



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Ultrasound for monitoring of gallbladder polyps
Topic exploration report number:	TER239

Introduction and aims

Health Technology Wales researchers searched for evidence on the use of ultrasound for monitoring gallbladder polyps. It is estimated that around 5% of the population have gallbladder polyps which are small growths that protrude from the organ lining and these are sometimes identified during routine abdominal ultrasound. While a large majority of these are benign, a small number are malignant and can cause gallbladder cancer. Where gallbladder cancer is suspected or there relevant risk factors are present, surgery is recommended. However, in some cases a decision will be needed on whether to monitor polyps. Ultrasound is one tool that can be used to do this but there is a lack of consensus regarding the optimal duration and frequency of follow up.

Summary of evidence

Guidance

Joint guidance on management and follow-up of gallbladder polyps from European and international societies has been published (Wiles et al. 2017). Based on a Delphi consultation with experts, the joint guidance recommends that people with gallbladder polyps of between 6 and 9mm and no risk factors should receive ultrasound monitoring at 6 months, 1 year, and then yearly for 5 years. For those with a polyp of 5mm or less, monitoring is recommended at 1, 3 and 5 years. For both groups, surgery is advised if polyp growth of 2mm or more occurs and discontinuation of monitoring is recommended if the polyp disappears. However, the guidelines highlight that the management of gallbladder polyps is contentious and that these recommendations rely on low and moderate quality evidence.

The NICE guideline on recognition and referral for suspected cancer (NG12) makes brief reference to gallbladder cancer and recommends that ultrasound is considered for people with an upper abdominal mass. However, it does not make recommendations for ongoing monitoring of polyps.

Clinical Evidence

We identified one systematic review that examined the malignancy of gallbladder polyps and included 12 primary studies (Elmasry et al. 2016). Pooled results suggest that only 0.57% of polyps were malignant even when polyps over 10mm in size were considered. The reporting of malignancy by size is limited in this review but they state only one of 31 polyps under 6mm was malignant. It is unclear if this is due to the inclusion of few small polyps or true rates of malignancy being low in this group.

The topic proposer provided another large-scale study published last year that also suggested few polyps are malignant (Szpakowski et al. 2020). For polyps sized between 6 and 10mm, gallbladder cancer had a rate of only 4.5 per 100,000 person years at one year follow up, increasing to 6.6 per 100,000 person years at five year follow up. For polyps under 6mm, no cases of gallbladder cancer were identified within 5 years of polyp discovery.

Economic Evidence

The topic proposer provided two economic evaluations based on an observational cohort of patients with gallbladder polyps in the UK (Cairns et al. 2012; Patel et al. 2019).

The more recent study used a cohort of patients, recruited from Addenbrooke's Hospital Cambridge, whose polyps were identified during ultrasound and then were or were not followed up with subsequent monitoring (Patel et al. 2019). The study suggests that monitoring led to identification of pre-malignant or malignant pathology at a rate of 12 per 1000 polyps surveyed. They then made calculations on the cost of treating cancer that could be avoided by surgical intervention and suggest savings of over £200,000 per 1000 polyps surveyed. An earlier study reported similar findings with another cohort of patients recruited from Leicester who had or had not received follow up monitoring after identification of polyps (Cairns et al. 2012). They report that surveillance could prevent 5.4 gallbladder cancers per 1000 individuals and would lead to cost savings of £130,000 per year.

Areas of uncertainty

There appears to be substantial conflict between primary and secondary studies on the rate of malignancy of gallbladder polyps with Elmasry et al. (2016) and Szpakowski et al. (2020) suggesting a limited role for monitoring and economic studies suggesting higher rate of malignant polyps that supports the use of monitoring (Cairns et al. 2012; Patel et al. 2019). A more comprehensive review would be needed to assess potential reasons for this conflict.

The studies included here rely on observational evidence and we found no interventional studies that assigned patients to differing monitoring schedules in a prospective way.

For the economic evidence, neither study used a modelling approach nor considered quality of life in their analyses. Both studies also focused most on monitoring vs. no monitoring as opposed to different monitoring schedules. There may be benefit to examining this further.

Conclusions

Guidelines on monitoring gallbladder polyps with ultrasound are available. However, the guidelines acknowledge monitoring is contentious and relies on low to moderate quality evidence. The studies identified for this TER have conflicting findings on the rate of malignancy from polyps and on whether monitoring presents value. The reasons for this require further review.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant guidance or advice from this source
Health Technology Assessment Group	Health Technology Assessment Group publications were not available online at the time of the search
Health Information and Quality Authority	We did not identify any relevant guidance or advice from this source
EUnetHTA	We did not identify any relevant guidance or advice from this source
International HTA Database	We did not identify any relevant guidance or advice from this source
UK guidelines and guidance	
SIGN	We did not identify any relevant guidance or advice from this source
NICE	NICE guideline [NG12] Suspected cancer: recognition and referral. Published date: 23 June 2015. https://www.nice.org.uk/guidance/ng12
Secondary literature and economic evaluations	
Cochrane library	We did not identify any secondary literature from this source
Medline	Elmasry et al. (2016). The risk of malignancy in ultrasound detected gallbladder polyps: A systematic review. <i>International Journal of Surgery</i> , 33, 28-35. https://doi.org/10.1016/j.ijso.2016.07.061
Ongoing primary or secondary research	
PROSPERO database	We did not identify any ongoing systematic reviews
Other	
Provided by the topic proposer	<p>Cairns et al. (2012). Risk and Cost-effectiveness of Surveillance Followed by Cholecystectomy for Gallbladder Polyps. <i>Archives of Surgery</i>, 147, 1078-1083. https://doi:10.1001/archsurg.2012.1948</p> <p>Patel et al. (2019). Five year experience of gallbladder polyp surveillance and cost effective analysis against new European consensus guidelines. <i>HPB</i>, 21, 636-642. https://doi.org/10.1016/j.hpb.2018.10.008</p> <p>Szpakowski et al. (2020). Outcomes of Gallbladder Polyps and Their Association With Gallbladder Cancer in a 20-Year Cohort. <i>JAMA Network Open</i>, 3, e205143. https://doi.org/10.1001/jamanetworkopen.2020.5143</p> <p>Wiles et al. (2017). Management and follow-up of gallbladder polyps. Joint guidelines between the European Society of Gastrointestinal and Abdominal Radiology (ESGAR), European Association for Endoscopic Surgery and other Interventional Techniques (EAES), International Society of Digestive Surgery - European Federation (EFISDS) and European Society of Gastrointestinal Endoscopy (ESGE). <i>European Radiology</i>, 27, 3856-3866. https://doi.org/10.1007/s00330-017-4742-y</p>

Date of search:

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Concepts used:

gallbladder, gastrointestinal, polyps, cancer, ultrasound, monitoring