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The Surgeon, Journal of the Royal Colleges of Surgeons of Edinburgh and Ireland
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Evidence based management of polyps of the gall bladder: A systematic review of the risk factors of malignancy☆

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ARTICLE INFO

Article history:
Received 23 May 2015
Received in revised form
29 November 2015
Accepted 4 December 2015
Available online 26 January 2016

Keywords:
Gallbladder
Polyp(s)
Systematic review
Malignant
Size

ABSTRACT

Background: There are no evidence-based guidelines to dictate when Gallbladder Polyps (GBPs) of varying sizes should be resected.
Aim: To identify factors that accurately predict malignant disease in GBP; to provide an evidence-based algorithm for management.
Methods: A systematic review following PRISMA guidelines was performed using terms "gallbladder polyps" AND "polypoid lesion of gallbladder", from January 1993 and September 2013. Inclusion criteria required histopathological report or follow-up of 2 years. RTI-IB tool was used for quality analysis. Correlation with GBP size and malignant potential was analysed using Euclidean distance; a logistics mixed effects model was used for assessing independent risk factors for malignancy.
Results: Fifty-three articles were included in review. Data from 21 studies was pooled for analysis. Optimum size cut-off for resection of GBPs was 10 mm. Probability of malignancy is approximately zero at size <4.15 mm. Patient age >50 years, sessile and single polyps were independent risk factors for malignancy. For polyps sized 4 mm–10 mm, a risk assessment model was formulated.
Conclusions: This review and analysis has provided an evidence-based algorithm for the management of GBPs. Longitudinal studies are needed to better understand the behaviour of polyps <10 mm, that are not at a high risk of malignancy, but may change over time.
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☆ Presented as e-poster in ASGBI 2015.[1]

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http://dx.doi.org/10.1016/j.surge.2015.12.001
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Introduction

Gallbladder carcinoma usually presents late in diagnosis and carries a poor prognosis. Early detection is key in limiting spread.[2] Prevalence of Gallbladder polyps (GBPs) is approximately 5% in the global adult population,[3] and detection of GBPs has been increasing due to more frequent use of abdominal imaging.[4] Prevalence of malignancy among GBPs varies from 0% to 27%.[2] It is still not known how best to differentiate the rare, early malignant lesions from common benign lesions of the gallbladder. Gallbladder cancer has a dismal outcome, and carries an economic burden of approximately $78 million yearly in the United States.[5]

Despite the fact that gallbladder polyps are common, current literature lacks uniformity and a single consensus on management, leading to uncertainty. The majority of data for risk factors of GBP malignancy have been defined by individual, observational studies. These results involve limited numbers of participants, and are often retrospective, requiring careful interpretation due to possible bias. Randomised controlled trials are difficult to conduct in this study population.[6] Due to the lack of high-level data, there is a paucity of evidence-based guidelines for the treatment and surveillance of GBPs.[7]

The primary objective of this systematic review was to review the literature surrounding management of this topic to create a data pool for analysis. Selected risk factors in common clinical use in the management of GBP were identified and their accuracy to predict the presence of a malignant disease was assessed. The second objective was to provide evidence-based guidelines to allow a more standardised approach to the management of gallbladder polyps based on size at presentation.

Methods

The PRISMA guidelines for reporting on systematic reviews and meta-analysis were followed to conduct this review.

Search methods for identification

A systematic search of the electronic databases PubMed, Cochrane, Embase and Scopus, from January 1993 and September 2013 was conducted. A combination of MeSH and text words was used. The terms used were "gallbladder polyps" AND "polypoid lesion of gallbladder" with restriction to human.

Inclusion criteria

All cross-sectional, cohort and those case-series that involved more than two patients were included. No restrictions were placed on presenting symptoms or reason for investigation (e.g. incidental finding). Studies required the reporting of a specific end point either histopathological review or a median of 2 years follow up after diagnosis. Only articles published in full text in the English language were included.

Exclusion criteria

All case reports, case series with <2 patients, reviews and letters to the editor were excluded. Studies that evaluated PSC as a single risk factor were also excluded, as this paper focussed on risk factors common to the general population. Studies that only assessed sensitivity and specificity of an investigation modality with no reference to gallbladder polyp risk factors were excluded.

Selection of studies

Two authors (NB and AG) independently conducted the search; and reviewed the articles for inclusion and exclusion criteria. A third author (PFR) was available for arbitration of any disputes.

Quality assessment

Methodological quality of the included studies was assessed using the Research Triangle International (RTI-IB) tool for assessment of risk of bias and precision of observational studies.[8] The standard tool contains 29 questions, and was modified for the study designs of the included papers. Questions not relevant to the study design were removed, leaving 9 applicable questions for quality assessment. (see Appendix 1).

Data extraction

A standardised data extraction sheet was used. For 10% of the studies, two authors extracted data independently to ensure uniform interpretation. A selected numbers of authors were contacted for missing data.

Items included in data abstraction:

a) Year of publication, country of publication, journal, study design, study population, demographics of study participants, imaging study used to diagnose the gallbladder polyp.
b) Size (specific/categorical), number (single/multiple), morphology (sessile/pedunculated) and histopathological type (benign/adenoma/malignant) of the gallbladder polyps. Risk factors were stratified according to histopathological sub-type.
c) Study endpoint was identified (surgery/long term follow-up), the period of follow up and reason for surgery recorded.

Statistical analysis

In order to predict the effect of size on malignant potential of gallbladder polyps, polyp size data were bucketed into the following size ranges: 0–5 mm, 6–10 mm, 11–15 mm, 16–20 mm, >20 mm. A logistic mixed-effects model was fit using the LME4 package[9] in R[10] to the data with the goal of predicting malignancy. Size was considered as a fixed effect and study name was considered as a random effect. The model was compared to a null model by means of an ANOVA test. The polyp sizes were then reformulated so that each polyp was labelled as having a true/false status with respect to four size classifications: ≤5 mm, ≤10 mm, ≤15 mm and ≤20 mm. Four separate logistic mixed-effects models were fitted to the data. Each model attempted to predict the true/false status for each

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