

Rationale of the Study and Objective

- ❖ Focal Liver Lesions (FLLs) are often detected incidentally during imaging performed for unrelated conditions
- ❖ Early and accurate characterization (benign vs malignant) is crucial to optimize patient management and avoid unnecessary procedures [1]
- ❖ CEUS (Contrast-Enhanced Ultrasound) combines the non-invasiveness of ultrasound with contrast enhancement, improving diagnostic accuracy and potentially reducing the need for CT (computed tomography) and MRI (magnetic resonance imaging) [2]
- ❖ Despite recommendations from major clinical guidelines - such as those issued by the National Institute for Health and Care Excellence (NICE), and the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) [3-4] - the adoption of CEUS in Italy remains limited, mainly due to training gaps, operator dependence, low reimbursement, and often insufficient awareness of CEUS accuracy in the characterization of incidentally detected FLLs



To investigate the potential benefits of CEUS on economic and organizational sustainability when utilized FLLs characterization in patients without history of chronic liver diseases and cancer disease referred for non-contrast abdominal ultrasound

Methods

An economic and organizational analysis was conducted, using real-life data collected in two Italian hospitals, currently using CEUS

A **retrospective observational analysis** was conducted in two hospitals in the Emilia-Romagna Region (Italy) with established use of CEUS as a second-line diagnostic tool after abdominal ultrasound. These hospitals represented the BEST-CASE scenario for CEUS implementation

A **Scenario-based decision-analytic model** was developed to simulate alternative diagnostic strategies for incidental FLLs, reflecting the current non-optimized practice in Italy. The model was informed by expert consensus through focus groups and the Nominal Group Technique involving five clinical and organizational experts

An **economic assessment** was performed from the Italian National Health Service (NHS) perspective, using national outpatient reimbursement tariffs valid for 2025, as published in the *Gazzetta Ufficiale* on December 28, 2024

Organizational benefits of CEUS implementation were analyzed to understand potential efficiency gains at hospital level

Model Structures & Scenarios

A focus on the Scenarios under assessment

Diagnostic Pathways	BEST-CASE	AS IS 1	AS IS 2	AS IS 3	AS IS 4
Abdominal Ultrasound + CEUS	79.03%	n.a	n.a	n.a	n.a
Abdominal CT + CEUS	5.99%	n.a	n.a	n.a	n.a
Abdominal Ultrasound + Abdominal CT + CEUS	n.a	n.a	n.a	79.03%	39.51%
Abdominal Ultrasound + Abdominal MRI + CEUS	n.a	n.a	79.03%	n.a	39.51%
Abdominal CT + CEUS	n.a	28.57%	5.99%	5.99%	5.99%
Abdominal CT with Contrast + CEUS	4.12%	19.64%	4.12%	4.12%	4.12%
Abdominal CT + Abdominal Ultrasound + CEUS	2.62%	12.50%	2.62%	2.62%	2.62%
Abdominal MRI + CEUS	1.50%	7.14%	1.50%	1.50%	1.50%
Abdominal Ultrasound + CEUS + Abdominal MRI with Contrast	1.12%	5.36%	1.12%	1.12%	1.12%
Abdominal Ultrasound + Abdominal MRI with Contrast + Abdominal Ultrasound + CEUS	1.12%	5.36%	1.12%	1.12%	1.12%
Abdominal MRI with Contrast + CEUS	1.12%	5.36%	1.12%	1.12%	1.12%
Abdominal Ultrasound + CEUS + PET	0.75%	3.57%	0.75%	0.75%	0.75%
Abdominal Ultrasound + CEUS + Abdominal MRI	0.75%	3.57%	0.75%	0.75%	0.75%
Abdominal CT + Abdominal MRI + CEUS	0.37%	1.79%	0.37%	0.37%	0.37%
Abdominal CT + Abdominal MRI with Contrast + CEUS	0.37%	1.79%	0.37%	0.37%	0.37%
Abdominal Ultrasound + CEUS + MR Cholangiography	0.37%	1.79%	0.37%	0.37%	0.37%
Abdominal Ultrasound + CEUS + Abdominal CT with Contrast	0.37%	1.79%	0.37%	0.37%	0.37%
Abdominal Ultrasound + CEUS + Biopsy	0.37%	1.79%	0.37%	0.37%	0.37%

Economic Results

Adopting the optimized pathway (BEST-CASE scenario) would result in cost savings ranging from 38.22% to 51.15% for the management of 688,811 individuals with potential incidental FLLs, assuming the Italian NHS perspective

Economic assessment related to CEUS implementation

Economic impact for the management of 688,811 national patients	
“As Is” 1 Scenario	150,111,505.98 €
BEST CASE Scenario	73,326,724.18 €
Difference (Euro)	-76,784,781.80 €
Difference (%)	-51.15%
“As Is” 2 Scenario	138,674,854.79 €
BEST CASE Scenario	73,326,724.18 €
Difference (Euro)	-65,348,130.61 €
Difference (%)	-47.12%
“As Is” 3 Scenario	118,697,284.08 €
BEST CASE Scenario	73,326,724.18 €
Difference (Euro)	-45,370,559.89 €
Difference (%)	-38.22%
“As Is” 4 Scenario	128,706,575.09 €
BEST CASE Scenario	73,326,724.18 €
Difference (Euro)	-55,379,850.91 €
Difference (%)	-43.03%

Conclusions

- ❖ Using Real-World Evidence (RWE) and a scenario-based decision-analytic model, this study demonstrated that integrating CEUS into diagnostic pathways for FLLs can significantly improve efficiency and sustainability within the Italian healthcare system, in line with NICE and EFSUMB recommendations [3-4]
- ❖ Wider CEUS implementation can enhance diagnostic capacity, reduce waiting times, and ensure a more appropriate use of healthcare resources



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Efficiency Improvements Results

Procedure execution time was reduced on average by 12–23 minutes per procedure, freeing up healthcare professional time and generating organizational savings between €19.11 and €36.27 per procedure

Across all cases, the Best-Case Scenario enabled earlier lesion characterization, allowing for faster clinical decision-making

Organizational assessment related to CEUS implementation

	Average times for procedures (weighted by population distribution)	Average days to confirmed diagnosis (weighted by population distribution)
“As Is” 1 Scenario	66.96 minutes	40.50 days
“As Is” 2 Scenario	78.54 minutes	42.69 days
“As Is” 3 Scenario	67.32 minutes	70.01 days
“As Is” 4 Scenario	72.94 minutes	56.33 days
BEST CASE Scenario	54.83 minutes	9.28 days
Difference between BEST CASE Scenario and Scenario “As Is” 1	-12.13 minutes (-18%)	-31.22 days (-77%)
Difference between BEST CASE Scenario and Scenario “As Is” 2	-23.71 minutes (-30%)	-33.41 days (-78%)
Difference between BEST CASE Scenario and Scenario “As Is” 3	-12.49 minutes (-19%)	-60.72 days (-87%)
Difference between BEST CASE Scenario and Scenario “As Is” 4	-18.11 minutes (-25%)	-47.04 days (-84%)

References

- [1] Algarni AA, Aishuhri AH, Alonazi MM, et al. Focal liver lesions found incidentally. *World J Hepatol* 2016; 8(9): 446
- [2] Westwood ME, Joore MA, Grutters JPC, et al. Contrast-enhanced ultrasound using SonoVue® (sulphur hexafluoride microbubbles) compared with contrast-enhanced computed tomography and contrast-enhanced magnetic resonance imaging for the characterisation of focal liver lesions and detection of liver metastases: a systematic review and cost-effectiveness analysis. *Health Technol Assess* 2013;17(16).
- [3] National Institute for Health and Clinical Excellence - NICE. SonoVue (sulphur hexafluoride microbubbles) – contrast agent for contrast-enhanced ultrasound imaging of the liver. NICE diagnostic guidance 5. August 2012
- [4] Dietrich CF, Nolsae CP, Barr RG, et al. Guidelines and Good Clinical Practice Recommendations for Contrast-Enhanced Ultrasound (CEUS) in the Liver-Update 2020 WFUMB in Cooperation with EFSUMB, AFSUMB, AIUM, and FLAUS. *Ultrasound Med Biol*. 2020 Oct;46(10):2579-2604.

