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# Efficacy of cholecystectomy in patients with positive HIDA Scans with typical or atypical biliary pain: A retrospective study

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### ABSTRACT

**Introduction:** Our investigation aimed to discover the benefits of performing cholecystectomy in patients who had a positive or negative HIDA scan result, presented with either typical or atypical biliary pain. **Methods:** We performed a retrospective analysis of medical records of patients who had a HIDA scan at Peninsula Health between 2012 and 2017, those who had a HIDA scan and cholecystectomy for biliary pain were selected for this study, and prospective analysis of patient reported outcome post cholecystectomy included. **Results:** In the past five years, 190 patients had had a HIDA scan to investigate biliary pain without a structural cause. Of those 190, 65 had a positive HIDA result and 20 of these patients went on to have a cholecystectomy. Of the latter, 17 who reported typical biliary pain had their pain resolved post-surgery but 2 out of 3 patients with atypical biliary pain had ongoing pain despite surgery (1 did not respond). Of the 125 patients with a negative HIDA scan, 14 proceeded with a cholecystectomy. Twelve patients had pre-operative typical biliary pain and 5 of these continued to have pain post-operatively. Finally, 1 of the 2 patients with atypical pain continued to have ongoing pain post-surgery. **Conclusion:** In summary, in patients without a structural cause for biliary pain HIDA scans and patient's symptoms greatly aid in the decision-making process whether to proceed with a cholecystectomy, as a negative scan should prompt further clinical investigation before proceeding with surgery.

**Keywords:** Hepatobiliary Imino Diacetic acid (HIDA) scans; Cholescintigraphy, Dysfunctional gallbladder, Cholecystectomy

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## Introduction

Functional gallbladder disorder is presenting with classic biliary symptoms and normal findings on ultrasonography of the right upper quadrant and usually normal liver and pancreatic enzyme levels. [1] The Rome III criteria can be helpful in guiding a clinical diagnosis but HIDA SCAN is usually used to investigate these patients. HIDA scans involve injecting a radioactive tracer into the patients' veins and allowing it to circulate to the liver. The tracer is then secreted through the hepatic ducts and accumulates in the gall bladder. Imaging is then performed to measure the percentage of dye excreted by the gall bladder and to calculate the ejection fraction (EF). An EF of less than 35% is considered a positive scan. [2]

Current available literature supports use of HIDA scan when patients present with right upper quadrant pain and normal ultrasonography [3]. But studies have also suggested that the character and type of pain reported may be a better predictor of whether to proceed with cholecystectomy or not than the result of the HIDA scan [4]. There is no clear criteria for patient selection for the operation, consequently the incidence of cholecystectomies performed over the past couple of decades has increased from baseline 5% to between 20 and 25% [5].

The aim of our study was to determine the benefit of laparoscopic cholecystectomy on patients presented with typical or atypical biliary pain with positive (EF less than 35%) or negative (EF more than 35%) HIDA scan.

The hypothesis is that patients with atypical biliary pain do not benefit from a cholecystectomy.

Rome III criteria:

Functional Gallbladder Disorders

Diagnostic criteria must include episodes of pain located in the epigastrium and/or right upper quadrant and all of the following:

- . Gallbladder is present
- . Normal liver enzymes, conjugated bilirubin, and amylase/lipase
- . Episodes lasting 30 minutes or longer
- . Awakens from sleep in the middle of the night

- . Recurrent symptoms occurring at different intervals (not daily)
- . The pain builds up to a steady level
- . The pain is moderate to severe enough to interrupt patient's daily activities
- . The pain is not relieved by bowel movements, postural change or by antacids
- . Exclusion of other structural disease that would explain the symptoms.

Supportive criteria

The pain may present with one or more of the following:

- . Associated with nausea and vomiting
- . Radiates to the back and/or right infra subscapular region

## Method:

A retrospective analysis was performed of all patients that had HIDA scans over the period of five years at Peninsula Health. The exclusion criteria were paediatric (younger than 18 years), pregnant, and individuals with a preoperative diagnosis of cholecystitis, gallstones, or unknown ejection fractions, and patients who didn't consent to participate in the study. Data from patients who had HIDA scan (whether positive or negative) and laparoscopic cholecystectomy for biliary pain were included for analysis.

This data was obtained from patients' medical records, their General Practitioner records and referral forms, and via telephone survey of the participants which focussed on typical or a typical biliary pain, and whether pain had resolved by six weeks post cholecystectomy. In this questionnaire, typical pain was defined as: 1) pain located in the RUQ 2) post-prandial pain and 3) pain associated with nausea. If 2 out of 3 of these questions were positive, individual was classified as having typical biliary pain. The patients were also questioned to whether the pain had resolved by 6 weeks post-operatively.

Data was entered onto an excel spreadsheet and analysed using STATA v14 (STATA Corp, Texas, USA).

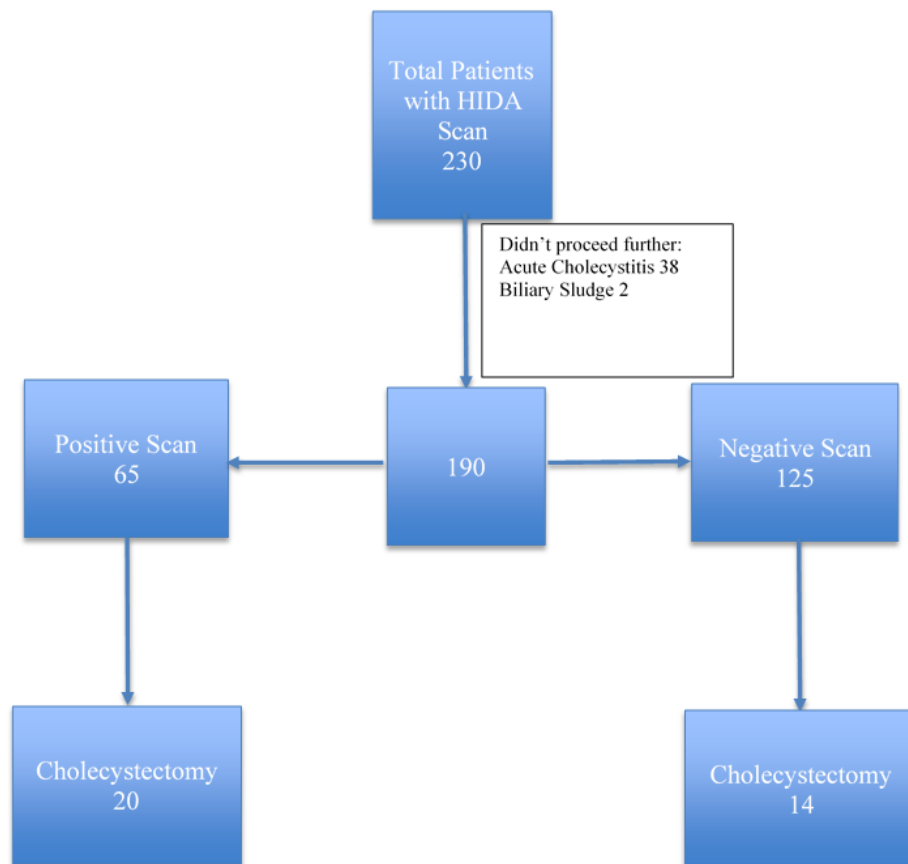
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Health Department of Surgery to complete this study. This study was approved by the Peninsula Health Human Research Ethics Committee (LRR/16/PH/13).

### Results

Over the five years period (2012-2017), two hundred and thirty patients were identified having HIDA scan to investigate biliary pain that was without a structural cause. Forty of these

patients were excluded due to other conditions including acute cholecystitis and biliary sludge. Within this group of patients (n=190) according to their medical records, 65 had a positive HIDA and 30.8% of these proceeded to have a cholecystectomy. In contrast, only 11.2% patients who had a negative HIDA scan proceeded with a cholecystectomy, these proportions were statistically significantly different (by Chi-square test:  $p=0.002$ , Figure 1).



**Figure 1: Flow chart of patients**

Out of the 190 patients who had had a HIDA scan, 34 proceeded to have a cholecystectomy and included in this study. Only patients who consented to be part of this study and responded to the questionnaire were included. Patients that didn't have clear medical records and didn't respond to questionnaire were excluded.

Sample population consisted of 23.5% males, aged  $44.8 \pm 14.5$  (mean  $\pm$  standard deviation,  $n=34$ ).

For the remaining analysis, data were grouped according to whether the patients had a positive or negative HIDA scan result. The average

positive HIDA scan ejection fraction was statistically significantly different from the average negative HIDA scan (mean  $\pm$  standard deviation ejection fraction % positive versus negative HIDA:  $58 \pm 16.4$  versus  $20.2 \pm 9.3$ ,  $p=0.000$  by student's t-test). However, there was no statistically significant difference in average age (positive versus negative HIDA: mean  $\pm$  standard deviation Age  $41.4 \pm 14.3$  versus  $49.8 \pm 13.8$ ,  $p=0.1$  by student's t-test) or proportion of males (positive versus negative HIDA %Male: 21.4% versus 25%,  $p = 1.0$  by Fisher's exact test).

**Table 1. Telephone survey responses, comparing answers from patients with HIDA positive and negative scan results, shown as proportions and (percentages). Proportions were tested for statistically significant differences using Fisher's exact test,  $p < 0.05$  achieved statistical significance.**

	HIDA positive	HIDA negative	Fisher's Exact test results:
N	65	125	
Had cholecystectomy	20/65 (30.8%)	14/125 (11.2%)	$p=0.002^*$
Post-prandial pain	17/20 (85%)	10/14 (71.4%)	$p=0.41$
Pain associated with nausea	14/20 (70%)	8/14 (57.1%)	$p=0.323$
Reported RUQ pain	17/20 (85%)	13/14 (92.9%)	$p=0.627$
Reported typical pain	17/20 (85%)	12/14 (85.7%)	$p=1.00$
Reported pain resolved	17/20 (85%)	8/14 (57.1%)	$p=0.047^*$

As shown in table 2, of the 20 patients with a positive HIDA scan result that proceeded with a cholecystectomy, 17 patients that had typical biliary pain had their pain resolved while 2 of 3 patients with atypical biliary pain had ongoing pain post-surgery. Twelve of the 14 patients with

a negative HIDA scan who had cholecystectomy had typical biliary pain and 5 of these 12 reported ongoing pains post-operatively. Finally, 1 of 2 (50%) of the patients with atypical pain continued to have ongoing pain post-surgery.

**Table 2: Summary of participant numbers whose pain resolved post-operatively whether they had typical or a-typical pain and a positive or negative HIDA scan.**

HIDA	N	Cholecystectomy	typical pain		a-typical pain	
				pain resolved		pain resolved
Positive	65	20	17	17	3	1
Negative	125	14	12	7	2	1

A multivariate logistics regression was used to determine whether post-operative pain resolution was statistically significantly predicted by a positive HIDA scan or by typical biliary pain presentation. Regression analysis found that following cholecystectomy, patients who had a positive scan were seven times more likely to have their pain resolved ( $p=0.042$ ). However, having typical pain did not statistically significantly predict pain resolution post-cholecystectomy ( $p=0.322$ ).

### Discussion

Right upper quadrant pain consistent with biliary disease but with negative ultrasound creates a diagnosis and management challenge to gastroenterologists and surgeons. History and clinical presentation are often the key in establishing the diagnosis of biliary pathology. Functional gallbladder disorder is a motility disorder of the gallbladder that results in decreased gallbladder contractility and colicky

pain, these group of patients have negative ultrasound and warrants further investigation with computed tomography (CT), magnetic resonance pancreatocholangiography and HIDA scan being the most commonly used modalities for investigation of right upper quadrant pain [2, 3].

A HIDA scan is a well-recognised nuclear medicine imaging that has been available for twenty years and is used to aid in diagnosing gall bladder dyskinesia or dysfunction. However, there has not been many studies relating to the level of dysfunction (measured by EF) at which a cholecystectomy is clearly indicated [2, 3]. But a GBEF  $<35\%$  are deemed to be an "abnormal" test. It is not at all clear from the literature, nor intuitive, that a GBEF  $<35\%$  should accurately identify all the curable patients and exclude all those who are not [2,3].

There is controversy in the literatures on utilising the HIDA scan as Sorenson et al concluded that

cholecystectomy would be beneficial in patients with a positive HIDA scan (EF of  $\leq 35\%$ ) [2] and some other study revealed the potential benefit of cholecystectomy in patients who have normal HIDA Scan result [4]. On the contrary Richmond in West Virginia concluded that there is no evidence to suggest that a HIDA scan result should be used as a criterion for patients to undergo a cholecystectomy [10].

As there are no clear criteria for patients' selection for surgery, there is an increasing number of cholecystectomies performed for functional gallbladder disorder over the past two decades from a baseline incidence of 5% to between 20% and 25% [5]. This puts some patients in unnecessary risk of operation and anaesthetic risk and also increase burden in our health sector.

Our study demonstrates the effectiveness of cholecystectomy in patients with typical and atypical biliary pain with positive or negative HIDA Scan, which should help with selection of patients for surgery and also guide the usage of HIDA Scan in a clinical situation. In terms of efficacy of HIDA scans, we have demonstrated successful resolution of biliary pain at least 6 weeks post-operatively in patients with positive HIDA scans. This highlights the benefit of obtaining a HIDA scan pre-operatively in patients with typical biliary pain without other structural causes. As shown in Table 1, the only relatively reliable beneficial outcome from a cholecystectomy is seen in up to 85% of patients with typical biliary pain with a positive HIDA scan. In addition, 50% or more of patients with negative HIDA scans with typical, improved following cholecystectomy.

Furthermore, numerous other studies have confirmed that cholecystectomy in patients presenting with symptoms of biliary colic that meets ROME III criteria, and who have low EF's (less than 35%) on HIDA scan have a high percentage (94-100%) of resolution or significant improvement of symptoms. [6-9]

Our study is the first, in the Australian health of that evaluate both patients reported outcome, the effectiveness of a HIDA Scan, and

cholecystectomy outcome in typical and a typical biliary pain, in both positive and negative HIDA Scan patients' group.

In our opinion the best reliable way to select patient for cholecystectomy is the combination of clinical symptoms and the positive result of HIDA (EF  $< 35\%$ ).

We do acknowledge that the significance of our study would be limited by the study design (retrospective bias), recall bias (during the questionnaire phase), and sample size. There is a need for a multi-centre prospective studies to provide a better selection criterion for patients who benefit from surgery and whether cholecystectomy is a solution to normokinetic and hyperkinetic gall bladder dyskinesia.

### Conclusion

In summary, positive HIDA scans and typical biliary pain would greatly aid in the decision-making process to proceed with a cholecystectomy. With a negative scan, further clinical investigation should be carried out before proceeding to surgery in both patient's group, with typical or atypical biliary pain.

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### Previous Association

Presented in RACS 2017 Adelaide Scientific Congress

### Disclosure

Authors declare there was no conflict of interest

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