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#### Review

# The risk of malignancy in ultrasound detected gallbladder polyps: A systematic review\*



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#### HIGHLIGHTS

- The potential malignant risk of gallbladder polyps (GBPs) is low, but missing gallbladder cancer is potentially catastrophic.
- A cholecystectomy should be considered in any patient with a GBP of size of 10 mm or greater.
- For polyps of less than 10 mm, follow-up with Ultrasound imaging should be carried out until the stability of a GBP is firmly established.
- Where there is uncertainty, the patients should be managed within a recognised hepatobiliary centre.

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#### ABSTRACT

Introduction: Gallbladder polyps (GBPs) are a common incidental finding on ultrasound (US) examination. The malignant potential of GBPs is debated, and there is limited guidance on surveillance. This systematic review sought to assess the natural history of ultrasonographically diagnosed GBPs and their malignant potential.

Methods: The keywords: "Gallbladder" AND ("polyp" OR "polypoid lesion") were used to conduct a search in four reference libraries to identify studies which examined the natural history of GBPs diagnosed by US. Twelve studies were eligible for inclusion in this review.

Results: Of the 5482 GBPs reported, malignant GBPs had an incidence of just 0.57%. True GBPs had an incidence of 0.60%. Sixty four patients of adenomatous and malignant polyps were reported. Only in one patient was a malignant GBP reported to be <6mm. Risk factors associated with increased risk of malignancy were GBP >6mm, single GBPs, symptomatic GBPs, age >60 years, Indian ethnicity, gallstones and cholecystitis.

Conclusion: With the reported incidence of GBP malignancy at just 0.57%, a management approach based on risk assessment, clear surveillance planning, and multi disciplinary team (MDT) discussion should be adopted. The utilization of endoscopic ultrasound(EUS) should be Only considered on the grounds of its greater sensitivity and specificity when compared to US scans.

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#### 1. Introduction

**The incidental detection of** gallbladder polyps (GBPs) is more frequently being reported as the use and the quality of ultrasound

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(US) scanning increases [1–4]. The term GBPs or polypoid lesions of the gallbladder refers to any elevated lesion of the mucosal surface of the gallbladder wall. These polyps have been classified into adenomatous polyps, pseudotumours and malignant polyps [5–7]. Evidence suggests that adenomas (an example of a "true tumours") have malignant potential, though this is a subject of debate, with conflicting opinions on the validity of an adenoma-adenocarcinoma pathway [8–11].

Polyps are incidentally detected in 0.3—12.3% of patients who undergo ultrasonography (US) of the gallbladder, or

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cholecystectomy [12–25]. The malignant potential of these lesions is small but significant, with previous studies suggesting between 3 and 8% of all GBPs are malignant [26,27]. Studies investigating the malignant potential of GBPs are however often limited by numbers with the majority including less than 100 patients [1,28,29].

Factors associated with an increased risk of malignancy are the subject of debate, and a number have been proposed to be significant including; increasing age, the presence of gallstones, gall-bladder wall thickening, rapid polyp growth, a sessile polyp on US, smoking, Indian ethnicity, and symptomatic polyps [11,30–32]. Studies tend to agree that the larger the polyp the higher the risk of malignancy, with some studies reporting a malignant risk of between 45 and 67% in polyps measuring between 10 and 15 mm [2,7,14,30,31,33–48]. Studies are unclear whether gender is a risk factor for malignancy [16,17,44,49,50].

Current literature advise that all GBPs greater than 10 mm in diameter and/or causing symptoms should be surgically removed [49]. There is no clear guidance on how best to manage those patients not offered surgery at the outset. It has been suggested GBPs less than 10 mm may be safely followed conservatively, yet the frequency, duration and mode of surveillance remain unclear [40]. The aim of current practice is to promote early detection and treatment of potential or actual malignant polyps, as detection of gallbladder carcinoma (GBC) at either stage 1 or 2 carries 95–99% and 70% 5-year survival rates respectively [51]. In contrast GBC discovered at stage 3 or 4 has only a 5–12% 5-year survival rate [52].

Given the advances in radiological imaging, and the absence of evidence-based guidance on follow-up surveillance protocols for those patients not offered surgery at diagnosis, this review has sought to further investigate evidence to inform practice. This systematic review seeks to summarise the available literature and provide guidance on the risk of an ultrasound detected gallbladder polyp being either a true polyp or a gallbladder malignancy, and the relevant risk factors to consider in such patients.

#### 2. Methods

#### 2.1. Study protocol

A search of PubMed, DISCOVER (University of Liverpool), Scopus and ScienceDirect was conducted using the keywords:

"Gallbladder" AND ("polyp" OR "polypoid lesion")

The titles and abstracts were reviewed to establish potential eligibility, based on the criteria listed in Table 1. Duplicate references were excluded. All potentially relevant studies were retrieved and assessed for eligibility and data quality by two reviewers. The bibliographies of each included study were searched for other potentially relevant studies. Studies were assessed for both relevance and study quality.

**Table 1**Review inclusion criteria.

#### Inclusion criteria

- Papers including the keywords: "Gallbladder" AND ("polyp" OR "polypoid lesion")
- Language of paper: English
- Study subject: Human
- Publish date: Post 1950
- Studies assessing the risk of malignancy in cases of gallbladder polyps
- Studies assessing the natural history of gallbladder polyps when followed up using Ultrasound.

#### 2.2. Study selection

Studies that were included described patients who had GBPs detected by US. Studies were only included if they followed up the natural history of GBPs, or assessed their risk of malignancy.

#### 2.3. Data extraction

Data extraction was performed using a standardised data extraction form. Information collected included the year of publication, country of origin, prevalence of GBPs, patients' demographics, size and distribution of GBPs, indications for cholecystectomy, histological results and follow up.

#### 3. Results

#### 3.1. Search results

The search identified 3744 references; following title review 474 abstracts were retrieved. Following dual author review 80 abstracts were deemed potentially relevant and retrieved for full paper review. Twelve papers were selected for inclusion in this systematic review, ten from the initial search and two from a search of the bibliographies of the eighty papers included for a full article review (Fig. 1).

#### 3.2. Descriptive analysis of included studies

#### 3.2.1. Quality of studies and risk of bias

Only twelve papers met inclusion criteria. Follow-up varied from eighteen months to eight years. Study group size varied from 34 to 18,610 patients. There was marked variance in study designs, five were retrospective [27,32,40,48,53] and seven were prospective [1,22,28,29,54–56].

A diagnosis of GBP is subject to a degree of observer bias, and all studies attempted to minimise observer bias by implementing standardised criteria for the diagnosis of GBPs. Ansari et al. had four sonographers/radiologists independently review patient US images and combine the radiology reports [28]. Kratzer et al. had eight trained assistants perform the US examinations [29].

Five studies retrospectively reviewed radiological reports to assess patients followed-up by ultrasound [27,32,40,48,53]. Corwin et al. reviewed the reports alongside the US images, with two authors assessing each image, whilst in the four other studies radiological reports were reviewed in isolation. The studies comment on the difficulties of reviewing reports retrospectively, as the quality of images is significantly lower than those during live imaging.

Aldouri et al. did not specifically study GBPs [32]. They studied the significance of ethnicity with regards to a patient's risk of gallbladder malignancy. As a result, there was some difficulty relating their data to GBPs.

#### 3.2.2. Prevalence of gallbladder polyps

Two of twelve studies were able to calculate the prevalence of GBPs in their population. In a population of diabetic and non-diabetic out-patients the prevalence was calculated as 6.7% [1]. In a population of a rural German community the prevalence was significantly lower at 1.4% [29]. Both studies reported a higher prevalence of GBPs in males.

### 3.2.3. Demographics of patients with gallbladder polyps

Ten of twelve studies reported the age range of their populations. In nine studies the youngest patient was aged 14–25 years, and the oldest 74–94 [1,22,27,29,32,40,48,53,56]. The one remaining study had a narrower age range, 35–63 years of age [54].

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