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The future of gallstone treatment in Australia

Chris Hagan

Hagan & Co, Solicitors, Australia

REVIEW

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Corresponding Author:
C.C. Hagan
PO Box 28 North Sydney, NSW 2060
Email: hagan@haganv.com

ABSTRACT

Background
The standard treatment for gallstones to avoid risk of gallbladder attacks or other complications is to remove the gallbladder. The removal of gallstones is deemed futile because gallstones just return (if there is no change in diet).

Aims
To remove the gallstones and not the gallbladder to avoid possible side effects or ongoing discomfort from gallbladder removal.

Methods
An alternative surgical procedure exists to just remove the gallstones which have been proven clinically which, despite being of a higher degree of difficulty, can produce superior results if it is combined with a strict change in diet by the patient to avoid the return of gallstones after their removal.

Results
A previous paper concludes: 'Gallstones were completely cleared in 66 (81 percent) patients and complete symptom relief was obtained in more than 95 percent of these patients. There were no deaths or serious complications.'

Conclusion
A viable pathway to removal of gallstones using a modified cholecystoscope exists rather than removal of the gallbladder providing that a strict diet change (possibly aided by medication) is implemented to avoid recurrence of gallstones.

Key Words
Gallstone extraction, gallbladder removal, cholecystoscope, ERCP, endoscopy, cannulation, bile acid, spiral valves of Heister, cystic duct, catherization, laser

What this review adds:

1. What is known about this subject?
The standard treatment for gallstones is laparoscopic removal of the gallbladder. Endoscopic techniques exist to remove stones for high risk or 'special needs' patients.

2. What new information is offered in this review?
A combination of previous clinical experience with removing gallstones, dietary changes and advances in technology may prompt removal of gallstones rather than gallbladders.

3. What are the implications for research, policy, or practice?
Advances in Cholecystoscope technology could make removal of stones in the gallbladder viable as an alternative to gallbladder removal.

Introduction

As the son of a senior surgeon and a solicitor of 38 years standing who has handled many medico legal cases, I have always taken a keen interest in new medical treatments (my father – now deceased- devoted most of his life to cancer research and I am trying to continue his work).

I suffered 2 gallbladder attacks over 2 years ago – an ambulance was called for one – it felt like a heart attack. Since that time I was advised there was a 50%- 50% chance of re occurrence so I could have my gallbladder out – or not. I decided to keep my gallbladder and research the matter. The first query I had was "Why can't the gallstones be just removed?" The answer was – "it is best to remove the gallbladder because the stones would probably just re occur. There is no standard treatment to remove stones as

they are larger than the gallbladder duct" I learned this was the standard medical response. I then read a number of British Medical Journal articles and 4 books on gallbladder treatment. These 4 books are *Overcoming Gallstones,*[1] *Save your Gall Bladder Naturally,*[2] *Keep your Gall Bladder*[3] and *The Gall Bladder Survival Guide*.[4] I have also consulted with 3 medical practitioners in Sydney including a surgeon (a Gastrointestinal laparoscopic and Bariatric specialist) who removes gallbladders, a gastroenterologist and a general practitioner to hear their views.

Whilst these books by medical practitioners might, at first sight, be 'populist' medicine, I believe they do raise a valid mainstream medical practice issue for review – Bernal[4] refers to 750,000 gallbladders being removed every year in the US so if there is an issue it is a big issue. The results of my research (which refer to existing solutions used in clinical practice overseas) are as follows:

1. If the gallbladder has insufficient function left its removal causes minimal side effects.

2. If the gallbladder has function then side effects after removal in some people can be uncomfortable for unknown duration – possible conditions can occur such as diarrhoea which can be treated , sometimes conditions can re occur , sometimes irritable bowel syndrome can occur – again nothing is certain except that the removal of the gallbladder may not be the end of discomfort – indeed the gallbladder – whilst we can live without it – does aid digestion in a complex interplay between the liver, pancreas, gallbladder in their servicing of the digestive tract.

3. Stones outside the gallbladder can be removed by ERCP (Endoscopic Retrograde Cholangio-Pancreatography) where a mechanical tube is fed down the mouth and eventually navigates to the place where the stone is caught – usually a bile duct. If the duct is too narrow, a stent is placed to widen the duct and the tube can then reach the stone. A good example is Spy Glass ERCP – e.g., on 22 July 2015 ERCP Spyglass technology was introduced to Liverpool Hospital's endoscopy unit in Sydney. A laser can destroy the stone or other removal methods can occur.
A video of this ERCP procedure is noted in note.[5]

4. The wisdom common in all 4 books is that the formation of gallstones can be inhibited by a change in diet. For instance, common stones would be cholesterol stones which would not precipitate as often if the patient's diet reduced foods producing cholesterol. Certain other dietary changes help e.g., apple juice (malic acid) softens stones.

5. A further treatment , referred to in a British Medical Journal article *Gallstone Dissolving*[6] is the taking of 'Gallstone Dissolving Agents' e.g., Chenodeoxcholic Acid or Ursodeoxycholic acid which are intended to reduce the cholesterol in the bile and thus reduce precipitation or enlargement of stones. In perhaps 25% of patients, stones can disappear and with the dietary changes stones should not re appear. Testing success is recommended by successive cholecystograms.

6. Thus, the question arises as to whether ERCP instruments such as the Spyglass can be used to enter the gallbladder and destroy the stones with laser. The cystic duct to enter the gallbladder contains the Spiral Valves of Heister where the presence of the spiral folds, in combination with the tortuosity of the cystic duct, makes endoscopic cannulation and catheterization of the cystic duct extremely difficult. Also, the valves of Heister are susceptible to lacerations and *were* a serious obstacle to the surgical canalization. Thanks to newer technologies, nowadays this procedure is possible.[7] "Cannulation of the cystic duct and gallbladder", where it was successful in 9 out of 12 patients.[7] (my italics). There is also video of the gall- bladder being stented.[8]

7. In a letter to The Lancet[9] Peter Sipos of Semmelweis Medical University, Hungary writes: "Oral bile acid dissolution therapy, contact solvent dissolution, or mechanical extraction through a catheter placed into the gallbladder (percutaneously or endoscopically), and fragmentation by shock-wave lithotripsy combined with bile- acid dissolution therapy have been developed and used in selected populations of patients" (p76 ibid). Stone clearances were 95% for smaller stones and 60% for larger stones.

8. Parallel to this progress, a new instrument and technique has been developed in China described in a paper appearing in the journal Review of Scientific Instruments in 2012 which is referred to in the article below (Review of Scientific Instruments is a monthly peer-reviewed scientific journal published by the American Institute of Physics).

Design and application of a new series of gallbladder endoscopes that facilitate gallstone removal without gallbladder excision by Tie Qiao[10];
The new 'gun like' cholecystoscope instrument treated 120 patients aged 18–70 with good success – although no precise details of trials or issues appears in the article – the instrument is said to be as safe as and better than the Olympus CHF –P20 cholecystoscope.

There is a video purporting to be of a gallstone removal operation but there is no audio or written description of the procedure being carried out.[11]

9. In a paper: *Gallstone removal with a modified cholecystoscope: an alternative to cholecystectomy in the high-risk patient*.[12] the following extracts from the Headnote indicate a viable pathway to removal of gallstones using a modified cholecystoscope:

Conclusions

Percutaneous cholecystolithotomy under regional anaesthesia is an effective means of gallstone treatment in selected high-risk patients.

The primary risk seems to be one of puncture or damage to the Spiral Valves of Heister in the cystic duct. The papers involving use of cholecystoscopes do not refer to use of stents to stabilise and protect the cystic duct. (The Chinese method uses water to expand the gallbladder but preparation of the duct was not mentioned).

In conclusion, it seems that technical advances exist in the world which are enough to warrant a review to determine whether there have been sufficient advances in technology and techniques to justify a change to the standard advice given in Australia today namely "Just remove the gallbladder to alleviate discomfort and further risk* from gallstones". (*risks include contracting an infected gallbladder which can produce acute gallbladder attacks, stones migrating to pancreas, or even more serious conditions providing a clinical basis to remove gallbladders for 'risk minimization' apart from the mere discomfort of pain or feeling sickly after meals etc). If the gallstones can be removed safely and diet changed (possibly aided by medication referred to in paragraph 5 above) to prevent gallstones returning then, to avoid risk of discomfort or worse conditions from having no gallbladder, a change in clinical practice is warranted because this is a clear advantage over the risks inherent in removing a gallbladder (despite the higher degree of difficulty involved in removing stones rather than the gallbladder).

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PEER REVIEW

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