Republic of Iraq
Ministry of Higher Education and Scientific Research
University of Baghdad
Al-Kindy College of Medicine

# RELATIONSHIP BETWEEN GALLLSTONES & SYSTEMIC IMMUNE INFLAMMATION INDEX (SII INDEX)

**A research project submitted to the Family & Community Medicine Department, Al-Kindy College of Medicine as a partial fulfillment of Research Module**

**YEAR III**

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(نَرْفَعُ دَرَجَاتٍ مَنْ نَشَاءُ وَفَوْقَ كُلِّ ذِي عِلْمٍ عَلِيمٌ)

(صدق الله العظيم)

(يوسف: الآية76)

## Acknowledgement and Dedication:

We would like to thank our supervisor Dr. Kamal Abdulhussein who advised us on this study and gave us general directions how to conduct and finish this work.

A special thank should go to the lab. staff for their assistance in providing us with information.

We would also like to dedicate this work to everyone who stood by our side during the preparation of this research.

We hope that it will get your acceptance and appreciation.

# ABBREVIATION

| | |
|---|---|
| **SIII** | Systemic immune inflammation index |
| **CBC** | Complete blood count |
| **P** | Platelets |
| **N** | neutrophils |
| **L** | lymphocytes |
| **ERCP** | Endoscopic retrograde cholangiopancreatography |
| **SD** | Standard deviation |
| **WBC** | White blood cell |
| **PLT** | platelets |
| **ROC** | Receiver operating characteristic |
| **IL** | Interleukins |
| **CRP** | C-reactive protein |

# List of contents



# List of figures



# List of tables

# Abstract

## Background:

Cholecystitis is inflammation of the gallbladder that occurs most commonly because of the presence of stones in the gallbladder or an obstruction of the cystic duct by gallstones arising from the gallbladder (cholelithiasis). Uncomplicated cholecystitis has an excellent prognosis; the development of complications such as gangrene or perforation renders the prognosis less favorable.this study was made to figure the relation between cholecystitis as a complication of gallstones & increased Systemic Immune Inflammatory index value.

## Aim of the study:

To study the relationship between severity of gallstone disease and the level of SII index value.

## Patients and methods:

The current cross sectional study was conducted at Al-Kindy teaching hospital in Baghdad/Iraq during the period from October 2022 to March 2023. The data of 58 male and female patients with gallstones regarding their CBC and Ultrasonography were collected. They were grouped into three age groups: (1) 0-25 years , (2) 26-50 years and (3) 51-75 years. The SII was calculated according to the equation: SII = P x N/L, where P, N and L are the preoperative peripheral blood platelet, neutrophil and lymphocyte counts per liter, respectively.

## Results:

The results of this study showed that the elective cases were higher than the acute cases of gallstones. The females (55) were more affected than males (3), the incidence of gall stones were the highest in the age group 26-50 years (22) cases. The multiple stones were found to be more (44) than the single stone cases (14). There were significant differences in mean lymphocyte counts and SII between acute and elective gall stone patients ($p<0.05$). while other parameters showed non-significant differences ($p>0.05$).

## Conclusions:

In conclusion, SII, which is primarily used to predict the inflammatory response, is also used as simple, inexpensive, and easily accessible markers used to predict clinical course in gallstones.

# 1.1.Introduction

Gallstones disease is a common health issue worldwide, affecting 10-15% of the global population. These are hardened deposits of digestive fluid that can form in the gallbladder. The gallbladder is a small organ found just below the liver. The gallbladder stores bile, a digestive fluid that is released into the small intestine. The majority of gallstones are asymptomatic. The likelihood of developing symptoms or complications in patients with asymptomatic gallstones discovered incidentally is 1% to 2% per year. Asymptomatic gallbladder stones discovered in a healthy gallbladder and biliary tree do not require treatment unless they cause symptoms. However, after 15 years of follow-up, approximately 20% of these asymptomatic gallstones will develop symptoms. Complications from gallstones include cholecystitis, cholangitis, choledocholithiasis, gallstone pancreatitis and, in rare cases, cholangiocarcinoma [1].

The majority of gallstones are asymptomatic. The likelihood increases with age. Obesity increases the risk of gallstones, particularly in women, due to increased biliary cholesterol secretion. Patients who lose a lot of weight or fast have a higher risk of developing gallstones due to biliary stasis. Gallstones are also associated with a hormonal imbalance. Estrogen has been shown to increase bile cholesterol while also decreasing gallbladder contractility. When compared to men, women of reproductive age or on estrogen-containing birth control medication have a two-fold increase in gallstone formation. Chronic illnesses, such as diabetes, are associated with an increase in gallstone formation and decreased gallbladder wall contractility due to neuropathy. [2]

Gallstones may not show any symptoms at all. If a gallstone lodges in a duct and causes a blockage, the resulting signs and symptoms may include Upper right abdominal region pain that develops suddenly and quickly ,Pain in your right shoulder ,Nausea or vomiting. [3][4]

The exact reason that why gallstones form is unknown. Doctors think gallstones may result when There is too much cholesterol in your bile. Typically, the molecules in your bile are

sufficient to break down the cholesterol your liver excretes. But, if your liver excretes more cholesterol than your bile can break down, it may crystallize and eventually turn into stones . [5]

**Treatment options for gallstones include:**

**1-Nonsurgery method** like Endoscopic retrograde cholangiopancreatography (ERCP) ,Oral dissolution therapy and others used only in special situations, like if you have cholesterol stones and you have a serious medical condition that prevents surgery. Even with treatment, gallstones can return. Therefore, you may have to be regularly treated for gallstones for a very long time, or even for the rest of your life. [6]

**2-Surgery method** Laparoscopic cholecystectomy is a minimally invasive surgical procedure for removal of a diseased gallbladder. This technique essentially has replaced the open technique for routine cholecystectomies since the early 1990s. At this time, laparoscopic cholecystectomy is indicated for the treatment of cholecystitis (acute/chronic), symptomatic cholelithiasis, biliary dyskinesia, acalculous cholecystitis, gallstone pancreatitis, and gallbladder masses/polyps. These indications are the same for an open cholecystectomy.[7]

Systemic immune-inflammation index (SII) is a relatively new biomarker that reflects the systemic inflammatory response in the body. SII is calculated by combining the absolute counts of neutrophils, lymphocytes, and platelets. Recent studies have shown that SII can be used as a prognostic factor in various cancers and inflammatory diseases. In this essay, we will discuss the relationship between gallstones disease and SII.

# 1.2.Aim of the study

To study the relationship between severity of gallstone disease and the level of Systemic Immune Inflammation Index (SII Index).

# 2.Methods

## Design, Sample and Data collection

This cross sectional study was conducted in Al-Kindy Teaching Hospital, Baghdad-Iraq. The records were included during the period from October 2022 to March 2023. The study was approved by the scientific and ethical committee of Al-Kindy College of Medicine.

In the current study, 58 medical files of patients were included. The files contained complete blood count tests and ultrasonography images of male and female patients who were diagnosed with cholelithiasis.

## Exclusion criteria

The following cases were excluded from the study:

1-Patients taking anti-inflammatory drugs.

2-Patients with chronic infections.

The SII was calculated according to the formula: SII = $P \times N/L$, where $P$, $N$, and $L$ were the pre-therapeutic peripheral blood platelet, neutrophil, and lymphocyte counts in cells/L in patients diagnosed with gallstones, respectively.

## Statistical analysis

The SPSS software was used for analysis of the data to determine the optimal cutoff value of SII, which was found to be $505.79\times10^9$ cells/L. Consequently, the patients were divided into high SII ($\geq505.79\times10^9$ cells/L) and low SII ($< 505.79\times10^9$ cells/L) groups for evaluating the usefulness of SII.

# 3. Results

In this study data regarding hematologic parameters and ultrasonography images were taken from 58 patients with gallstones.

The results in figure (1) showed that 44(75%) of the cases were elective and 14(25%) were acute.

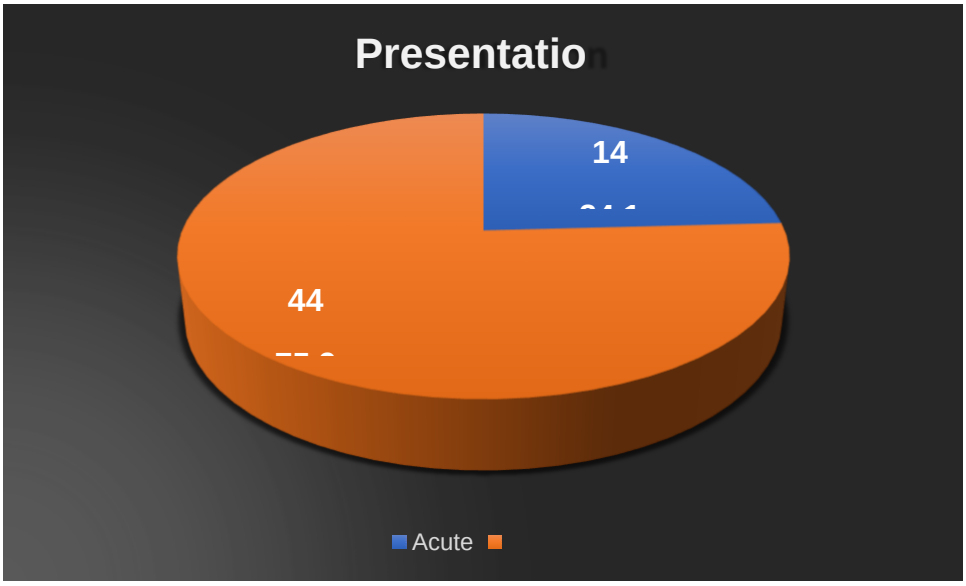


Figure (1) : Data distribution according to presentation

In table (1), the patient demographics showed that the number and percentage of male patients was 1(7.1%) in acute cases and 2(4.5%) in elective cases, while the number and percentage of female patients was 13(92.9%) in acute cases and 42(95.5%) in elective cases. The results also showed that in the age group 0-25 years, the number and percentage of acute cases was 2(14.3%) and 10(22.7%) in elective cases, while in the age group 26-50 years, the number and percentage of acute cases was 6(42.9%) and 22(50%) in elective cases, and in the age group 51-75 years, 6(42.9%) acute cases and 12(27.3%) in the elective cases. Results of the number of stones showed that 2(14.3%) of the acute cases had single stones and 12(27.3%) of the elective cases had single stones, while 12(85.7%) of the acute cases had multiple stones and 32(72.2%) of the elective cases had multiple stones.

No significant differences were shown regarding gender, age groups and number of stones ($p>0.05$).

Table (1): Patients demographics and gallstone number

| Variables | | Acute | Elective | P value |
|---|---|---|---|---|
| | | No. (%) | No. (%) | |
| Gender | Male | 1 (7.1) | 2 (4.5) | 0.702 |
| | Female | 13 (92.9) | 42 (95.5) | |
| Age group | 0-25 Years | 2 (14.3) | 10 (22.7) | 0.520 |
| | 26-50 Years | 6 (42.9) | 22 (50) | |
| | 51-75 Years | 6 (42.9) | 12 (27.3) | |
| Number of stones | Single | 2 (14.3) | 12 (27.3) | 0.323 |
| | Multiple | 12 (85.7) | 32 (72.7) | |

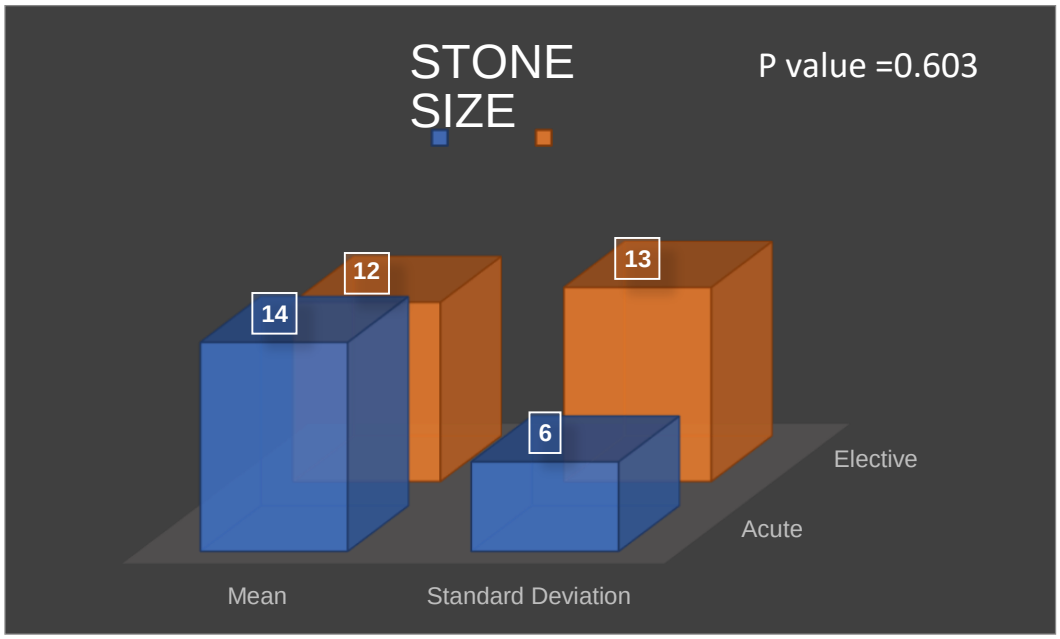


Figure (2): Stone sizes according to presentation

Figure (2) demonstrated the mean and standard deviation of stone sizes in both acute and elective cases of patients with gallstones.

The mean and SD values of WBC count in acute cases was 8.74 ±2.58, and 8.53 ±2.31in elective cases. The mean and SD values of Neutrophil count in acute cases was 5.57 ±2.78, and 4.44 ±1.9 in elective cases. The mean and SD values of Lymphocyte count in acute cases was 2.44 ±0.86, and 3.09 ±0.6 in elective cases. The mean and SD values of platelets count in acute cases was 248.73±67.52, and 272.43±115.96in elective cases. The mean and SD values of SII in acute cases was 652.06±534.16, and 383.51±236.21in elective cases. The results of lymphocyte count and SII showed significant differences (P=0.010) and (p=0.011) respectively, while other hematologic parameters showed non-significant differences (P>0.05) as shown in table (2).

Table (2): Hematologic parameters and SII in patients with gall stones

| Variables | Acute | | Elective | | P value |
|---|---|---|---|---|---|
| | Mean ±SD | Range | Mean ±SD | Range | |
| WBC | 8.74 ±2.58 | 5.07-14.97 | 8.53 ±2.31 | 6.27-12.15 | 0.775 |
| Neutrophil | 5.57 ±2.78 | 1.75-11.95 | 4.44 ±1.9 | 1.75-7.04 | 0.096 |
| Lymphocyte | 2.44 ±0.86 | 1.18-4.28 | 3.09 ±0.6 | 2.32-3.97 | **0.010** |
| PLT | 248.73 ±67.52 | 92-367 | 272.43 ±115.96 | 25-374 | 0.478 |
| SII | 652.06 ±534.16 | 173.69-2622.92 | 383.51 ±236.21 | 46.11-704.89 | **0.011** |

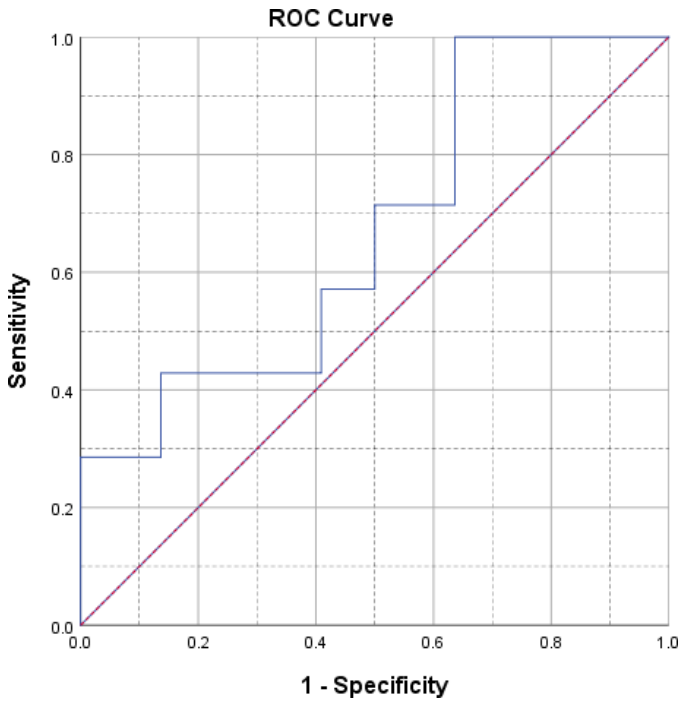


Figure (3): ROC curve analysis of SII

Table (3): Interpretation of ROC curve analysis of SII.

| Indicator | Level |
|---|---|
| Area under the curve | 0.669 |
| Cutoff point | ≥505.79 |
| Sensitivity | 71.4% |
| Specificity | 50% |
| Positive predictive value | 31.3% |
| Negative predictive value | 84.6% |
| Accuracy | 55.2% |
| Odd ratio | 2.5 |
| 95% confidence interval | 0.7-9.2 |

# 4. Discussion

Gallstones can be classified into two categories: cholesterol gallstones and pigment gallstones. Cholesterol gallstones, which make up more than 70% of gallstone cases, are commonly associated with obesity and other factors affecting cholesterol concentration in the bile, Lammert F et al [8]. Pigment gallstones, however, are more associated with biliary infections and haemochromatosis, Liu Z et al [9]. The risk factors for GSD include old age, female sex, ethnicity, pregnancy, family history, sedentary lifestyle, obesity and weight gain, Cao AM, Eslick GD [10]. Diet is a major lifestyle factor that plays a vital role in GSD causal network. Various studies have shown a link between GSD and dietary factors such as high-calorie intake, low consumption of fiber-rich foods, vegetables and fruits, hypertriglyceridemia, and high consumption of refined carbohydrates and polyunsaturated and monounsaturated fats, Davidović DB [11].

In our study, it was shown that females had gallstones (colelithiasis) more than men, which agreed with most of previous studies like [12] Medisoglu MS, Colak T, Yalniz A, Sezikli M, Baltrak YA, who found the presence of gallstones was observed to be significantly higher in women compared to men (p=0.011). the same result was revealed by , Hands S et al[13] .

All studies show that women experience cholelithiasis more often than men. There are many studies examining the reasons for this phenomenon. Sun et al. (2009) stated in their study that the prevalence of cholelithiasis in women more than men may be due to factors such as fertility and sex hormones, and that the increase in estrogen hormone levels increases cholesterol secretion and causes supersaturation of cholesterol, Sun H et al [14].

In line with this, some studies state that the risk of cholelithiasis increases in women who receive hormone replacement therapy due to menopause. There are a high number of studies in the literature analyzing the relationship between gender and

cholelithiasis, and also studies on women experiencing stone formation more often, Jin S.P et al [15].

Our results demonstrated that the presence of gallstones was higher in the age group (26-50) years. This result was almost in agreement with [16] Şahin M, Erbilen M, Hasanoğlu A et al, who reported the presence of gall stones to be highest near the age 40 years.

With age, the risk of gallstones was found to be increased in all ethnic groups. The threshold between the high and relatively low rates of cholecystectomy seems to be the age 40. The cholesterol stone prevalence increased linearly with age for both genders and reached 50% in women at age 70. With age, cholesterol secretion and saturation were also found to increase, Çavuş B, Karaca Ç [17].

A 4 to 10-fold increased risk of gallbladder disease has been associated with people older than 40 years. Obesity, rapid weight loss, high-caloric diet, drugs, type 2 diabetes, metabolic syndrome, dyslipidemia, smoking and sedentary lifestyle have also been documented as influencing factors. Moreover, obesity, especially abdominal obesity, is related to gallstone formation, Figueiredo J C et al [18].

Inflammation can also play a role in the formation of gallstones.The studies that have examined the association between inflammation and the risk of gallstones have shown a significant correlation between circulating inflammatory biomarkers and inflammatory proteins measured in bile. Some inflammation-related conditions, such as obesity, diabetes and infections (eg, Helicobacter pylori), are also linked with an increased risk of cholesterol gallstones, Shabanzadeh DM et al [19].

Several studies have examined the effect of inflammatory factors on the formation of gallstones. In one of these studies, Liu et al investigated the relationship between circulating inflammatory proteins and gallstones, finding four ILs, including IL-6, IL-10, 1L-12 and IL-13 are associated with an increased risk of gallstones, Liu Z et al [9].

Hupp et al. stated that leukocytes respond early after infections, whereas there is a time delay in the production of CRP, peaking around 48 h after inflammation or initiation of infection. Furthermore, Because their values exclusively have limited predictability to determine the severity of infection accurately, a prognostic indicator based on counts of neutrophils, lymphocytes, and platelets is expected to be more robust than one based on only a single factor , Hupp, J.R.; Ferneini, E.M [20].

In 2014, Hu et al. [21] 14 developed an indicator called the Systemic Immune-inflammation Index, SII, to predict the prognosis of patients after curative resection for hepatocellular carcinoma. The SII was estimated from preoperative peripheral blood counts of platelets (P), neutrophils (N), and lymphocytes (L) per liter by the equation: SII = P × N/L. This index, based on peripheral platelet, neutrophil, and lymphocyte counts, has been proven to be a promising prognostic indicator in various inflammatory diseases, including malignant tumors, coronary artery disease, acute ischemic stroke, and several chronic systemic diseases. Its application in infectious diseases has not yet been fully clarified. The utility of SII to identify patients at higher risk of developing severe infections is given by the differential roles that lymphocytes, neutrophils, and platelet play during the immune response. The lymphocytes are the only cells in the body capable of precisely recognizing and perceiving different antigens. They play a crucial role in most chronic inflammatory lesions, especially in autoimmune diseases and in diseases with persistent antigens. Neutrophils are the most important cellular defense against infections, and platelets contribute to hemostasis and participate in inflammation and host defense. Considering these factors, SII might be better able to reflect the balance of host inflammatory and immune status, Mikhak et al [22].

The most studied hematological parameters are the neutrophil count, white blood cell count, and lymphocyte count. To determine the ideal marker, researchers

have worked on a combination of these parameters. The systemic immuno-inflammation (SII) is a newly developed inflammatory index, Sahinli H et al [23].

Neutrophils, one of the primary response agents to acute inflammation, constitute 50–70% of circulating leukocytes, and an increase in neutrophils is usually expected in acute cholecystitis. Lymphocytes are among markers representing immunity. Platelet plays a role in inflammation, in addition to being an important element of the coagulation cascade. The platelet count is a well-known predictor of many infectious diseases, especially sepsis, Özdemir S et al [24].

To the best of our knowledge, there is no study in the literature evaluating the role of SII in patients with gallstones or choliolithiasis.

Systemic immune inflammation index (SII) is a new parameter for assessing inflammation. Essentially, it is a composite inflammatory indicator that combines three significant immune cells, namely, neutrophils, lymphocytes, and platelets. Recently, SII has been proposed to assess both inflammatory and immune status, is considered an excellent indicator of local immune response and systemic inflammation. Initially, SII was used to assess the prognosis of cancer patients , Yang R et al [25].

The systemic immune-inflammation index (SII) is a recently proposed scoring system that includes immune-inflammatory cells in the peripheral blood count. This system is believed to reflect the immune-inflammatory load in the patient. Although this system was first developed in cancer studies, it was later studied in non-cancerous clinical conditions such as vasculitis or coronary artery disease, Yang YL et al [26].

In infections, trauma, inflammatory diseases, and similar conditions, a series of changes occur as a response at or away from the inflammation area. This response is called the acute phase response, including neuroendocrine, hematopoietic, and metabolic changes. Proteins with increasing or decreasing serum concentrations (acute phase reactants) and some hematological parameters are used in the clinical evaluation of the inflammatory acute phase response and response to therapy. The most studied

hematological parameters are the neutrophil count, white blood cell count, and lymphocyte count. To determine the ideal marker, researchers have worked on a combination of these parameters. The systemic immuno-inflammation (SII) is a newly developed inflammatory index, Sahinli H et al [23].

## CONCLUSION:

In conclusion, SII, which is primarily used to predict the inflammatory response, is also used as simple, inexpensive, and easily accessible markers used to predict clinical course in gallstones.

## RECOMMENDATIONS:

More studies should be done about the relationship between gallstones & SII index on a larger group of patients with a different presentations.

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# الخلاصة


**العلاقة بين حصى المرارة مؤشر التهاب جهاز المناعة النظامي**

**خلفية :**

**التهاب المرارة هو التهاب يحدث بشكل شائع بسبب وجود حصوات في المرارة أو انسداد في القناة الكيسية بسبب حصوات المرارة (تحص صفراوي). التهاب المرارة غير المعقد له تشخيص ممتاز.**

**يؤدي تطور المضاعفات مثل الغرغرينا أو الانثقاب إلى تقليل التشخيص.**

**تم إجراء هذه الدراسة لمعرفة العلاقة بين التهاب المرارة كمضاعفات لـ حصى في المرارة وزيادة قيمة مؤشر الالتهاب المناعي.**

**الطرق:**

**أجريت الدراسة المقطعية الحالية في مستشفى الكندي التعليمي في بغداد / العراق**

**خلال الفترة من أكتوبر 2022 إلى مارس 2023. بيانات 58 مريضا من الذكور والإناث**

**مع حصوات في المرارة فيما يتعلق بـ صورة الدم الكاملة و Ultrasonography.**

**تم تجميعهم**

**إلى ثلاث فئات عمرية: (1) 0-25 سنة ، (2) 26-50 سنة ، (3) 51-75 سنة. تم حساب استقصاء الأثر الاستراتيجي**

**وفقًا للمعادلة: SII = P x N / L ،**

**حيث P و N و L هي الدم المحيطي قبل الجراحة**

**عدد الصفائح الدموية ، خلايا الدم البيضاء العدلة والخلايا الليمفاوية لكل لتر ، على التوالي.**

**النتائج:**

**أظهرت نتائج هذه الدراسة أن الحالات الاختيارية كانت أعلى من الحالات الحادة حصى في المرارة. كانت الإناث (55) أكثر تأثراً من الذكور (3) ، وكانت نسبة الإصابة بحصوات المرارة الأعلى في الفئة العمرية 26-50 سنة (22) حالة. تم العثور على الحجارة المتعددة لتكون أكثر (44) من الحجر الواحد الحالات (14). كانت هناك اختلافات كبيرة في متوسط الخلايا الليمفاوية التهم و SII بين مرضى حصوات المرارة الحاد والاختياري (P <0.05). بينما المعلمات الأخرى أظهرت اختلافات غير معنوية (p> 0.05).**