Percutaneous image-guided biopsy of the spleen: systematic review and meta-analysis of the complication rate and diagnostic accuracy

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CRD summary
This generally well conducted review concluded that image-guided percutaneous biopsy of the spleen, using 18-gauge or smaller needles, provided a safe and accurate alternative to splenectomy. The small number of studies, particularly for test accuracy, and weaknesses in the meta-analytic methods mean that the pooled estimates of accuracy and complication rates should be interpreted cautiously.

Authors' objectives
To assess the complication rate and diagnostic accuracy of image-guided percutaneous needle biopsy of the spleen.

Searching
MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), DARE and the Cochrane Database of Systematic Reviews were searched to July 2010, without language restrictions. Search terms were reported. The bibliographies of retrieved articles were screened for additional studies.

Study selection
Studies of diagnostic accuracy were included if they: assessed image-guided biopsy using computed tomography, ultrasound or fluoroscopy; used an acceptable reference standard (surgery, biopsy of a different organ, imaging, and/or clinical follow-up) in most participants; reported sufficient data to populate 2x2 contingency tables (numbers of true positive, false negative, false positive and true negative test results); and included adult patients.

Studies of complication rates were included if they assessed image-guided biopsy using computed tomography, ultrasound or fluoroscopy; performed biopsies in in-patients or in out-patients with a minimum of 24-hour post-biopsy follow-up; reported complication rates; were conducted in adult patients.

Where reported, studies were conducted between 1985 and 2009. The indication for biopsy varied (full details reported in the article) and included lymphoma, uncertain diagnosis from imaging alone and other malignancies. Studies included both core-needle biopsy and fine-needle aspiration biopsy. Core-needle biopsy needle size ranged from 14 to 22 gauge and fine-needle biopsy needle size ranged from 20 to 25 gauge. Imaging details were not reported. The proportion of male study participants ranged from 17 to 88%. Only half of the studies reported mean age of participants (38 to 55 years).

Two reviewers independently assessed studies for inclusion and disagreements were resolved by discussion.

Assessment of study quality
The methodological quality of diagnostic accuracy studies was assessed using the 14-item QUADAS (Quality Assessment of Diagnostic Accuracy Studies) tool and the methodological quality of observational studies of complication rates was assessed using the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) score (maximum 22).

Two reviewers independently assessed study quality and disagreements were resolved by consensus.

Data extraction
For studies of diagnostic accuracy, data were extracted on the numbers of true positive, false negative, false positive and true negative test results and used to calculate sensitivity and specificity values, with 95% confidence intervals (CIs), for the detection of spleen disease.

For studies of complication rates, the numbers and details of biopsy-related complications were extracted and used to calculate overall event rates (major and minor complications), with 95% confidence intervals.
Two reviewers independently extracted data and disagreements were resolved by consensus. Study authors were contacted for clarification of data, as needed.

Methods of synthesis
Accuracy and complication rate data were summarised in forest plots.

Pooled estimates of sensitivity and specificity were calculated using a random-effects model weighted by inverse variance. Pooled complication rates were calculated separately for core-needle biopsy and fine-needle aspiration biopsy, using a random-effects model weighted by inverse variance. Sensitivity analysis was conducted for complication rates, removing data for needles larger than 18-gauge.

Between-study heterogeneity was assessed using the I² statistic. Publication bias was assessed, for studies of complication rates, using a funnel plot and Egger's test.

Results of the review
Ten studies were included in the review. Six studies assessed complication rates only, one assessed test accuracy only and three assessed both. For the nine studies that assessed complication rate, the median STROBE score was 14 (range 13 to 19). QUADAS assessment of the four studies that reported test accuracy data showed that nine of the 14 criteria were met by all studies. No study interpreted the reference standard blind to the results of the index test and that the delay between the index test and the reference standard was unclear in three out of four studies.

Test accuracy (714 biopsies in 639 patients):
The pooled estimate of sensitivity was 87.0% (95% CI 80.7 to 91.4%), I²=47.6% (moderate heterogeneity), and the pooled estimate of specificity was 96.4% (95% CI 81.4 to 99.4%), I²=73.6% (substantial heterogeneity). Results were similar when core-needle and fine-needle aspiration biopsy were analysed separately. For these subgroup analyses there was no evidence for between-study heterogeneity in most estimates; however, the very small numbers of studies involved meant that this assessment was unlikely to have been reliable.

Complication rates:
A total of 859 biopsies were performed in 741 patients (370 core-needle and 489 fine-needle aspiration). Complications were reported in 46 biopsies (10 major and 36 minor). Of the 10 major complications, nine were related to haemorrhage and one was pneumothorax. Of the 36 minor complications, 29 were related to pain, six were related to haemorrhage, and one was a vasovagal episode. Four of the major, and 16 or the minor complications occurred in 33 biopsies that were performed with needles larger than 18-gauge.

The pooled overall (major and minor) complication rates were 4.2% (95% CI 1.0 to 15.5%) for all biopsies, 4.3% (95% CI 2.7 to 6.7%) for fine-needle aspiration biopsy (six studies), and 5.8% (95% CI 1.1 to 26%) for core-needle biopsy (seven studies). The sensitivity analysis (33 biopsies performed with needles larger than 18-gauge excluded) gave an overall complication rate of 3.9% (95% CI 2.7 to 5.6%) for all biopsies and 3.6% (95% CI 2.0 to 6.4%) for core-needle biopsies. Separate data were also reported for major and minor complications. There was no evidence of publication bias.

Authors' conclusions
Image-guided percutaneous biopsy of the spleen showed high diagnostic accuracy and, where 18-gauge or smaller needles were used, was associated with a major complication rate similar to that reported for image-guided biopsy of the liver and kidney.

CRD commentary
The review reported two clearly stated research questions and specified appropriate inclusion criteria for both. Several sources were searched for relevant studies and no language restrictions were applied, which decreased the likelihood of relevant studies being omitted. Unpublished material was not sought. Measures to minimise error and/or bias were applied throughout the review process and the methodological quality of included studies was assessed and included in the results.
The calculation of pooled estimates of sensitivity and specificity was of questionable value given the apparent between-study heterogeneity. Similarly the pooled estimates of complication rates were problematic because of the very high complication rates (62.5%) observed in one early (1985) study of core-needle biopsy. Although this study was excluded from the sensitivity analysis (all of its 32 biopsies used needles larger than 18-gauge), it might have been clearer to treat this study separately from the outset. The use of a sensitivity analysis implied that the exclusion of biopsies using needles larger than 18-gauge involved data from several studies, but all but one of these biopsies were actually conducted in a single study. The small number of studies, particularly for test accuracy, and weaknesses in the meta-analytic methods mean that the pooled estimates of accuracy and complication rates should be interpreted cautiously.

Implications of the review for practice and research

**Practice:** The authors stated only using biopsy of the spleen where no other organ was available was reasonable because other organs may have lower associated complication rates and physicians may have more experience in biopsying other organs. They further concluded that, for cases where the spleen was the only abnormal or most accessible organ for biopsy, this study supported the use of image-guided percutaneous biopsy of the spleen as a safe and accurate alternative to splenectomy.

**Research:** The authors did not specify any recommendations for future research.

**Funding**
Not stated.

**Bibliographic details**

**PubMedID**
21693659

**DOI**
10.1148/radiol.11110333

**Original Paper URL**
http://radiology.rsna.org/content/260/3/699.abstract

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Diagnostic Imaging /statistics & numerical data; Hemorrhage /epidemiology; Humans; Incidence; Pain /epidemiology; Postoperative Complications /epidemiology; Risk Assessment; Risk Factors; Spleen /pathology; Surgery, Computer-Assisted /statistics & numerical data

**AccessionNumber**
12011005668

**Date bibliographic record published**
26/03/2012

**Date abstract record published**
13/09/2012

**Record Status**
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.