

## CLINICAL SCIENCE

## ECONOMIC EVALUATION OF COST-EFFECTIVENESS IN EARLY VERSUS DELAYED LAPAROSCOPIC CHOLECYSTECTOMY IN ACUTE CHOLECYSTITIS

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## Abstract

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**Key words:** acute cholecystitis, early laparoscopic cholecystectomy, hospital stay, hospital costs

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Diseases of the biliary tree are prevalent in the gastrointestinal tract (GIT) and can have significant implications in terms of morbidity and mortality. Among these diseases, acute cholecystitis holds particular importance as it requires immediate attention and mandates timely diagnosis and appropriate treatment. Early laparoscopic cholecystectomy (LC) is a safe and effective procedure for managing acute cholecystitis, providing definitive treatment during the initial hospital stay and it is considered a superior option compared to delayed LC for the treatment of acute cholecystitis. The objective of the study was to examine the overall expenses incurred by hospitals and the duration of hospitalization concerning delayed laparoscopic cholecystectomy in patients diagnosed with acute cholecystitis. Materials and methods: An analytical (case-control) study was conducted involving 139 patients diagnosed with acute cholecystitis and admitted to the University Clinic for Digestive Surgery. Among them, 71 patients were assigned to the study group, while 68 patients were placed in the control group. Patients in the study group received early LC treatment within 0-7 days from the onset of symptoms, while patients in the control group underwent delayed LC treatment between 6-12 weeks from symptom onset. The selection of patients was made using a simple random selection method, following predetermined inclusion and exclusion criteria. Results: Among patients from both groups, there was no statistically significant distinction in age, gender, education, place of residence, past illnesses, comorbidity, and previous abdominal surgery for  $p>0.05$ . However, a notable dissimilarity existed between the groups regarding total costs, with significantly higher expenses observed during delayed treatment of patients with acute cholecystitis (t-test for independent samples = -37.644 df=137  $p=0.0001$ ). Conclusion: Significant variations were observed in total hospital length of stay and hospital costs between the two groups, indicating that laparoscopic treatment for acute cholecystitis was associated with higher expenses and longer hospital stays.

## КЛИНИЧКИ ИСПИТУВАЊА

## ЕКОНОМСКА ЕВАЛУАЦИЈА НА ТРОШОЦИ-ЕФЕКТИВНОСТ КАЈ РАНАТА НАСПРОТИ ОДЛОЖЕНА ЛАПАРОСКОПСКА ХОЛЕЦИСТЕКТОМИЈА КАЈ АКУТЕН ХОЛЕЦИСТИТ

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## Извадок

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**Конкурентски интереси:** Авторот изјавува дека нема конкурентски интереси.

Болестите на билијарното дрво се распространети во гастроинтестиналниот тракт (ГИТ) и може да имаат значителни импликации во однос на морбидитетот и морталитетот. Меѓу овие болести, акутниот холециститис има особено значење бидејќи бара итно внимание и бара навремена дијагноза и соодветен третман. Раната лапароскопска холецистектомија (LC) е безбедна и ефикасна процедура за управување со акутен холециститис, обезбедувајќи дефинитивен третман за време на почетниот престој во болница и се смета за супериорна опција во споредба со одложената LC за третман на акутен холециститис. Целта на студијата беше да се испитаат вкупните трошоци направени од страна на болниците и времетраењето на хоспитализацијата во врска со одложената лапароскопска холецистектомија кај пациенти со дијагноза на акутен холециститис. Материјали и методи: Спроведена е аналитичка (случај-контрола) студија во која учествуваа 139 пациенти со дијагноза на акутен холециститис и примени на Универзитетската клиника за дигестивна хирурџија. Меѓу нив, 71 пациент беа распоредени во испитуваната група, додека 68 пациенти беа во контролната група. Пациентите во испитуваната група добија ран третман со LC во рок од 0-7 дена од почетокот на симптомите, додека пациентите во контролната група беа подложени на одложен третман со LC помеѓу 6-12 недели од почетокот на симптомите. Изборот на пациенти беше направен со користење на едноставен метод на случаен избор, следејќи ги однапред одредени критериуми за вклучување и исклучување. Резултати: Кај пациентите од двете групи, немаше статистички значајна разлика во возраст, пол, образование, место на живеење, минати болести, коморбидитет и претходна абдоминална операција за  $p>0,05$ . Сепак, постоеше сигнификантна разлика помеѓу групите во однос на вкупните трошоци, со значително повисоки трошоци забележани при одложен третман на пациенти со акутен холециститис (t-тест за независни примероци = -37,644 df=137  $p=0,0001$ ). Заклучок: Беа забележани значајни варијации во вкупната должина на болничкиот престој и болничките трошоци помеѓу двете групи, што укажува дека лапароскопскиот третман за акутен холециститис е поврзан со повисоки трошоци и подолг престој во болница.

## Introduction

Diseases affecting the biliary tree are prevalent in the gastrointestinal tract (GIT) and are known for their significant morbidity and mortality rates<sup>1</sup>. Acute infection of the biliary tree typically manifests as acute cholangitis or acute cholecystitis. Acute cholangitis is a systemic infectious disease that can potentially be life-threatening, thus requiring urgent treatment. In contrast, acute cholecystitis refers to the inflammation of the gallbladder<sup>2</sup>. The nature of acute cholecystitis is frequently obstructive, primarily resulting from impacted stone in the cystic duct. The incidence of cholecystitis increases with age. There is a notable rise observed among the elderly population as opposed to younger individuals. When considering gender distribution, cholecystitis is found to be 2 to 3 times more frequent in females than in males. Acalculous cholecystitis is more frequent in older men<sup>3,4</sup>. Among patients with abdominal pain, 3-10% are found to have acute cholecystitis<sup>5,6</sup>. Treatment of calculous gallbladder by laparoscopic cholecystectomy has been in use since 1987. The literature has reported a growing number of studies focusing on the laparoscopic removal of the gallbladder in cases of acute cholecystitis in recent years<sup>7</sup>. Early laparoscopic cholecystectomy is defined as a procedure in which the gallbladder is removed laparoscopically within the first 7 days from the onset of symptoms, while delayed laparoscopic cholecystectomy is laparoscopic removal of the gallbladder within 6-12 weeks from the onset of symptoms after conservative treatment for acute cholecystitis. According to the Cochrane Database<sup>8</sup>, there

are no significant disparities in complication and conversion rates between laparoscopic cholecystectomy procedures conducted during the acute phase and those performed 6-12 weeks after symptoms have subsided. The intervention should ideally be put into effect as soon as possible, and the golden period is typically within the first 72 hours following the onset of symptoms<sup>9</sup>. Numerous meta-analyses of randomized clinical trials have consistently shown that early laparoscopic cholecystectomy is a safe procedure for acute cholecystitis. This approach not only reduces hospital stay and total costs, but also improves the patients' quality of life. In comparison to delayed laparoscopic cholecystectomy, early intervention is considered the most effective treatment option<sup>8-15</sup>.

The aim of the study was to examine the overall expenses incurred by hospitals and the duration of hospitalization concerning delayed laparoscopic cholecystectomy in patients diagnosed with acute cholecystitis.

## Materials and methods

This analytical (case-control) study included 139 subjects diagnosed with acute cholecystitis (study group and control group), treated with laparoscopic cholecystectomy. The sample of participants in each group was chosen by the method of simple random sampling, ensuring that the set inclusion and exclusion criteria were met. To achieve the study objectives, information gathered directly from patients, data extracted from existing medical records, and observations made by the researcher were utilized.

The study group consisted of 71 patients diagnosed with acute cholecystitis and hospitalized at the University Clinic for Digestive Surgery in Skopje. Within a span of 0 to 7 days following the onset of symptoms, these patients received a prompt treatment in the form of early laparoscopic cholecystectomy. To analyze the proposed hypotheses, this patient group was categorized into two subgroups. The first subgroup consisted of individuals diagnosed with acute cholecystitis who underwent laparoscopic treatment within 0-3 days after the initial onset of symptoms. The second subgroup included patients with acute cholecystitis who underwent laparoscopic treatment within 4-7 days from the onset of symptoms.

The control group consisted of 68 individuals who had been diagnosed with acute cholecystitis and were subjected to delayed laparoscopic cholecystectomy. These patients were initially admitted and treated conservatively at the University Clinic for Digestive Surgery and other healthcare facilities. Subsequently, within the timeframe of six to twelve weeks from the onset of symptoms, they were readmitted to the same clinic for laparoscopic intervention.

In our study focusing on the analysis of total hospital expenses in patients treated for acute cholecystitis with early or delayed laparoscopic cholecystectomy, the following health services grouped by DRG with DRG code were used:

- H07B Open cholecystectomy with reference price 31,797 MKD – rounded to 32 000 MKD
- H08B Laparoscopic cholecystectomy with reference price 39,118 MKD – rounded to 39 000 MKD
- H64B Hospital conservative treatment of acute cholecystitis with reference price 13 841 MKD – rounded to 14 000 MKD.

## Results

The average length of patients' postoperative hospital stay was  $2.1 \pm 1.5$  days. The minimum recorded duration of stay was one day, while the maximum lasted eight days (Table 1). The postoperative stay of the study group patients lasted an average of  $2.32 \pm 2.3$  days, while of the control group patients  $1.9 \pm 1.5$  days. Notably, more than 50% of patients in both groups had an average postoperative stay of 2 days.

**Table 1** Descriptive analysis of the study group and control group according to postoperative hospital stay

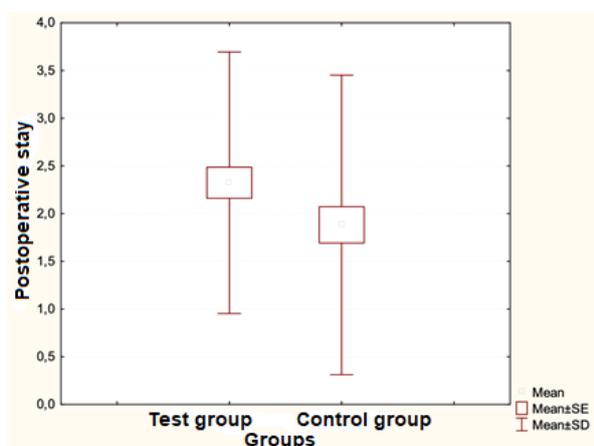
Group	Number	Average days (Means)	Standard Deviation (Std.Dev.)	Standard Error (Std.Err.)	Minimum (Min)	Maximum (Max)
Study group	71	2,32	1,37	0,16	1	8
Control group	68	1,88	1,57	0,19	1	8
Total	139	2,10	1,48	0,12	1	8

t-test for independent samples=1.769 df=137 p=0.0792

There was no statistically significant difference in the average postoperative stay between the two groups of patients, as indicated by the t-test for independent samples ( $t=1.769$ ,  $df=137$ ,  $p=0.0792$ ). The tabular and graphic display of the descriptive analysis of patients from both groups in terms of their postoperative hospital stay duration is presented in Table 1 and Figure 1.

**Figure 1.**

Descriptive analysis of the study group and control group according to postoperative hospital stay



**Table 2** Analysis of the control group according to duration of hospital stay during conservative treatment

**Total hospital length of stay during conservative treatment**

To understand the total hospital length of stay during the conservative treatment in the group treated with delayed laparoscopic cholecystectomy (control group), patients were divided into four categories: a) from 0 to 3 days; b) from 4 to 6 days; c) from 7 to 9 days and d) over 10 days. According to Table 2, the majority of patients, 39 (57.3%) had a total postoperative hospital stay of 4 to 6 days, followed by 15 (22.1%) with a stay of 7 to 9 days. Among patients in this specific group, 8 patients (11.8%) had a duration of hospitalization exceeding 10 days. Notably, this included 3 men (13%) and 5 women (11.1%). Only a small percentage of patients, specifically 2 (8.7%) males and 4 (8.9%) females, had a conservative treatment duration of zero to three days. There was no significant variation observed between the sexes concerning the overall length of hospital stay for conservative treatment, whether it was  $\leq 3$  days or  $\geq 4$  days. Similarly, no significant difference was found in terms of hospital stay durations of  $\leq 6$  days or less, or  $\geq 7$  days.

Total hospital length of stay during conservative treatment (days)		Gender		Total
		Male	Female	
0 - 3	Number	2	4	6
	%	2.94	5.88	8.82
4 - 6	Number	12	27	39
	%	17.65	39.71	57.35
7 - 9	Number	6	9	15
	%	8.82	13.24	22.06
$\geq 10$ days	Number	3	5	8
	%	4.41	7.35	11.76
Total	Number	23	45	68
	%	33.82	66.18	100

Pearson Chi-square=0.467, df=3, p=0.926

Fisher exact, two tailed test p=1,000 ≤ 3 days/ ≥ 4 days

Pearson Chi-square=0.44, df=1, p=0.508426 ≤ 6 days/ ≥ 7 days

The analysis indicated that for p>0.05 there was no significant difference in the total hospital length of stay of patients with acute cholecystitis treated with delayed laparoscopic cholecystectomy concerning the presence/absence of a comorbid condition, i.e., the hospital stay of these patients could not be attributed to any other health problem (Table 3).

**Table 3**

Analysis of the control group according to total hospital length of stay during conservative treatment and comorbid condition

Total hospital length of stay during conservative treatment (Days)		Comorbid condition		Total
		Yes	No	
0 - 3	Number	0	6	6
	%	0	8.82	8.82
4 - 6	Number	18	21	39
	%	26.47	30.88	57.35
7 - 9	Number	5	10	15
	%	7.35	14.71	22.06
≥10 days	Number	4	4	8
	%	5.88	5.88	11.76
Total	Number	27	41	68
	%	39.71	60.29	100

Pearson Chi-square=5.237, df=3, p=0,155

There was no statistically significant variation in the overall duration of hospitalization of patients who underwent delayed laparoscopic cholecystectomy (p>0.05), regardless of whether they resided in a village or a city. This implies that the place of residence does not have a significant impact on the frequency of hospitalization (Table 4).

**Total Hospital Costs**

An analysis was conducted in terms of total costs based on individual prices (for both groups separately) under the DRG system of the Health Insurance Fund of the Republic of North Macedonia (HIFRNM) expressed in Macedonian denars (MKD).

**Table 4**

Analysis of the control group according to total hospital length of stay during conservative treatment and place of residence

Total hospital length of stay during conservative treatment (Days)		Place of residence		Total
		Village	City	
0 - 3	Number	0	6	6
	%	0	8.82	8.82
4 - 6	Number	18	21	39
	%	26.47	30.88	57.35
7 - 9	Number	5	10	15
	%	7.35	14.71	22.06
≥10 days	Number	4	4	8
	%	5.88	5.88	11.76
Total	Number	27	41	68
	%	39.71	60.29	100

Pearson Chi-square=2.730 df=3, p=0.435

**Table 5** Descriptive analysis of the study group and control group according to total costs

Group	Number	Average (Means)	Standard Deviation (Std.Dev.)	Median (Median)	Maximum (Max)
Study group	71	39000,00	0,000	39000,00	39000,00
Control group	68	53823,53	3 318,610	53000,00	67000,00

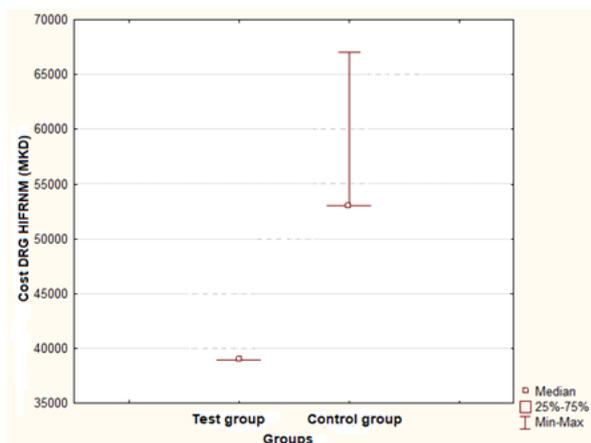
t-test for independent samples=-37.644 df=137 p=0.0001

The average cost per patient suffering from acute cholecystitis who received early laparoscopic cholecystectomy in the study group was 39000 MKD (Table 5). In the control group, the average cost for a patient who underwent delayed laparoscopic cholecystectomy for acute cholecystitis was 53823 MKD. The cost ranged from a minimum of 53 000 MKD to a maximum of 67 000 MKD (Table 5). In terms of total costs, there was a statistically significant difference (t-test for independent samples=-37.644 df=137 p=0.0001) between the study group and control group with significantly higher costs during delayed treatment of patients diagnosed with acute cholecystitis.

Total costs, showing the single prices within the DRG system of the HIFRNM in Macedonian denars, are illustrated in Figure 2.

**Figure 2.**

Descriptive analysis of the study group and control group according to total costs



## Discussion

In the present day, cholecystectomy is presented as a surgical method for management of acute cholecystitis. Numerous studies have been conducted regarding the utilization of cholecystectomy during the era of open surgery, as well as in the present age of laparoscopic surgery. These studies have shown that undergoing early surgery within 7 days of the onset of symptoms (preferably within 72 to 96 hours) leads to a shorter hospital stay, faster recovery, and lower overall hospital expenses. Moreover, this approach does not show any significant variance in terms of mortality and morbidity, offers an improved quality of life and is considered the optimal treatment option for acute cholecystitis<sup>7, 9</sup>.

The economic evaluation involves the comparison of the costs and benefits of multiple medical treatments and strategies to improve the most appropriate decision-making process in solving a particular medical problem. The findings in multiple randomized studies involving patients who have undergone treatment for acute cholecystitis indicate that the realization of an early laparoscopic cholecystectomy leads to decreased overall hospital expenses and improved quality of life when compared to a delayed laparoscopic cholecystectomy<sup>14, 15</sup>.

Compared to delayed laparoscopic cholecystectomy in cases of acute cholecystitis, early laparoscopic cholecystectomy has been found to result in decreased overall hospital expenses as it requires only one hospital admission and a shorter postoperative recovery period. Starting from the 1980s (when laparoscopic cholecystectomy was not a common procedure), early cholecystectomy was characterized as an effective procedure in terms of economic benefit for patients with acute cholecystitis<sup>16,17</sup>. Over the past decade, there has been a growing emphasis on the economic benefits of early cholecystectomy, particularly the laparoscopic approach. Performing early laparoscopic cholecystectomy leads to a notable decrease in intraoperative blood loss, as well as a reduction in both hospital stay duration and overall hospital expenses<sup>18</sup>. A large meta-analysis of early laparoscopic cholecystectomy for acute cholecystitis demonstrated that overall hospital costs were lower compared to delayed laparoscopic cholecystectomy<sup>15</sup>.

According to the results obtained in our study, the average patients' postoperative hospital length of stay was  $2.1 \pm 1.5$  days, with the shortest stay being one day and the longest eight days. In the study group, the average length of postoperative stay was  $2.32 \pm 2.3$  days, whereas in the control group, it was slightly shorter  $1.9 \pm 1.5$  days. Over 50% of patients in both groups experienced an average postoperative stay of 2 days. Similar results were presented in the study by Ashraf F *et al.*, where the postoperative stay in early laparoscopic cholecystectomy was 2.1 days, while delayed laparoscopic

cholecystectomy led to a stay of 2.3 days<sup>19</sup>. In another study, different results were shown, where the postoperative stay in the early intervention was  $6.5 \pm 2.3$  days, i.e.  $12 \pm 5.5$  days in the delayed intervention<sup>20</sup>. In the Biswas' study, the postoperative stay for the first group averaged 2 days, while for the second group 3.5 days<sup>13</sup>. Another study revealed that patients in the early group had a hospital stay lasting anywhere from 3.5 to 6 days, with an average of  $4.8 \pm 0.91$  days. On the other hand, individuals in the delayed group had a total hospital length of stay ranging from 7 to 12 days, with a mean of  $9.2 \pm 1.61$  days<sup>22</sup>.

The majority of patients in our study, 39 (57.3%), had a total postoperative hospital length of stay of 4 to 6 days, during conservative treatment in the group treated with delayed laparoscopic cholecystectomy. In comparison to delayed laparoscopic cholecystectomy, patients who underwent early treatment experienced a shorter overall hospital stay by 4 days<sup>13</sup>.

Both groups of patients were examined in terms of total costs calculated according to the single prices under the DRG system of the Health Insurance Fund of Macedonia (HIFRNM) in Macedonian denars (MKD). The Macedonian DRG model is built upon the Australian classification referred to as Australian Refined Diagnosis Related Groups (AR-DRG version 5.2). The foundation of AR-DRG lies in IKB-10-AM, specifically the tenth revision of the International Classification of Diseases and Related Health Problems. The Australian Classification of Health Interventions (ACHI) and Australian

Coding Standards (ACS) are available for reference on the NHS website. By the introduction and implementation of the DRG model in Macedonia, a key objective has been met: the standardization of health service costs across all healthcare facilities in the Republic of Macedonia for identical diagnostic groups and complexity levels. HIFRNM has set reference prices for each DRG service.

The fundamental concept behind DRG payment involves reimbursing per episode, which refers to the entire duration of treatment from hospital admission to discharge. This episode can span over one or multiple days, encompassing all healthcare services provided, and is covered within a single payment.<sup>(23)</sup>

The mean expense per patient in the study group receiving early laparoscopic cholecystectomy for acute cholecystitis reached 39 000 MKD. In the control group, the average cost per patient with acute cholecystitis treated with delayed laparoscopic cholecystectomy was 53 823 MKD, with a minimum cost of 53 000 MKD and a maximum cost of 67 000 MKD. There was a statistically significant difference between the study group and control group in terms of total hospital expenses with a notable inclination towards higher costs in patients with acute cholecystitis who received delayed treatment. In a multicenter randomized study, patients who underwent early laparoscopic cholecystectomy incurred an average total hospital cost of 2,919 euros, while those who underwent delayed elective laparoscopic cholecystectomy following conservative treatment had costs averaging 4 262

euros<sup>24</sup>. Another study revealed that patients who underwent early laparoscopic cholecystectomy had total hospital costs of £5 911, whereas those in the delayed group had expenses amounting to £6,132 14. The national health system of Great Britain saves an average of 8 million pounds (8.9 million euros) annually by utilizing early laparoscopic cholecystectomy for acute cholecystitis<sup>25</sup>. Another study found that each early laparoscopic cholecystectomy operation could have the potential to save £645. Assuming that 74% of cholecystectomies are delayed laparoscopic cholecystectomies and using a figure of 57,000 cholecystectomies per year, this study suggests that implementing early rather than delayed laparoscopic cholecystectomy could save the national health system £27,000,000 per year. Moreover, the calculations show that the current net value of early laparoscopic cholecystectomy is £3 920 and that of delayed laparoscopic cholecystectomy is £4 565, indicating that early laparoscopic cholecystectomy is also the more cost-effective treatment<sup>26</sup>. According to Gallagher's study, the average healthcare cost for early and delayed laparoscopic cholecystectomy was €4400 and €6004, respectively. A total of five studies provided sufficient data for a combined analysis<sup>27</sup>.

Our data analysis and comparison with previously published papers reveal consistent findings regarding the effectiveness of early versus delayed laparoscopic cholecystectomy in acute cholecystitis on overall hospital expenses.

## Conclusions

The total hospital length of stay of patients with acute cholecystitis treated with delayed laparoscopic cholecystectomy was significantly longer compared to that of patients treated with early laparoscopic intervention. The analysis demonstrated a statistically significant difference in terms of overall hospital costs between the two groups, indicating a tendency towards greater expenses for delayed laparoscopic treatment in acute cholecystitis.

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