# Evaluation of Gallbladder contractility using both CCK and milk consecutively

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## Introduction:

Hepatobiliary imaging (HIDA) has an important role in the evaluation of the function and dynamics of the hepatobiliary system and the flow of bile to the gastrointestinal system. Contractility of the gallbladder is one of the functions that are uniquely evaluated using a HIDA scan. Poor contractility of the gallbladder can be the source of pain in many patients. Anatomic imaging studies like ultrasound, CT and/or MRI are usually normal in these patients.

Contractility of the gallbladder is evaluated during a HIDA scan by intravenous injection of cholecystokinin (CCK) a physiologic peptide enzyme produced in the duodenum in response to the presence of fatly meal which causes the gallbladder to contract and the sphincter of Oddi to relax, thus allowing the flow of bile from the gallbladder to the duodenum. CCK is usually administered during a HIDA scan intravenously after filling of the gallbladder with radioactive tracer to simulate the action of the endogenous CCK in contracting the gallbladder and relaxation of sphincter of Oddi. Gallbladder ejection fraction (GBEF) in response to CCK injection is calculated using special computer software program. A normal gallbladder ejection fraction is equal to or greater than 35%. Alternative to CCK injection, the patient may be administered milk as a fatty drink that should stimulate a normal gallbladder to contract when it reaches the duodenum approximately 15-20 minutes after oral administration. Thus, gallbladder contractility may be evaluated during a HIDA scan either by injecting CCK intravenously or oral administration of milk. Poor contractility of the gallbladder may result in abdominal pain usually triggered by meals. However, in many patients with abdominal pain and a decreased gallbladder contractility as evaluated by IV CCK or milk may continue to suffer from pain even after surgical removal of the gallbladder. This suggests that abnormally decreased GBEF after CCK or milk stimulation may represent false positive finding resulting in unnecessary cholecystectomies in some of the patients. There are no reports in the literature that have used both intravenous CCK stimulation and oral milk administration together in the same patient.

This study aims to combine the use of IV CCK administration followed by oral milk during a HIDA scan to further stimulate gallbladder contractility and decrease the number of false positive HIDA scans and unnecessary cholecystectomies in some patients.

**Objectives:**

- To evaluate any change in gallbladder contractility as reflected by a change in GBEF in the same patient when milk is administered orally after intravenous CCK administration during a HIDA scan.
- To evaluate the number of patients that might change from an abnormal low GBEF to a normal value.
- To estimate the average change in GBEF with the administration of milk after intravenous CCK administration.
- Follow up the outcome of the patients up to 6 months interval after the study.

**Methods:**

- A total of 50 patients will be included in this study.
- The patients will be referred to the Nuclear Radiology department by their primary physician or referring physician for a HIDA scan to evaluate gallbladder function.
- The patient will be injected with a standard dose of 4-6 mCi Tc-99m Choletec IV and dynamic blood flow images in 1 second/frame images for 1 minute followed by 60 min acquisition of sequential images of the abdomen at 1 min / frame rate.
- If gallbladder is visualized during the first 60 min of images, CCK will be administered IV at 0.02mg/Kg slowly over 3 min as per standard of care protocol.
- Additional imaging will be obtained of the abdomen for 30 min to evaluate gallbladder contractility as per standard of care protocol. The GBEF will be calculated using the usual computer analysis program.
- If the gallbladder ejection fraction is less than the normal value of 35%, the patient will have the study explained and will be consented to be a participant of this study. The patient, who agrees to participate, will drink 8oz of half and half milk. After 15-20 minutes waiting period, the patient will be imaged again with sequential static images of the abdomen at 1min/ frame for an additional 30 minutes which will conclude the study.
- The GBEF will be recalculated again after the ingestion of milk and compared to the GBEF after CCK administration.
- The patients' outcome in 6 month will be reviewed and data will be collected. In the event there are no medical records for the patient at 6 months, the patient may be contacted for a follow up call by the PI or his/her designee.

**Inclusion Criteria:**

- All patients referred for a HIDA scan for evaluation of gallbladder function.
- Patients with gallbladder ejection fraction of less than 35% after administration of CCK.
- Patients who are able to lie flat on the imaging table for an additional 30 min. of imaging after the standard of care 1.5 hour HIDA scan.

**Exclusion Criteria:**

- Patient allergic to milk or dairy products.
- Non visualized Gall bladder.
- Patients below age of 18.

**Data Collection:**

A list of enrolled subjects will be compiled electronically. Each subject will be given a coded ID. The list of name, MR# and coded ID will be kept separate from the database, in a password-protected computer and/or locked room. The list will be used to correlate the image interpretation with the follow-up clinical information.

The database will contain the coded ID, as well as:

- Patient demographics including gender, age and age at onset of abdominal pain.
- Clinical information regarding the nature and frequency of abdominal pain.
- HIDA with CCK image interpretation findings.
- HIDA with milk interpretation findings.
- Summary of findings of other imaging modalities.
- Clinical follow-up parameters: Patients' outcome data regarding relief of symptoms, any surgical intervention, medical intervention or no intervention.

The electronic database will be transferred between team members via secure share software approved by UT.

**Data Analysis:**

The study results will be analyzed using descriptive statistics. The change in abnormal GBEF between CCK alone versus CCK with milk will be evaluated. Finally, the number of studies that were changed from abnormal to normal will be summarized.

**Outcomes:**

There are two possible groups of patients after ingestion of milk and the addition of 30 minutes of imaging. The first group will have an abnormal study which will remain abnormal after the milk and the second group with an abnormal study with CCK alone which will become normal after administering milk. Both results with CCK alone and after milk will be reported. The follow up data will clarify if there were less cholecystectomies performed in the second group of patients compared to the first one and if the patients in the second group continued to have the pain or not. Also the follow up will help in evaluating if there were other causes to the pain or if it responded to medical therapy. This will be compared with the incidence of cholecystectomies in the first group and resolution of pain and other symptoms if they had cholecystectomies or medically treated.

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