrome (p<0.001) between group S and group L The average duration of the painful syndrome in patients in group S, 10.37  $\pm$  2.85 days, is statistically significantly longer (p<0.001) than in patients in group L, where it was 3.01  $\pm$ 

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1.38 days. Similar data are presented by foreign authors 1, 3, 4, 91, 92, 93, 103, 104, 108, 109, 112, 114, 115, 118, 119, 122, 125, 139, 141, 151, 152, 153, 173...

Antibiotics were not routinely administered during this study. In the group of patients operated by the standard method, antibiotics were used in 26 patients, and in the group operated by the laparoscopic method, antibiotics were used in 14 patients. There is a statistically significant difference ( $\chi^2 = 3.89$ , df=1, p=0.0486) between group S and group L in relation to the use of antibiotics. There is statistical significance in the sample (p=0.0486), and antibiotics were used statistically significantly more often with the standard method of operative treatment. It must be said that in both groups antibiotics were administered postoperatively therapeutically for acute inflammation of the gallbladder and similar conditions, and not preventively 1, 3, 4, 91, 92, 93, 103, 104, 108, 109, 112, 114, 115, 118, 119, 125, 139, 141...

In the entire sample, 39 patients developed a cough and 141 patients did not develop cough. In the entire sample, significantly more patients who did not cough were operated. Cough appeared in 21%. Patients who did not cough were operated on statistically more significantly, about 5 times more than those who coughed. In the group of patients who were operated using the standard method, there were 25 patients who coughed, and in the group who were operated using the laparoscopic method, there were 14 patients who coughed. There is a statistically significant difference ( $\chi^2 = 3.96$ , df=1, p = 0.0466) between group S and group L in relation to the occurrence of cough. In the sample, there is a statistical significance (p=0.0466) of the association between cough and the method of operative treatment. Cough occurs statistically significantly more often in group S.

All these data of ours fit in with all the world literature data on the frequency of this condition in the general population, but in operations for biliary diseases. These data prove that surgeons more often recommend the laparoscopic method due to the prevention of respiratory, but also in the case of developed respiratory complications. Laparoscopic cholecystectomy, regardless of the degree of inflammation of the gallbladder, leads to incomparably less trauma. In patients with a disorder of respiratory function, laparoscopic surgery enables faster activation and better respiratory function in the postoperative period. This is especially important in elderly patients, in patients with compromised respiration, as well as in patients with acute inflammation of the gallbladder, because this approach reduces the number of postoperative complications. In the entire sample, the average duration of coughing in all patients was 1.73 days. The average duration of coughing in postoperative patients who were operated on using the standard method was in group S (n=25)  $2.0 \pm 1.25$  (Min 1, Max 4) days. The average duration of coughing in postoperative patients who underwent laparoscopic surgery in group L (n=14) was 1.33  $\pm$  0.5 (Min 1, Max 3) days. The duration of coughing was statistically significantly shorter in group L. There is a statistically significant difference (t=2.3635, df=378, p < 0.05) in the average duration of coughing postoperatively (p < 0.05) between group S and group L. The average duration of cough in of patients in group S,  $2 \pm 1.25$  days, is statistically significantly longer (p<0.05) than in patients in group L, where the value was  $1.33 \pm 0.5$  days. Similar data are

presented by foreign authors 1, 3, 4, 74, 75, 78, 80, 91, 92, 93, 108, 109, 110, 111, 112, 118, 119, 120, 122, 139, 141, 142, 144, 146, 147, 148...

In the entire sample, 85 patients developed postoperative nausea and vomiting (PONV). In the entire sample, the same number of patients with and without PONV were operated. In the group of patients who were operated on with the standard method, there were 58 patients who got postoperative nausea and vomiting (PONV), and in the group who were operated on with the laparoscopic method, there were 27 patients who got postoperative nausea and vomiting (PONV). There is a statistically significant difference ( $\chi^2 = 21.42$ , df=1, p = 0.0000) between group S and group L in relation to the occurrence of PONV. In the sample, there is a statistical significance (p=0.0000) of the connection between PONV and the method of operative treatment. PONV occurs statistically significantly more often in group S. All these data of ours fit in with all the world literature data on the frequency of this condition in the general population during operations. These data prove that surgeons more often recommend the laparoscopic method due to the prevention of complications. Laparoscopic cholecystectomy leads to incomparably less trauma and enables faster activation and better function in the postoperative period. This is especially important in high-risk patients. In the entire sample, the average duration of postoperative nausea and vomiting (PONV) in all patients was 0.90 days.

The average duration of postoperative nausea and vomiting (PONV) in patients who were operated using the standard method was  $1.25 \pm 0.75$  (Min 0.5, Max 4) days in patients in group S. The average duration of post-operative nausea and vomiting (PONV) in patients who underwent laparoscopic surgery was 0.66  $\pm$  0.3 (Min 0.5, Max 1.5) days in group L. There is a statistically significant difference (t=5.1683, df=83, p<0.001, p<0.001) in the average duration of PONV patients (p<0.001) between group S and group L. Average duration of PONV in patients in group S, 1.25  $\pm$  0.75 days, is statistically significantly longer (p<0.001) than in patients in group L where it was 0.66  $\pm$  0.3 days. Similar data are presented by foreign authors 1, 13, 91, 92, 104, 108, 109, 110, 111, 112, 114, 115, 118, 119, 139, 141, 151, 156, 194...

In the entire sample, the average duration of hospitalisation was 4.89 days for all patients. The total number of hospital days in group **S** was 562 hospital days, and in group L it was 309 hospital days. The average length of hospitalisation was  $6,244 \pm 3.89$  (Min 2, Max 24) days in patients who were operated on using the standard method in group **S**. The average length of hospitalisation was  $0.66 \pm 0.3$  (Min 0.5, Max 1.5) days in patients who underwent laparoscopic surgery in group L. There is a statistically significant difference (**t=5.8570**, **df=178**, **p<0.001**, **p<0.001**) in the average duration of hospitalisation for patients in group **S**,  $6,244 \pm 3.89$  days, is statistically significantly longer (**p<0.001**) than in patients in group **S**,  $6,244 \pm 3.89$  days, is statistically significantly longer (**p<0.001**) than in patients in group **L** where it was  $3,433 \pm 2,366$  days. The average length of hospitalisation differs significantly in the operated patients of these two groups and is significantly shorter in the laparoscopic method. Similar data are presented by foreign authors 1, 3, 4, 91, 92, 93, 103, 104, 108, 109, 112, 114, 115, 118, 119, 125, 139, 141...

In the entire sample, the average duration of convalescence in all patients was 28.54 days. The total number of lost working days and total convalescence in group **S** was 3221 days, and in group **L** it was 1628 working days. The average length of convalescence was 35,789  $\pm$ 4,555 (Min 25, Max 48) days in patients who were operated using the standard method in group **S**. The average length of convalescence was 18,089  $\pm$  2,993 (Min 14, Max 28) days in patients who were operated using the laparoscopic method in group L. There is a statistically significant difference (**t=30,808, df=178, p<0.001, p<0.001**) in the average duration of patient convalescence (**p<0.001**) between group **S** and group **L**. The average duration of convalescence in patients in group **S**, 30,789  $\pm$  4,555 days, is statistically significantly longer (**p<0.001**) than in patients in group **L** where it was 18,089  $\pm$  2,993 days. The average length of convalescence differs significantly in the operated patients of these two groups and is significantly shorter in the laparoscopic method. Similar data are presented by foreign authors 1, 3, 4, 91, 92, 93, 103, 104, 108, 109, 112, 114, 115, 118, 119, 125, 139, 141...

The price of a standard cholecystectomy operation based on 8 days of treatment is 1920 BAM, and without days it is 1280 BAM. The price of a laparoscopic cholecystectomy operation based on 3 days of treatment is 900 BAM, and without days it is 660 BAM. Self-paying patient, one day in hospital is 80 BAM for both methods. The patient with a referral pays a co-payment of BAM 8 for each day in the hospital. day with both methods. The patient's sick leave is paid for up to 4 months by the organization in which he is employed, and over 4 months by the fund, for both methods. Sick leave is 70% of salary, so the work organization loses 70% per month during sick leave because the sick person does not work, and the sick person receives 30% less per month than his regular salary as long as he does not work. The Gettinge (1999) sterilisation apparatus costs about 67,000 BAM, and is used for both methods. Specific sterilisation in laparoscopy can be neglected. The anesthesia machine Dräger (1995) costs about 20,000 BAM, and is used for both methods. A set of instruments for standard abdominal surgery costs around 12,000 BAM and must be present for both methods. The laparoscopic apparatus R. Wolf (2002) costs about 60,000 BAM and is used only for the laparoscopic method. The average salaries in the civil service are as follows: the lowest is around 170 BAM, the average is around 450 BAM, and the highest (managers 1450 BAM and directors 3500 BAM). Average salaries in the private sector are as follows: the lowest is around 250 BAM, the average is around 650 BAM and the highest is around 1800 BAM. It is normal for owners of private companies to have incomes greater than 5,000 BAM per month.

We will assume two hypothetically same hospitals where about 300 cholecystectomies are performed annually. The first operates exclusively standard, and the second exclusively laparoscopically. Let's assume that the basic equipment and instruments and drugs are the same, that they operate the same, that they have all other parameters the same. The only difference is that the other hospital had to spend 60,000 BAM for the purchase of laparoscopic equipment.

In the standard group, annual basic hospital costs are 1,280 BAM x 300 operations plus 300 patients x 6,244 average days of hospitalization x 80 BAM. (384,000 + 149,856) = 533,856 BAM. In the

laparoscopic group, annual basic hospital costs are 660 BAM x 300 operations plus 300 patients x 3,433 average days of hospitalization x 80 BAM. (198,000 + 82,392) = 280,392 BAM. The difference between these total prices is the annual financial benefit of the laparoscopic method (about 534,000 - about 281,000 is about 253,000 BAM). This difference only based on the annual estimate of 300 operations allows for the purchase of laparoscopic equipment and earnings.

Losses for state-owned enterprises are based on the same estimate of 300 cholecystectomy operations per year in the previous two hypothetical hospitals.

In a hospital with a standard operating method, the loss of a state-owned enterprise with an average salary of 450 BAM per month is 70% of 15 BAM per day, which is 10.5 BAM per day. Hospitalisation and convalescence of the standard method is 6,244 + 35,789 days = about 42 days. Doctors prescribe an additional sick leave of about 10 to 15 days, and it can be assumed that the total absence is about 55 days. 10.5 BAM per day x 55 days x 300 patients = 173,250 BAM per year.

In a hospital with a laparoscopic operative method, the loss of a state enterprise with an average salary of 450 BAM per month is 70% of 15 BAM per day, which is 10.5 BAM per day. Hospitalisation and recovery of the laparoscopic method is 3,433 + 18,089 days = about 21.5 days. Doctors prescribe additional sick leave for another 10 to 15 days, so it can be assumed that the total absence is about 33 days. 10.5 BAM per day x 33 days x 300 patients = 103,950 BAM per year.

The difference between these two results is that 69,300 more is paid annually for sick leave, i.e. about 70,000 BAM with the standard method. If the calculation used 2.5 times the value of the lowest average wages, the total benefit for laparoscopy would be around 28,000 BAM. If the calculation used 5 times the value of the highest average salaries, the total benefit for laparoscopy would be around 350,000 BAM. One can accept with high statistical certainty the calculation for the average salary in the civil service as complete and accurate, and claim that the laparoscopic method is more favorable for state enterprises on an annual basis by about 70,000 BAM. The state and state-owned enterprises should stimulate the purchase of laparoscopic equipment, maintenance of equipment and instruments, as well as favor the laparoscopic method due to its lower costs.

Losses to private companies are based on the same estimate of 300 cholecystectomies per year in the previous two hypothetical hospitals.

In a hospital with a standard operating method, the loss of a private company with an average salary of 650 BAM per month is 70% of 21.7 BAM per day, which is 15.2 BAM per day. Hospitalisation and convalescence of the standard method is 6,244 + 35,789 days = about 42 days. Doctors prescribe an additional sick leave of about 10 to 15 days, and it can be assumed that the total absence is about 55 days. 15.2 BAM per day x 55 days x 300 patients = 250,800 BAM per year. For each patient, the loss of a private company is 836 BAM.

In a hospital with a laparoscopic operative method, the loss of a private company with an average salary of 650 BAM per month is 70% of 21.7 BAM per day, which is 15.2 BAM per day. Hospitalisation and recovery of the laparoscopic method is 3,433 + 18,089 days = about 21.5 days.

Doctors prescribe additional sick leave for another 10 to 15 days, so it can be assumed that the total absence is about 33 days. 15.2 BAM per day x 33 days x 300 patients = 150,480 BAM per year. For each patient, the loss of a private company is 502 BAM.

The difference between these two results is that approximately 100,000 BAM more is paid annually for sick leave with the standard method. If the calculation used 2.5 times the value of the lowest average wages, the total benefit for laparoscopy would be around 40,000 BAM. If the calculation used 5 times the value of the highest average salaries, the total benefit for laparoscopy would be around 500,000 BAM. One can accept with high statistical certainty the calculation for the average salary in the civil service as complete and accurate, and claim that the laparoscopic method is more favorable for private companies on an annual basis by about 100,000 BAM. Private companies should stimulate the purchase of laparoscopic equipment, maintenance of equipment and instruments, and favor the laparoscopic method ue to its lower costs. The difference between the costs of the standard and laparoscopic methods is 22 days x the value of one day's sick leave. Payment for laparoscopy is 485 BAM and divided by 22 is 22 BAM per sick day value. The salary should be at least 22 x 30 x 1.42 = 937 BAM in order for the private company to pay the costs of the laparoscopy so that the worker can return to work sooner.

### We will analyze working hypotheses.

The first working hypothesis, which states that the duration of the operative procedure in laparoscopic and standard cholecystectomy does not differ, was rejected. The results showed that the operative procedure in laparoscopic cholecystectomy is shorter than in standard cholecystectomy.

The second working hypothesis, which states that the duration of hospitalisation in laparoscopic and standard cholecystectomy does not differ, was rejected. The results showed that the duration of hospitalisation in laparoscopic cholecystectomy is shorter than in standard cholecystectomy.

The third working hypothesis, which states that the number of postoperative complications in laparoscopic and standard cholecystectomy does not differ, was proven by our results.

The fourth working hypothesis, which states that mortality in laparoscopic and standard cholecystectomy does not differ, was proven by our results.

The fifth working hypothesis, which states that the duration of the pain syndrome in laparoscopic and standard cholecystectomy does not differ, was rejected. The results confirmed that the duration of the pain syndrome is significantly shorter with laparoscopic than with standard cholecystectomy.

The sixth working hypothesis, which states that there is no difference in the speed of recovery between laparoscopic and standard cholecystectomy, was rejected. Our results proved that the speed of convalescence is significantly shorter with laparoscopic than with standard cholecystectomy.

The seventh and eighth working hypotheses, which state that there are no differences in the financial effects of treatment with laparoscopic and standard cholecystectomy for patients, for the hospital and for society, were refuted by our results. Our results showed that laparoscopic cholecystectomy is more favorable for patients, the hospital and society than standard cholecystectomy.

And finally, the final analysis of the null and working hypothesis. According to our results, the null hypothesis that there is no difference in the method and effects of treatment between laparoscopic cholecystectomy and standard cholecystectomy is rejected. An alternative hypothesis is accepted, which states that there are differences in the method and effects of treatment between laparoscopic cholecystectomy and standard cholecystectomy.

The differences that exist in medical and economic parameters between laparoscopic cholecystectomy and standard cholecystectomy are such that it can be said that laparoscopic cholecystectomy is a superior method from a medical and economic point of view.

### 8. Conclusions

**1.** There are significant preferences in the treatment ways and effects between laparoscopic cholecystectomy and ordinary cholecystectomy treatments.

**2.** Postoperative nausea and vomiting appeared oftentimes at the ordinary cholecystecomy treatments.

**3.** Operation and hospital stay are significantly shorter at the laparoscopic cholecystectomy treatment.

**4.** Pain duration and recovery period are significantly shorter at the laparoscopic cholecystectomy treatment.

**5.** Laparoscopic and ordinary cholecystectomy treatments have no difference in the mortality and postoperative complications.

**6.** Financial effects at the laparoscopic cholecystectomy treatments are favourable for patients, hospital and community.

63