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Expert Review of Gastroenterology & Hepatology

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/ierh20

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To cite this article: Antonio Facciorusso, Stefano Francesco Crinò, Daryl Ramai, Carlo Fabbri, Benedetto Mangiavillano, Andrea Lisotti, Nicola Muscatiello, Christian Cotsoglou & Pietro Fusaroli (2021): Diagnostic yield of endoscopic ultrasound-guided liver biopsy in comparison to percutaneous liver biopsy: a systematic review and meta-analysis, Expert Review of Gastroenterology & Hepatology, DOI: 10.1080/17474124.2022.2020645

To link to this article: https://doi.org/10.1080/17474124.2022.2020645

EXPERT REVIEW OF GASTROENTEROLOGY & HEPATOLOGY
https://doi.org/10.1080/17474124.2022.2020645

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META-ANALYSIS

Diagnostic yield of endoscopic ultrasound-guided liver biopsy in comparison to percutaneous liver biopsy: a systematic review and meta-analysis

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ABSTRACT

Background: It is still unclear whether endoscopic ultrasound liver biopsy (EUS-LB) determines superior results in comparison to percutaneous liver biopsy (PC-LB). Aim of this meta-analysis was to compare the diagnostic outcomes of these two techniques.

Research Design and Methods: Literature search was conducted through June 2021 and identified 7 studies. The primary outcome was total length of specimen. Results were expressed as odds ratio (OR) or mean difference along with 95% confidence interval (CI).

Results: Pooled total length of specimen was 29.9 mm (95% CI 24.1–35.7) in the EUS-LB group and 29.7 mm (95% CI 27.1–32.2) in the PC-LB group, with no difference between the two approaches (mean difference −0.35 mm, 95% CI −5.31 to 4.61; p = 0.89), although sensitivity analysis restricted to higher quality studies found a superior performance of PC-LB over EUS-LB. Pooled number of complete portal tracts was 12.9 (7.7–18) in the EUS-LB and 14.4 (10.7–18) in the PC-LB group, with no difference in direct comparison (mean difference −1.58, −5.98 to 2.81; p = 0.48). No difference between the two groups was observed in terms of severe adverse event rate (OR 1.11, 0.11–11.03; p = 0.93).

Conclusion: EUS-LB and PC-LB are comparable in terms of diagnostic performance and safety profile.

ARTICLE HISTORY
Received 30 September 2021
Accepted 16 December 2021

KEYWORDS
EUS; FNB; FNA; adequacy

1. Introduction

Noninvasive testing such as liver stiffness measurement through transient elastography is widely used as part of the diagnostic armamentarium in assessing focal liver lesions [1,2]. However, liver biopsy (LB) still represents the gold standard in the diagnostic algorithm of several hepatic parenchymal disorders and focal neoplasms. In particular, noninvasive tests have not obviated the need for histologic analysis particularly in the case of unclear etiology or when immunohistochemistry is needed.

For years the most commonly used route for LB has been through percutaneous approach (PC-LB) under CT-scan or ultrasonographic (US) guidance. The transjugular (TJ-LB) approach represents an option in the case of difficult locations or when PC-LB is contraindicated. However, even in high-volume centers PC-LB might determine a non-negligible sampling error rate thus decreasing the diagnostic performance of the procedure; furthermore, as usually only the right lobe is accessible for biopsy, focal lesions located in the left lobe are not easily sampled. Although these issues could be solved with TJ-LB, this approach represents a more complex procedure with potential complications including neck hematoma, vascular injury, arterio-venous fistula, and intra-abdominal hemorrhage [3].

Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) or, more recently, EUS-guided fine-needle biopsy (FNB) already represent a widely used and effective technique in the diagnostic assessment of pancreatic solid lesions and in tissue acquisition of a number of other abdominal organs [4–8].

In recent years, EUS-guided tissue acquisition has proved to represent a well-established diagnostic approach for targeting both focal lesions and parenchymal liver disease, as reported in a recent pooled analysis demonstrating a histologic diagnostic rate of 93.9% and adverse event rate of 2.3% [9]. These striking results seem to be further improved with newer FNB needles, such as the Franseen needle (Acquire® [Boston Scientific, Marlborough, Massachusetts, USA]) and the Fork-tip needle (SharkCore® [Medtronic, Dublin, Ireland]), as shown in recent reports [10].

Recent studies provided conflicting evidence on the comparative efficacy of EUS-LB as compared to PC-LB to diagnose parenchymal liver disease. In fact, while previous retrospective studies showed similar results between these two approaches [11–13], a recent small randomized-controlled trial (RCT) and another multicenter series suggested better diagnostic performance with PC-LB [14,15].

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Supplemental data for this article can be accessed here.

The aim of our meta-analysis was to compare the diagnostic outcomes and safety profile of EUS-LB and PC-LB in patients with liver parenchymal disorders.

2. Methods

2.1. Selection criteria

Studies included in this meta-analysis were randomized-controlled trials (RCTs) or non-randomized comparative series that met the following inclusion criteria: (a) Patients: adult patients with liver parenchymal disorders or focal liver lesions undergoing biopsy; (b) Intervention: EUS-guided liver biopsy (c) Comparator: US- or CT-guided percutaneous liver biopsy; and (d) Outcomes: primary outcome was total length of tissue specimen, whereas secondary outcomes were sample adequacy, number of complete portal tracts (CPTs), procedural duration. Safety data were also analyzed. Only studies reporting comparative data on total specimen length or number of CPTs were included.

We excluded (a) non-comparative single cohort studies, (b) case reports, (c) studies not reporting any of the aforementioned outcomes.

2.2. Search strategy

Computerized bibliographic search was performed on PubMed/Medline and Embase with no language restriction through June 2021, independently by two authors (AF, SFC) using the following search string: (((endoscopic ultrasound [MeSH Terms]) OR (EUS[MeSH Terms])) AND (liver biopsy [MeSH Terms])). Complementary manual search was performed on additional databases (Google Scholar, Cochrane library) and by checking the references of all the main review articles on this topic, in order to identify possible additional studies. In cases of overlap publications from the same population, only most recent and complete articles were included.

The quality of the included studies was assessed by two authors independently (AF, SFC) according to the Cochrane Collaboration's tool for assessing the risk of bias [16] for RCTs and the Newcastle-Ottawa scale [17] for non-randomized studies. Any disagreements were addressed by reevaluation and following a third opinion (PF).

2.3. Statistical analysis

Study outcomes were pooled and compared between the two groups through a random-effects model based on DerSimonian and Laird test [18], and results were expressed in terms of odds ratio (OR) or mean difference and 95% confidence interval (CI), when appropriate.

Presence of heterogeneity was calculated through I^2 tests with $I^2 < 30\%$ interpreted as low-level heterogeneity and I^2 between 30% and 60% as moderate heterogeneity [19]. Any potential publication bias was verified through visual assessment of funnel plots.

Primary outcome was total length of the tissue specimen (TLS), measured in mm, whereas secondary outcomes were the number of complete portal tracts (CPTs), where a CPT was defined as the presence of all three portal structures (portal vein, hepatic artery, and bile duct) in the sample, sample adequacy (defined as the proportion of samples defined as adequate for histological diagnosis), procedural duration, and severe adverse event rate. A severe adverse event was defined as one that required hospitalization, was life-threatening, or resulted in death or disability.

Sensitivity analyses in the context of the primary outcome were based on study design (RCT versus retrospective), EUS needle used (19 G FNA versus FNB needles), study quality (high versus low quality). A further sensitivity analysis was restricted to patients with liver parenchymal disease.

All statistical analyses were conducted using RevMan version 5 from the Cochrane collaboration. For all calculations, a two-tailed p value of less than 0.05 was considered statistically significant.

3. Results

3.1. Included studies

From 322 unique studies identified using the search strategy, we included seven studies [11–15,20,21] (Figure 1) recruiting 899 patients, of which 387 who underwent EUS-LB and 512 treated with PC-LB.

Main baseline characteristics of the included studies are summarized in Table 1.

Out of seven included studies, one was a single-center RCT [14], the others were retrospective series, of which 5 were conducted in the USA [11–14,20,21] whereas 1 was a two-center Italian study [15]. The recruitment period ranged from 2011 to 2021.

Baseline patient- and lesion-related characteristics were well balanced between the two study groups, with females forming the majority of participants in the included studies while mean age was 55 years. Abnormal liver function tests represented the most frequent indication to liver biopsy in both study groups, while only a single study reported data on focal liver lesions [15]. Number of EUS needle passes ranged from 2 to 4 (two for each lobe) and the needle used was 19 G FNA in two studies [12,13], 19 G Acquire® in other 2 studies [14,21] Sharkcore® (both 19 G and 22 G) in one study [20], whereas the remaining reports used either 19 G FNA or different kinds of FNB needles. On the other hand, different sizes of PC-LB needles were used, ranging from 15 G to 21 G, mainly US-guided.

Quality assessment of the studies was summarized in Supplementary Table 1. Overall, the studies were felt to be at moderate risk of bias, mainly due to incomplete outcome reporting. The single RCT [14] and the two-center retrospective series [15] were rated as high-quality studies.

3.2. Total length of tissue specimen

Overall, based on six studies [11–15,20] (252 patients treated with EUS-LB and 224 sampled with PC-LB), pooled TLS was 29.9 mm (95% CI 24.1–35.7) in the EUS-LB group and 29.7 mm (95% CI 27.1–32.2) in the PC-LB group, hence with no difference between the two approaches (mean difference −0.35 mm, 95% CI −5.31 to 4.61; p = 0.89). Evidence of

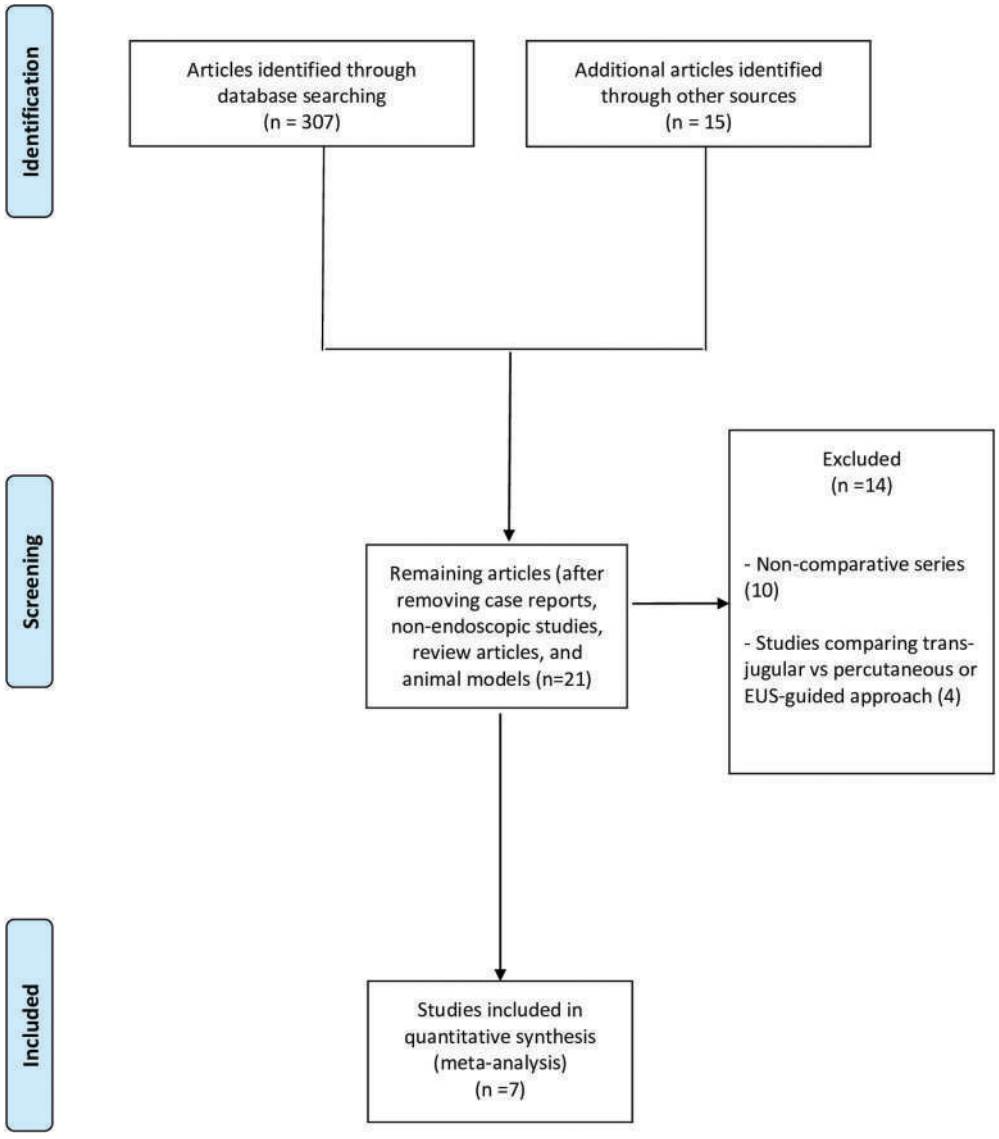

Figure 1. Study selection flow chart.

moderate heterogeneity (I^2 = 44% Figure 2) and no publication bias were found (Supplementary Figure 1a).

As reported in Table 2, sensitivity analyses restricted to the single RCT [14] and the two high-quality studies [14,15] found a superior performance of PC-LB over EUS-LB although this finding was based on a very limited sample size and it was not confirmed in the other subgroups. No difference in terms of TLS based on the EUS needle used was observed; in particular, mean difference for TLS was 2.25 mm (−13.9 to 18.4) and −7.31 mm (−9.67 to 4.94) with 19 G FNA and FNB needles, respectively (Table 2). Heterogeneity was confirmed as moderate in all the subgroups tested.

3.3. Secondary outcomes

As reported in Figure 3, based on six studies [11–13,15,20,21], pooled number of CPTs was 12.9 (7.7–18) in the EUS-LB and 14.4 (10.7–18) in the PC-LB group, with no statistical difference in the direct comparison (mean difference −1.58, −5.98 to 2.81; p = 0.48 and I^2 = 36%).

Based on four studies [11,14,15,20] (240 patients in the EUS-LB group and 428 in the PC-LB group), pooled sample adequacy was 96.4% (92.4%-100%) and 99% (98.1%-99.9%) in the two groups, respectively. As reported in Figure 4, no difference between the two groups was observed (OR 0.32, 0.08–1.28; p = 0.11) with no evidence of heterogeneity (I^2 = 0%) nor of publication bias (Supplementary Figure 1b).

Three studies reported overall eight severe adverse events, in particular two cases of severe abdominal pain and one death in the EUS-LB group and four cases of abdominal pain and one severe bleeding in the PC-LB group. Of note, the fatal event observed in the EUS-LB group in the study by Boghal *et al.* [11] was determined to be unrelated to the procedure.

As reported in the Supplementary Figure 2, no significant difference between the two groups was observed (OR 1.11, 0.11–11.03; p = 0.93) with no evidence of heterogeneity.

Three studies [14,15,21] reported procedural duration but the study by Rombaoa *et al.* [21] was excluded from the analysis as no details on how duration was calculated were provided. Therefore, as reported in the Supplementary

Table 1. Characteristics of included studies.

Study	Reference	Study period/ Country/design	Treatment	Age	Gender male	Indication (abnormal liver function tests)	Number of EUS passes	EUS needle used	PC needle used	Final diagnosis (Cirrhosis)	ROSE/Suction
Pineda 2016*	[12]	2011–2013/USA/ Retrospective	EUS-biopsy: 68 PC biopsy: 27	NR	NR	68 (100%) 27 (100%)	2	19 G FNA	18 G, 19 G, 20 G US or CT-guided	NR	no/slow pull
Bhogal 2020*	[11]	2013–2019/ USA/ Retrospective	EUS-biopsy: 135 PC biopsy: 287	53 ± 15 52 ± 15	49 (36%) 145 (51%)	120 (89%) 254 (89%)	NR	19 G FNA and 19 G Acquire®	NR	14 (10%) 9 (3%)	no/NR
Ali 2020	[20]	2018–2019/USA/ Retrospective	EUS-biopsy: 30 PC biopsy: 60	54 (46–63) 53 (45–59)	11 (37%) 22 (36.6%)	17 (57%) 10 (17%)	2	19 G or 22 G Sharkcore®	15 G or 18 G	0 (0%)	no/wet suction
Bang 2021	[14]	2019–2020/ USA/ Randomized controlled trial	EUS-biopsy: 21 PC biopsy: 19	55 (45–68) 55 (44–66)	8 (38.1%) 6 (31.6%)	NR	2 per lobe	19 G Acquire®	16 G US-guided	3 (14.2%) 2 (10.5%)	No/slow pull
Shuja 2019*	[13]	2016–2018/ USA/ Retrospective	EUS-biopsy: 69 PC biopsy: 47	54.39 ± 11.63 55.33 ± 14.39	NR	NR	3	19 G FNA	18 G or 21 G US- or CT-guided	NR	No/Slow pull
Rombaoa 2018[a]	[21]	2017/ USA/ Retrospective	EUS-biopsy: 10 PC biopsy: 10	NR	NR	8 (80%)	2	19 G Acquire®	NR	NR	No/NR
Facciorusso 2021	[15]	2017–2021/Italy/ Retrospective	EUS-biopsy: 54 PC biopsy: 62	56 (48–69) 54 (45–67)	32 (59.2%) 38 (61.2%)	Parenchymal disease: 50% Focal lesions: 50%	2 per lobe	19 G FNA, 22 G or 25 G Sharkcore®, 25 G ProCore®, 25 G Acquire®	16 G US-guided	0%	No/Slow pull

Data are reported as absolute numbers (percentages) or mean (± standard deviation or with range)
* Only data concerning percutaneous and EUS-biopsy were considered
[a]Study published as conference abstract
Abbreviations: FNA, Fine Needle Aspiration; NR, Not Reported; PC, PerCutaneous; ROSE, Rapid On-Site cytologic Evaluation

Table 2. Sensitivity analysis concerning the primary outcome (total length of biopsy specimen).

Variable	Subgroup	No. of Studies	No. of patients	Mean difference (95% CI)	Within-group heterogeneity (I^2)
Study design	Randomized controlled trial	1	EUS-biopsy: 21 PC biopsy: 19	−6.70 (−10.23 to −3.17)	Not applicable
	Retrospective	5	EUS-biopsy: 231 PC biopsy: 205	0.95 (−4.70 to 6.60)	48%
Needle	19 G FNA	3	EUS-biopsy:191 PC biopsy: 136	2.25 (−13.90 to 18.40)	33%
	FNB needles	3	EUS-biopsy: 105 PC biopsy: 141	−7.31 (−9.67 to 4.94)	40%
Study quality	High	2	EUS-biopsy: 75 PC biopsy: 81	−8.50 (−10.16 to −6.84)	30%
	Low	4	EUS-biopsy: 177 PC biopsy: 143	3.78 (−7.10 to 14.66)	45%
Indication	Parenchymal disease	6	EUS-biopsy: 225 PC biopsy: 193	−0.28 (−5.51 to 4.95)	37%

Abbreviation: CI, Confidence Interval; FNA, fine-needle aspiration; PC, percutaneous

Figure 3, procedural duration was significantly longer in the EUS-LB group as compared to the PC-LB group (mean difference 5.39 minutes, 3.79 to 6.99; $p < 0.001$). However, this result should be interpreted with caution due to the high heterogeneity ($I^2 = 65\%$).

4. Discussion

In spite of the recent evidence on the favorable diagnostic performance of noninvasive methods in both diagnosis and monitoring of fibrosis in chronic liver disease [22], liver biopsy still plays a pivotal role in several conditions when proper histology and immunohistochemistry are needed.

Given the recent development of newer EUS-FNB needles such as Franseen and Fork-tip that have two to three cutting edges at the tip to facilitate core tissue procurement [23–25], the appropriate comparison between EUS-guided and percutaneous liver biopsy is of paramount importance to guide the clinician in the daily practice.

A previous meta-analysis including 5 studies comparing all of the aforementioned three techniques (EUS-LB, PC-LB, and TJ-LB) showed that EUS-LB is comparable to the other approaches [26]; however, the strict inclusion criteria (restricted only to studies comparing all the 3 approaches) and the inclusion of three conference abstracts required a confirmation based on higher quality evidence.

Through a meta-analysis of seven studies, of which 1 RCT, we made several key observations.

First, there was no difference between the two techniques in terms of total length of tissue specimen (mean difference −0.35 mm, 95% CI −5.31 to 4.61; $p = 0.89$). However, sensitivity analysis restricted to the single RCT [14] and to the two high-quality studies [14,15] found a superior performance of PC-LB over EUS-LB although this finding was based on a very limited sample size and it was not confirmed in the other subgroups.

The two studies showing improved results with PC-LB used a 16 G needle that integrates a triaxial core, cut and capture system with an automated firing sequence, thus enabling the procurement of an optimal core of tissue. On the other hand, EUS-FNB needles were no more than 19 G in diameter and even newer designs have two to three cutting edges or side holes at the tip to facilitate core tissue procurement. Furthermore, EUS approach usually requires transgastric or transduodenal biopsies where the FNB needle tip is partially flexed as it moves back and forth in different trajectories within a target organ, while the PC method uses a single cut motion in a straight plane. As correctly pointed out by Bang *et al.* in their RCT [14], these differences are likely to at least partially explain the superior performance of PC-LB over EUS-LB in the aforementioned studies [14,15]. Also, EUS-LB represents a newer and operator-dependent diagnostic modality, hence the overall yield depends more upon training and skill of the physician who performs the procedure as compared to PC-LB. However, the limited evidence in this regard calls for further studies in order to confirm these findings.

Of note, no difference in terms of TLS based on the EUS needle used was observed, therefore at the moment definitive assumptions on the preferential use of newer FNB designs over standard 19 G FNA needle might not be drawn as already pointed out in previous meta-analyses [9,27].

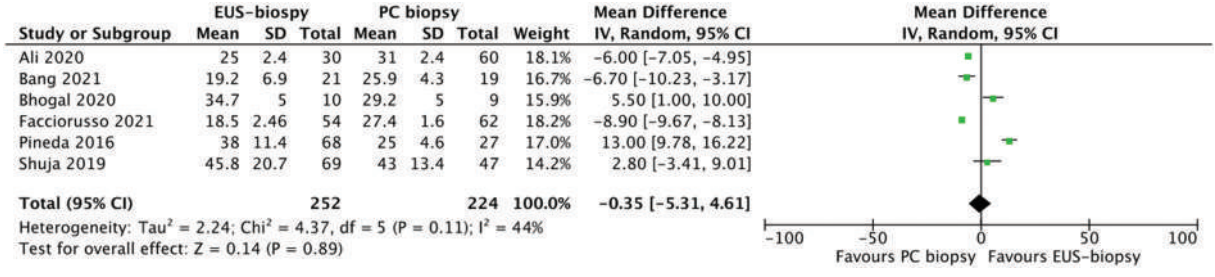

Figure 2. Forest Plot comparing EUS-guided versus percutaneous liver biopsy in terms of total length of tissue specimen Based on 6 studies, no difference between the two approaches was found (mean difference −0.35 mm, 95% CI −5.31 to 4.61; $p = 0.89$).

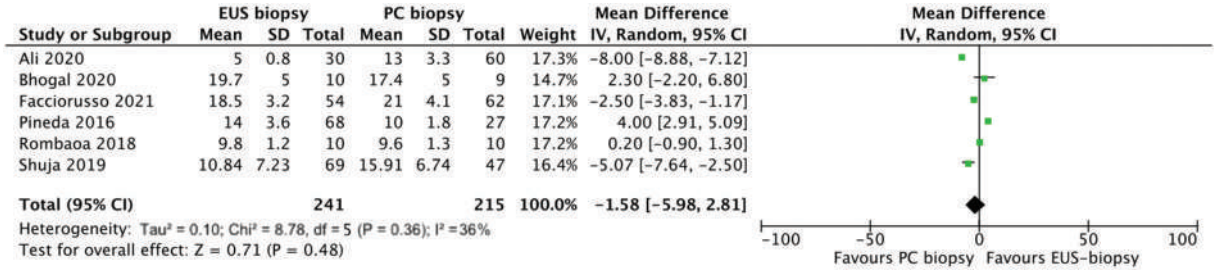

Figure 3. Forest Plot comparing EUS-guided versus percutaneous liver biopsy in terms of number of complete portal tracts Based on 6 studies' no statistical difference between the two approaches was observed (mean difference −1.58, −5.98 to 2.81; I^2 = 36%).

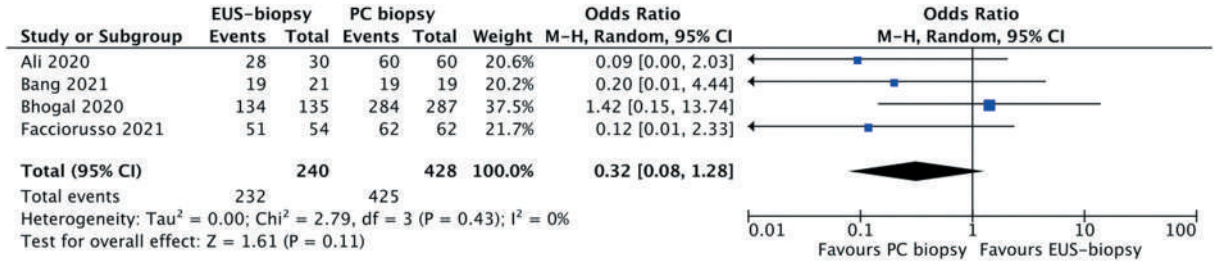

Figure 4. Forest Plot comparing EUS-guided versus percutaneous liver biopsy in terms of sample adequacy No difference between the two groups was observed (OR 0.32, 0.08–1.28; p = 0.11) with no evidence of heterogeneity (I^2 = 0%).

Our second observation was on the similar results in the comparison of the two techniques concerning other diagnostic outcomes, namely number of CPTs (mean difference −1.58, −5.98 to 2.81; p = 0.48) and sample adequacy (OR 0.32, 0.08–1.28; p = 0.11).

However, there is still no consensus on what an 'adequate' liver biopsy actually represents. AASLD guidelines suggest that adequate liver biopsy specimens be at least 1.5 cm in length and contain more than 11 portal tracts whereas the Royal College of Pathologists define adequacy as being greater than 1 cm in length and containing at least 6 portal tracts [28,29].

In order to obtain homogeneous results, the RCT by Bang *et al.* [14] that used a more stringent definition of sample adequacy was excluded from this analysis; however, this aspect represents a further note of caution in the interpretation of our findings.

A very limited rate of severe adverse events was registered with both techniques, with no evidence of any significant difference concerning the safety profile (OR 1.11, 0.11–11.03; p = 0.93), thus confirming that both approaches are safe and can be routinely used in the clinical practice.

Finally, procedural duration seemed to be clearly in favor of the percutaneous approach (mean difference 5.39 minutes, 3.79 to 6.99; p < 0.001), although this result should be interpreted with caution due to the high heterogeneity (I^2 = 65%) and the very limited sample size supporting this analysis.

There are certain limitations to our study which merit further discussion. First, the number of included studies and recruited patients was low and the evidence was based mainly on retrospective series. Furthermore, the included RCT was unblinded, hence prone to performance bias. However, it should be noted that this bias is not avoidable in endoscopy studies as the operator cannot be blinded to the device used. Moreover, several sensitivity analyses were conducted in order to take into account all the potential confounders in the analysis. Second, some relevant subgroup analyses could not be performed due to the lack of data, in particular specific comparisons based on technical aspects of tissue sampling such as use of stylet, suction technique, or indication to LB. In particular, a subgroup analysis restricted to focal liver lesions could not be performed although the preliminary results from the Italian study seem to confirm the aforementioned findings even in this setting [15]. Therefore, at the current state of the art, our results should be considered applicable only to liver parenchymal disease. Third, although most of the included studies were conducted in USA, local practice or protocols concerning these procedures might be different and this aspect could at least partially explain the heterogeneity observed in the analysis.

Finally, cost analysis was beyond the scope of this study and it was not performed. However, such analysis was already performed in the RCT by Bang *et al.* [14] where PC-LB appeared as significantly less costly than EUS-LB (US$1824 vs US$3240, p < 0.001).

5. Conclusion

In conclusion, EUS-LB and PC-LB appear comparable in terms of the diagnostic performance, although higher quality studies suggest that PC-LB could obtain better samples as compared to EUS-LB. Further RCTs are warranted in order to confirm these results.

Funding

This paper was not funded.

Declaration of interests

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Reviewer disclosures

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

Author contributions

Study concept and design: A Facciorusso designed the study, worked on the acquisition of data, conducted the statistical analysis, and drafted the manuscript. A Lisotti and SF Crinò drafted the manuscript. D Ramai, C Fabbri, B Mangiavillano, N Muscatiello, C Cotsoglou and P Fusaroli critically revised the final manuscript. All of the authors approved the final version of the manuscript.

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