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SPECIAL REPORT

# Appropriateness of cholecystectomy in the United Kingdom – a consensus panel approach

E A Scott, N Black

**Abstract**

**A consensus development approach was used to assess the extent to which doctors in the UK agreed about the appropriate indications for cholecystectomy. Two panels, one composed entirely of surgeons and one containing a mix of relevant specialists, were asked to rate a series of possible indications. A consensus was achieved for 61% (surgical panel) and 67% (mixed panel) of indications considered. The surgical panel considered more indications as being appropriate for cholecystectomy (29% *v* 13%) and fewer indications as being inappropriate (27% *v* 50%) than the mixed panel. For between one third and a half of all indications, the panels were unable to reach agreement, partly as a result of differences in views as to the role of endoscopic sphincterotomy.**

There are wide variations in the rates of cholecystectomy, both within and between countries.[1-3] Although geographic and ethnic differences in the prevalence of gall stones exist, these are insufficient to account for all the variations in surgical rates.[4,5] Factors affecting the supply of surgical services also contribute, including the availability of surgeons, theatres, and beds and the clinical judgement of surgeons.

A review of the published reports on appropriate indications for cholecystectomy shows that while agreement exists for some conditions, considerable disagreement persists for others. It is generally accepted that cholecystectomy is the treatment of choice for acute cholecystitis, although there is some divergence of views as to the optimum time for surgery after the acute episode. There is less agreement about the indications in chronic cholecystitis,[6] partly because of diagnostic difficulties and partly because of the availability of alternative treatments such as oral dissolution, lithotripsy, and contact dissolution.[7]

The management of the patient with stones in the biliary tract has changed considerably recently with the introduction of endoscopic sphincterotomy as a definitive alternative.[8-10] The long term outcome of patients treated solely in this way, however, remains unclear.[11,12] Endoscopic sphincterotomy has also been recommended as an alternative to cholecystectomy in patients with acute pancreatitis attributable to gall stones.[13]

Cholecystectomy is also recommended for other, less common conditions such as carcinoma of the gall bladder and porcelain gall bladder. Finally, while earlier work suggested that cholecystectomy was indicated for asymptomatic gall stones,[14,15] more recent studies have cast doubt on such practice.[16-19]

Similar variations in clinical opinion in the USA have been examined as part of the Rand/UCLA Health Services Utilization Study.[20] This inolved providing a panel of clinicians with an extensive review of the published reports on the effectiveness of cholecystectomy and then asking each panellist to rate the appropriateness of intervention in a series of hypothetical circumstances. These were then used as the basis for the subsequent panel discussions at which differences of opinions were explored and consensus sought.

In view of the difference in cholecystectomy rates between the USA and Israel, researchers at the Unit of Epidemiology and Evaluation of Health Services, University of the Negev decided to repeat the study so as to explore the contribution that variations in clinical judgement made. Given the even greater difference in the surgical rate between the USA and the UK, it was decided to repeat the study in the UK. The principal aim was to determine the appropriate indications for cholecystectomy in the UK and the extent to which clinicians agree about these indications. It was not the intention of this study to consider the much wider issue of the appropriate treatment of gall bladder disease. A second aim was to compare the views of UK clinicians with those of US and Israeli doctors. This will be reported in another paper.

## Method

The review of the published reports on cholecystectomy carried out originally in the USA and later modified by Fraser and Pilpel (personal communication) in Israel was updated to include reports published up to February 1989. Two hundred and ninety articles were reviewed, encompassing reports on the prevalence of gall stones, variations in surgical rates, indications for cholecystectomy, different imaging modalities, alternative treatment options, short and long term complications, and long term outcomes.

Two panels of practising clinicians were established. One was similar in composition to those in the USA and Israel, consisting of three

**Health Services Research Unit, Department of Public Health and Policy, London School of Hygiene and Tropical Medicine**
E A Scott
N Black

Correspondence to:
Dr E A Scott, Health Services Research Unit, Department of Public Health and Policy, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT.

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TABLE I *Medical indications for cholecystectomy that were considered*

| | |
|---|---|
| (A) | Asymptomatic. |
| (B) | Vague symptoms such as flatulence, heartburn, etc. |
| (C) | Biliary colic, both a single attack and multiple attacks. |
| (D) | Acute cholecystitis: |
| | Suspected. |
| | Confirmed, at least two months ago. |
| (E) | Asymptomatic porcelain gall bladder. |
| (F) | Silent onset of jaundice, in a patient in whom medical and therapeutic causes have been excluded. |
| (G) | Acute and acute recurrent pancreatitis, with and without a history of significant alcohol consumption. |
| (H) | Incidental cholecystectomy at the time of abdominal surgery for other reasons, excluding vascular surgery. |
| (I) | Long term total parenteral nutrition. |
| (J) | Asymptomatic cholecystenteric fistula. |

gastroenterologists, two general physicians, two surgeons, one general practitioner, and one radiologist. The second panel was composed of nine general surgeons. Panellists represented a variety of backgrounds – teaching and non-teaching hospitals, urban and rural districts – so as to reflect the mix of clinicians currently involved in deciding on the use of cholecystectomy. Each panellist was given a copy of the review of published reports and a copy of the possible indications for cholecystectomy.

Indications were first categorised according to their medical history and covered all clinically important indications for cholecystectomy (Table I). Categories of medical history were subdivided according to pathological findings: stones in the gall bladder (absent, crystals in the bile, multiple, single less than 2·5 cm and larger than 2·5 cm); chronic acalculous cholecystitis; stones in the common bile duct in patients aged 70 years or less and aged 71 years or more; non-functioning gall bladder; and dilated common bile duct. Finally, the influence of comorbidity was taken into account by considering patients with: no comorbidity; low comorbidity such as mild hypertension; medium comorbidity such as insulin dependant diabetes; and high comorbidity such as recent myocardial infarction. Overall, there were 70 subcategories of indications each with four levels of comorbidity, making a total of 272 indications to be assessed (no and low comorbidity were not compatible with long term parenteral nutrition).

Panellists were asked to record the appropriateness of cholecystectomy for each of the 272 indications. This was done by marking a scale of 1 to 9 in which 1 indicated a patient in whom the panellist felt that the risks of surgery outweighed any benefits, 5 meant a patient in whom the estimated risks and benefits of surgery were equal, and 9 meant a patient for whom the panellist would always strongly recommend surgery, as the benefits clearly outweighed any risks. Panellists were asked to consider the appropriateness of cholecystectomy only. If they felt that another form of treatment would be more appropriate as a first line therapy, cholecystectomy was to be rated as inappropriate.

The panellists then met for half a day. Each panellist was given a second copy of the 272 indications, which showed the distribution of the initial ratings of all the participants, plus his own rating. Indications for cholecystectomy were discussed in turn. Most of the discussion centred on those indications in which there was considerable disagreement. Cases where the risks were seen as roughly equal to the benefits were also discussed. Panellists were given the opportunity to reconsider their appropriateness rating and alter it if they so wished. This final rating was used in the analysis.

For each indication, the appropriateness of cholecystectomy was assessed along with the extent to which panel members agreed or disagreed. Appropriateness was assessed using the median of the panellists' ratings. The mean absolute deviation from the median was used as an overall measure of dispersion. The level of agreement and disagreement of panellists was classified according to the dispersion of individual ratings. To eliminate any undue influence of outliers, the data were analysed after first discarding the two ratings furthest from the median. Panellists were defined as being in agreement if their ratings fell within a three point range – inappropriate indication for cholecystectomy (1–3), appropriate (7–9), and equivocal (2–8). Disagreement was examined in a similar way. The panellists were deemed to disagree if one rating was in the 1–3 range and one rating in the 7–9 range. Panel ratings that met neither the agreement nor disagreement definitions were designated partial agreement.

## Results

### EXTENT OF CONSENSUS

The data are restricted to those panellists who attended the discussion (six for the mixed panel and eight for the surgical panel). The initial ratings of the missing panellists were similar to those who attended the discussion. In view of the smaller size of the mixed panel, only one rather than two outliers were eliminated when testing for consensus.

Table II compares the results of the initial panel ratings and the final ratings after the discussion. Overall, the surgical panel (mean= 5·0) were more likely to consider cholecystectomy appropriate than were the mixed panel (mean=3·2). The mixed panel was slightly more likely to rerate their scores than the surgical panel (15·9% compared with 13·3% of ratings) and the changes they made were more substantial. The effect on the mean of the median score for the mixed panel was to reduce it by 0·41 compared with a reduction of only 0·06 for the surgical panel.

Table III shows the outcome of the two panels. The two panels reached similar levels of agreement for the indications (67% for the mixed and 61% for the surgical panel). The most striking differences were that the surgical panel con-

TABLE II *Initial and final ratings of mixed and surgical panels*

| | *Mixed panel* | | *Surgical panel* | |
|---|---|---|---|---|
| | *Initial* | *Final* | *Initial* | *Final* |
| Mean of medians | 3·6 | 3·2 | 5·1 | 5·0 |
| Mean absolute deviation from median | 1·25 | 0·95 | 1·16 | 1·02 |
| Total no of ratings | 1632 | 1632 | 2038 | 2038 |
| Total no of times panellists changed rating | – | 260 | – | 271 |
| Mean change for those ratings altered | – | 3·8 | – | 2·2 |
| Mean change | – | −0·41 | – | −0·06 |

TABLE III *Comparison of final ratings of indications of two panels (%)*

| | *Mixed panel* | *Surgical panel* |
|---|---|---|
| Agreement: | 183 (67) | 165 (61) |
| Appropriate | 34 (13) | 79 (29) |
| Equivocal | 12 (4) | 13 (5) |
| Inappropriate | 137 (50) | 73 (27) |
| Partial agreement | 48 (18) | 85 (31) |
| Disagreement | 41 (15) | 22 (8) |

sidered 29% of indications were appropriate and 27% inappropriate compared with the mixed panel which considered only 13% appropriate and 50% inappropriate. The level of disagreement also differed between the panels (15% and 8%).

The mixed panel achieved significantly more agreement for indications in which there was a high level of comorbidity than for those with no, low, or medium comorbidity. No such pattern emerged from the surgical panel.

APPROPRIATENESS OF INDICATIONS

Tables IV and V shows the shows the indications for which cholecystectomy was felt to be appropriate. Broadly speaking, surgery was felt to be appropriate when a patient with no or low comorbidity had definite symptoms, as distinct from vague symptoms, and when gall stones were definitely visualised. The principal difference between the panels was over stones in the common bile duct: the surgical panel felt cholecystectomy was an appropriate treatment whereas the mixed panel did not. A similar difference in opinion arose over several other less common indications. The surgical panel would operate for pancreatitis in the presence of a history of high alcohol consumption; a porcelain gall bladder; and as an incidental procedure if there was a history of symptoms compatible with gall bladder disease. In addition, for suspected cholecystitis or acute recurrent pancreatitis, the surgical panel would operate even if there was a medium level of comorbidity.

In contrast, surgery was felt to be inappropriate in patients with high comorbidity who were asymptomatic or had vague symptoms, or who did not have demonstrable gall stones (Tables VI and VII). In addition, patients undergoing long term total parenteral nutrition and those with an asymptomatic cholecystenteric fistula were felt to be inappropriate candidates for cholecystectomy. The principal differences between the two panels were that unlike the mixed panel, the surgical panel did not rule out the use of cholecystectomy in all patients who were asymptomatic, in those who only had vague symptoms, or those suffering from a high level of comorbidity. Also, in line with the findings reported above, the surgical panel felt that cholecystectomy was sometimes useful if a stone was present in the common bile duct.

For all other indications, the panels either failed to achieve consensus (partial agreement or disagreement), or agreed that the risks and benefits of surgery were balanced (equivocal).

TABLE IV *Appropriate indications for cholecystectomy – mixed panel*

| *Indication* | *Investigative findings* | *Comorbidity* |
|---|---|---|
| Vague symptoms | Non-functioning GB | No |
| Multiple attacks biliary colic | Stones in GB only or non-functioning GB | No+low |
| Confirmed acute cholecystitis | Stone(s) in GB or CBD or non-functioning GB | No+low |
| Suspected acute cholecystitis | Stone(s) in GB | No+low |
| Acute pancreatitis – no significant alcohol intakes | Stone(s) in GB | No+low |
| Acute recurrent pancreatitis – no significant alcohol intake | Stone(s) in GB | No |

GB=gall bladder; CBD=common bile duct.

TABLE V *Appropriate indications for cholecystectomy – surgical panel*

| *Indication* | *Investigative findings* | *Comorbidity* |
|---|---|---|
| Vague symptoms | Stone in CBD | No+low |
| Single attack of biliary colic | Stone(s) in GB or CBD or non-functioning GB | No+low |
| Multiple attacks biliary colic | Stone(s) in GB or CBD or non-functioning GB | No+low |
| Confirmed acute cholecystitis | Stone(s) in GB or CBD or non-functioning GB | No+low |
| Suspected acute cholecystitis | Stone(s) in GB or CBD | No+low |
| Porcelain gall bladder | | No |
| Silent onset of jaundice | Stone in CBD or dilated CBD | No+low |
| Acute pancreatitis with and without appreciable alcohol intake | Stone(s) in GB or CBD | No+low |
| Acute recurrent pancreatitis – no significant alcohol intake | Stones in GB or CBD | No, low+med |
| Acute recurrent pancreatitis – appreciable alcohol intake | Stone in CBD | No+low |
| Incidental cholecystectomy+ compatable symptoms | | No |

CBD=common bile duct; GB=gall bladder.

## Discussion

The principal purpose of formal consensus methods is to define the level of agreement on controversial subjects. These methods have been employed in health and medical issues in several countries since the 1960s. Some of the disadvantages and limitations of these methods become apparent during this study. While the initial ratings of the indications presented few problems, several participants reported they were aware that their criteria for determining appropriateness changed during the process. This was partly related to earlier questions influencing their response to later ones.

The method did allow participants to alter their ratings during the panel meeting, however, so it is hoped that such biases were overcome in the final ratings.

The extent to which panellists' views were influenced by the review of the published reports was unclear. Some participants had read the review and claimed to have referred to it while completing the questionnaires. Others had clearly made little or no use of it. All the panellists, however, accepted the review as a balanced and comprehensive account of the reports.

Another problem panellists encountered was ambiguity in the brief descriptions of medical histories, pathologies, and comorbidities with which they were presented. For example, the meaning of 'chronic cholecystitis but no gall stones' was unclear, as was the mechanism by which such a diagnosis could be arrived at in clinical practice. It was felt that more information about the precise abnormality and any risk of malignancy was needed before a decision on the appropriateness of cholecystectomy could be made. The categorisation of comorbidity gave rise to similar misgivings. For example, the operative risks of a recent myocardial infarction and

TABLE VI *Inappropriate indications for cholecystectomy – mixed panel*

| *Indication* | *Investigative findings* | *Comorbidity* |
|---|---|---|
| Asymptomatic | Any | All |
| Vague symptoms | Chronic cholecystitis or stone in CBD | All |
| | Stone(s) in GB or non-functioning GB | Low+med+high |
| Single attack – biliary colic | Any | High |
| Multiple attacks – biliary colic | Stone in CBD | Med+high |
| | Stone(s) in GB, chronic cholecystitis or non-functioning GB | High |
| Confirmed acute cholecystitis | Any | High |
| Suspected acute cholecystitis | Normal GB | All |
| | GB disease but no stones | Med+high |
| | Stone(s) in GB or CBD | High |
| Porcelain gall bladder | | High |
| Silent onset of jaundice | No stones | All |
| | Stone(s) either in CBD or GB | All |
| | Stone in CBD and GB | Med+high |
| Acute pancreatitis – no appreciable alcohol intake | No stones | All |
| | Stones in CBD | Med+high |
| Acute pancreatitis – appreciable alcohol intake | No stones | All |
| | Stone(s) in CBD or GB | High |
| Acute recurrent pancreatitis – no appreciable alcohol intake | No stones | All |
| | Stone(s) in CBD or GB | High |
| Acute recurrent pancreatitis – appreciable alcohol intake | No stones | All |
| | Stone in CBD | Med+high |
| | Stone(s) in GB | High |
| Incidental cholecystectomy – asymptomatic | | Med+high |
| Long term TPN | Symptoms and/or stones | Med+high |
| | Incidental | Med+high |
| Asymptomatic cholecystenteric fistula | | All |

CBD=common bile duct; GB=gall bladder; TPN=total parenteral nutrition.

TABLE VII *Inappropriate indications for cholecystectomy – surgical panel*

| *Indication* | *Investigative findings* | *Comorbidity* |
|---|---|---|
| Asymptomatic | Single stone in GB | All |
| | Multiple stones in GB, chronic acalculous cholecystitis, or stone in CBD | Med/high |
| Vague symptoms | Stone in GB or chronic cholecystitis | Med+high |
| | Any | High |
| Single attack – biliary colic | Stone(s) in GB or non-functioning GB | High |
| Suspected acute cholecystitis | No stones | All |
| | Stones but no complications | High |
| Porcelain gallbladder | | High |
| Silent onset of jaundice | No stones | All |
| | Stone(s) in GB only | Low+med |
| | Stone in CBD-only | High |
| Acute pancreatitis – with+without significant alcohol | No stones | All |
| | Stones in GB only | High |
| Acute recurrent pancreatitis – no appreciable alcohol intake | No stones | Med+high |
| Acute recurrent pancreatitis – appreciable alcohol intake | No stones | All |
| | Stones in GB only | High |
| Incidental cholecystectomy – asymptomatic | | Med+high |
| Long term TPN | Symptoms only | Med+high |
| | Stones only | Med+high |
| | Symptoms+stones | High |
| | Incidental findings | Med+high |
| Asymptomatic cholecystenteric fistula | | Med+high |

GB=gall bladder; CBD=common bile duct; TPN=total parenteral nutrition.

of a lethal carcinoma were felt to be very different, yet both were classified as high comorbidity. It was felt that definitions of comorbidity in terms of life expectancy would be more useful.

Disagreement and some confusion arose over the possible sequence of events. Panellists were unclear whether they were to consider the appropriateness of cholecystectomy as a first line treatment only or as a secondary treatment should some other intervention, such as endoscopic sphincterotomy, fail. Panellists were advised that they were to consider the appropriateness of cholcystectomy as a first use treatment only. This played an important part in the differences observed between the two panels: the mixed panel was less inclined to approve of cholecystectomy, perferring endoscopic intervention as a first procedure whereas the surgical panel was more inclined to prefer cholecystectomy as a first and definitive procedure.

Finally, there were two other interpretive factors that some panellists felt should have been taken into account – patient pressure on surgeons, encouraging them to operate; and the possible medicolegal consequences of a second acute episode in a patient treated conservatively.

Both panels were much more likely to rate cholecystectomy as appropriate in patients with lower degrees of comorbidity. The surgical panel rated cholecystectomy as always appropriate in patients with medium comorbidity only once; neither panel rated cholecystectomy appropriate in patients with high comorbidity.

Both panels rated cholecystectomy as appropriate in patients who have had multiple attacks of biliary colic with stones in the gall bladder; the mixed panel also rated cholecystectomy as appropriate in patients with a non-functioning gall bladder, the surgical panel in patients with stones in the common bile duct. Similarly, cholecystectomy was felt by both panels to be appropriate in patients with acute cholecystitis, gall stones in the gall bladder and no or low comorbidity.

The surgical panel were much more likely to recommend cholecystectomy in patients with pancreatitis and visualised gall stones, despite a history of significant alcohol consumption. The mixed panel felt cholecystectomy was only appropriate in patients with acute pancreatitis if there were stones in the gall bladder, no alcohol history, and no or low comorbidity.

Overall, the mixed panel designated 50% of the indications inappropriate whereas the surgical panel felt that this was true for only 27%. Thus, the mixed panel would be less inclined to recommend cholecystectomy than the surgical panel. The principal reasons for these differences were that the surgeons felt cholecystectomy was appropriate even if patients had only vague symptoms or if there were stones in the common bile duct (Table V), whereas the mixed panel felt these indications were inappropriate (Table VI). There were also differences of opinion regarding less commonly occurring indications such as porcelain gall bladder.

In only 4% of indications did the panels feel that the risks and benefits of surgery were balanced. These indications require further scientific study to establish whether or not surgery is justified. That leaves many indications for which the panels failed to achieve consensus (33% for the mixed panel and 39% for the surgical panel). In many instances the panels expressed profound disagreement (mixed panel 15%; surgical panel 8%). The importance of this lack of consensus will of course depend on the frequency of occurrence of these particular indications. If they are rare events, then the extent of disagreement will have few implications for the management of clinical practice. It is therefore necessary to relate the panel's findings to the actual use of cholecystectomy in practice. Such a study using retrospective case notes, is underway.

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