International Journal of Gastroenterology
2025, Vol. 9, No. 2, pp. 122-133
https://doi.org/10.11648/j.ijg.20250902.15

Review Article

Commercialization of Elastography in India: A Critical Analysis of Screening Practices and Healthcare Policy Implications

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Abstract

Background: The elastography market in India has experienced unprecedented growth and is projected to reach significant valuations by 2030 as part of the broader Asia-Pacific expansion. This growth coincides with India's integration of NAFLD screening into the National Programme for Non-Communicable Diseases (NP-NCD), creating opportunities for both appropriate clinical use and commercial exploitation of these devices. *Objective:* This review critically examines the commercialization of elastography in the Indian healthcare context, focusing on the disconnect between evidence-based guidelines and current screening practices, particularly in corporate wellness programs and pharmaceutical industry partnerships. *Methods:* We conducted a systematic analysis of Indian clinical studies, market data, government health policies, and commercial screening programs, with specific attention to the prevalence of NAFLD, regulatory frameworks, and healthcare accessibility challenges unique to India. *Results:* Indian validation studies established a FibroScan cutoff of 12 kPa for F3/4 fibrosis (AUROC 0.93-0.95). However, primary screening using the Community-Based Assessment Checklist (CBAC) showed poor performance (AUC 0.59), creating implementation gaps exploited by commercial screening programs. Pharmaceutical partnerships following NorUDCA approval have intensified patient-identification schemes often exceeding evidence-based indications *Conclusions:* Successful elastography implementation in India requires strengthening regulatory oversight, improving healthcare worker training, and establishing clear guidelines that distinguish between appropriate clinical use and commercial patient-identification schemes.

Keywords

Elastography, India, NAFLD, CBAC, Healthcare Policy, Commercial Screening, Regulatory Oversight

1. Introduction

India's healthcare landscape presents unique challenges and opportunities for advanced diagnostic technologies, such as elastography. With a population exceeding 1.4 billion and rapidly increasing rates of metabolic diseases, India has become a focal point for medical technology commercialization [1, 2]. The integration of Non-Alcoholic Fatty Liver Disease (NAFLD) screening into India's National Programme for Prevention & Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) in February 2021 has created both legitimate clinical demand and commercial opportunities that may not always align with public health interests [3, 4]. The prevalence of NAFLD in India ranges from 20-30%,

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Received: 27 August 2025; **Accepted:** 8 September 2025; **Published:** 26 September 2025

affecting an estimated 188 million individuals, most of whom remain undiagnosed until significant liver damage occurs [5, 6]. This massive undiagnosed population has attracted considerable commercial interest from both diagnostic device manufacturers and pharmaceutical companies for the development of NAFLD therapeutics. The challenge lies in distinguishing between evidence-based clinical implementation and commercially driven screening programs that may not serve the patients' best interests. India's healthcare infrastructure presents additional complexities, with a dual system comprising government-funded primary healthcare delivered through Accredited Social Health Activist (ASHA) workers and a rapidly expanding private sector. This structure creates vulnerabilities to inappropriate commercialization while also offering opportunities for innovative screening approaches if properly regulated and implemented [7, 8]. The commercialization of elastography in India exemplifies the broader tension between technological innovation and healthcare equity. While elastography offers valuable diagnostic capabilities, its deployment must align with India's public health priorities rather than commercial imperatives. The current integration of NAFLD screening into NP-NCD using the Community-Based Assessment Checklist (CBAC) reveals both the potential and limitations of systematic screening approaches in resource-constrained settings [9, 10].

2. Methods

This critical policy analysis employed a multidimensional framework incorporating clinical evidence evaluation, market analysis, policy assessment, and commercial practice investigation. Unlike systematic reviews, this analysis focused on policy implications and implementation challenges specific to the Indian healthcare context. We examined peer-reviewed articles on elastography applications in Indian populations through PubMed, Scopus, and Indian medical journals using the terms "elastography," "FibroScan," "liver stiffness," "NAFLD," and "India" (2010-2024). Commercial data were obtained from Grand View Research, IMARC Group, Data Bridge Market Research, Credence Research, and Zion Market Research, focusing on the Asia-Pacific elastography market dynamics. Official documents from the Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare policies, and National Program for Non-Communicable Diseases (NPCDCS) guidelines were analyzed. Analysis of publicly available information on corporate screening programs, pharmaceutical partnerships, and commercial elastography deployment strategies.

2.1. Inclusion and Exclusion Criteria

Inclusion Criteria:

1) Studies conducted in Indian populations or with direct relevance to Indian healthcare Government policy documents and regulatory guidelines from Indian authorities
2) Commercial data specific to the Indian or Asia-Pacific elastography market
3) Clinical validation studies of elastography techniques in Indian patient populations
4) Market analyses published between 2015-2024 to capture recent commercialization trends

Exclusion Criteria:

1) Studies without relevance to the Indian healthcare context Commercial data without regional specificity
2) Opinion pieces without supporting data
3) Studies focused solely on technical development without clinical application context

2.2. Data Extraction and Analysis

We extracted data on diagnostic performance, validation studies, and clinical outcomes from Indian elastography research, focusing on studies that validated cut-off values and compared techniques. Commercial data were analyzed to determine growth patterns, market drivers, and competitive landscapes in India. We examined pricing, accessibility, and technology adoption in the healthcare sector. Government policies and regulatory guidelines were analyzed to understand the integration of NAFLD screening and elastography into India's healthcare system. We examined commercial screening programs and marketing strategies to identify patterns of elastography utilization.2.3. Quality Assessment and Evidence Grading Clinical studies were assessed using quality criteria for diagnostic accuracy. Evidence quality was graded with a focus on Indian population validation and healthcare settings, and market data quality was evaluated based on methodology transparency, sample sizes, and consistency across research providers. Regulatory and policy documents were assessed for their comprehensiveness and implementation feasibility.

3. Results

The elastography market in India is experiencing exceptional growth within the Asia-Pacific region. Private healthcare expenditure rose from USD 56 billion in 2014 to USD 60.8 billion in 2015, supporting the adoption of advanced diagnostic technology [11, 12]. Government healthcare investment has similarly grown, with India and China showing high increases during 2010-2015, supporting medical technology integration [13, 14]. India's medical tourism industry has enhanced the adoption of advanced diagnostics, including elastography, to attract international patients [15, 16]. Global market players and local manufacturing have reduced device costs, making elastography more accessible [17-20]. Perusal of data made us look into clinical

evidence, government screening policy, the emergence of the prevailing commercial model, and the ethical, evidence-based models.

3.1. Clinical Evidence in Indian Populations

Indian clinical research has provided important validation data for the application of elastography. Table 1 summarizes the key validation studies conducted on Indian populations. Studies have consistently demonstrated excellent diagnostic performance for significant fibrosis (F≥3) and cirrhosis (F4) detection, with AUROC values exceeding 0.90. The validated 12 kPa cutoff for F3/4 fibrosis provides India-specific reference values. (Table 1)

Table 1. Elastography Validation Studies in Indian Populations.

Study	Population	N	Technique	Cutoff (kPa)	AUROC	Clinical Application
Pathik et al. [19]	Western India NAFLD	110	FibroScan	12.0 (F≥3)	0.93	High-risk NAFLD fibrosis
Kumar et al. [20]	North India Mixed	156	FibroScan	11.5 (F≥2)	0.89	Chronic liver disease
Wong et al. [22]	Multi-center	246	FibroScan	12.1 (F4)	0.95	Cirrhosis detection
Sarin et al. [24]	Multi-regional	198	Multiple	Variable	0.91	Fibrosis staging

3.2. Government Policy and Primary Screening Challenges

The integration of NAFLD screening into India's NP-NCD program reveals significant implementation challenges [21-25]. The Community-Based Assessment Checklist (CBAC) by ASHA workers showed poor performance for NAFLD detection, with an AUC of 0.59 (0.53-0.65) [26, 27]. Despite 70% of patients scoring above the testing threshold of 4, the sensitivity remains inadequate for effective screening [28, 29]. This limitation has created a gap between primary screening and tertiary care diagnostics, allowing commercial entities to position themselves as intermediaries [30, 31].

3.3. Pharmaceutical-Technology Partnerships (Commercial Model)

The approval of Shilpa Medicare's Nor-Ursodeoxycholic Acid (NorUDCA) tablets by the CDSCO as the world's first approved NAFLD therapy has intensified commercial dynamics [32, 33]. The company's marketing strategy emphasizes FibroScan validation in clinical trials while simultaneously supporting screening programs that identify potential treatment candidates [34, 35]. Companies such as Mankind Pharma have conducted free liver screening camps in cities such as Varanasi and Moradabad, serving the dual purposes of brand building and patient identification [36, 37]. These programs often employ liberal screening criteria, targeting individuals with minimal risk factors without appropriate pre-test counseling regarding limitations and potential consequences [38, 39]. This is contrary to evidence-based applications (Figure 1).

3.4. Evidence-based Model

Establishes that elastography should be clinical indication-driven rather than used for general screening, emphasizing risk-stratified approaches and integration with existing healthcare infrastructure. It provides a three-tier system: a) primary level: Enhanced CBAC with biomarkers; b) secondary level: elastography as confirmatory testing; and c) tertiary level: advanced applications for complex cases with quality assurance components and standards of competency as an alternative to current commercial practices. The evidence-based model offers policymakers and healthcare administrators a structured approach that balances technological benefits with resource constraints and clinical appropriateness issues. It specifically addresses the gap between primary screening inadequacies (CBAC performance issues) and commercial exploitation by proposing systematic integration within established healthcare delivery systems rather than stand-alone commercial programs (Figure 1). Although the Liver Fibrosis Assessment is based on the most well-validated application for elastography, it is the assessment of liver fibrosis in chronic liver disease. The World Federation for Ultrasound in Medicine and Biology (WFUMB) guidelines only recommend its use in distinguishing significant (F≥2) or advanced fibrosis (F≥3) from non-significant fibrosis (F0-F1) and highlight the current limitations in differentiating between individual fibrosis stages [40-42].

Figure 1. *NAFLD Screening Approaches. -Commercial model vs Evidence based model.*

Table 2. *Evidence-Based Indications for Elastography in Professional Society Guidelines (38-48).*

Application	Technique	Professional Society	Recommendation Level	Evidence Quality
ESTABLISHED INDICATIONS				
Liver fibrosis staging (F≥2 vs F0-F1)	TE, pSWE, 2D- SWE	WFUMB, EFSUMB, SRU	Strong recommendation	High quality evidence
Liver cirrhosis detection (F4 vs F0-F3)	TE, pSWE, 2D- SWE	WFUMB, EFSUMB, SRU	Strong recommendation	High quality evidence
Breast lesion characterization (adjunct to B-mode)	Strain, SWE	WFUMB, EFSUMB	Conditional recommendation	Moderate quality evidence
CONDITIONAL INDICATIONS				
Portal hypertension screening	TE, SWE	WFUMB	Conditional recommendation	Low quality evidence
Thyroid nodule assessment	SWE	WFUMB	Conditional recommendation	Low quality evidence
INVESTIGATIONAL				
NAFLD screening in asymptomatic patients	TE, SWE	-	Not recommended for screening	Very low quality evidence
General population liver screening	TE, SWE	-	Not recommended	Very low quality evidence
Musculoskeletal screening	SWE	-	Investigational only	Very low quality evidence

TE: Transient Elastography; pSWE: Point Shear Wave Elastography; 2D-SWE: Two-dimensional Shear Wave Elastography; WFUMB: World Federation for Ultrasound in Medicine and Biology; EFSUMB: European Federation of Societies for Ultrasound in Medicine and Biology; SRU: Society of Radiologists in Ultrasound

Figure 2. *Financial Summary of NAFLD screening camps under commercial model.*

Analysis of commercial screening practices reveals several concerning patterns: *a) Liberal Patient Selection:* Programs often target individuals with minimal risk factors, such as elevated BMI or diabetes, without appropriate counseling about test limitations and potential consequences [43-47]. *b) Aggressive Result Interpretation:* Borderline liver stiffness measurements are frequently characterized as requiring immediate intervention, despite limited validation for screening in asymptomatic populations [48-53]. *c) Direct Treatment Pathways:* Positive screening results often lead directly to specialist referrals or treatment recommendations, bypassing the careful clinical assessment required by evidence-based medicine [54, 55]. *d) Corporate Wellness Integration:* Mobile diagnostic units and health camps increasingly include elastography as a premium service, often without established referral pathways for positive results [56, 57] (Figure 2). Data show that coupled with these two contradictory models are technical issues of device standardization with different technical specifications, making result comparison and clinical standardization difficult [58, 59]. Training infrastructure also varies significantly across India's healthcare landscape, from metropolitan tertiary centers to rural facilities [60, 61]. There are also studies pointing at issues of elastography reliability, including patient obesity, ascites, and acute inflammation, conditions with high prevalence in Indian populations [62, 63]. All these factors, in addition to the poor performance of CBAC at the primary level, create pressure for alternative screening approaches, with huge gaps remaining between community screening and tertiary care elastography capabilities [64, 65].

3.5. Regulatory Environment and Oversight

India's medical device regulatory landscape shows both progress and its limitations. Most elastography systems are approved based on substantial equivalence to existing devices rather than independent clinical efficacy data for specific Indian populations [66, 67]. The Central Drugs Standard Control Organization (CDSCO) has been strengthening medical device regulations, but gaps remain in post-market surveillance and inappropriate utilization monitoring [68, 69]. Current regulations inadequately address conflicts of interest in screening programs sponsored by pharmaceutical companies and diagnostic chains [70, 71]. Limited systematic monitoring of device utilization patterns and clinical outcomes creates regulatory blind spots regarding inappropriate use, and there is an urgent need for a robust regulatory framework [72, 73] (Figure 3).

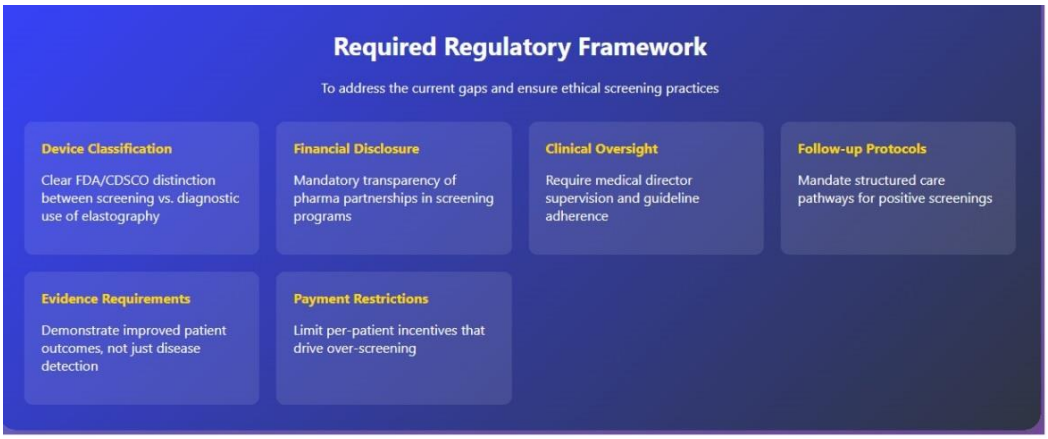

Figure 3. *Desirable Regulatory Framework to address in screening NAFLD.*

Figure 4 ***x.*** *NAFLD Screening Camp business cum Commercical model.*

3.6. Economic and Access Considerations

While decreasing costs have improved accessibility, elastography remains expensive relative to India's healthcare spending patterns, potentially limiting access [74, 75]. The predominance of out-of-pocket healthcare payments in India makes inappropriate screening particularly problematic from a resource allocation perspective [76, 77]. Commercial screening programs may exacerbate healthcare inequities by providing premium services to affluent populations, while basic care remains inadequate for many [78, 79]. Resources devoted to inappropriate screening could be better allocated to evidence-based interventions with demonstrated population health benefits [80, 81]. The currently practiced screening models in the form of camps run by pharmaceutical companies, doctors, and technology companies create a business nexus only with no significant patient benefit, rather a burden for the common man and a fear of impending liver disease (Figure 4).

4. Discussion

The analysis revealed a significant disconnect between evidence-based elastography applications and commercial implementation practices in India. While clinical studies have validated specific applications, particularly liver fibrosis assessment in high-risk populations, commercial expansion has exceeded these evidence boundaries [82, 83]. The approval of India's first NAFLD therapy (NorUDCA) has created new commercial dynamics that may prioritize patient identification over clinical appropriateness [84, 85]. This development exemplifies how pharmaceutical commercialization can influence diagnostic technology deployment in ways that may not align with optimal clinical practices or public health priorities. India's dual healthcare system creates unique challenges in the integration of elastography. The poor performance of primary screening tools (CBAC) administered by ASHA workers highlights the need for improved risk stratification approaches [86, 87]. Seventy% of participants scored >4 (referral threshold), yet the sensitivity remained inadequate. This paradox reflects the fundamental flaw in the CBAC design: the scoring system captures common metabolic risk factors (diabetes, hypertension, obesity) that are highly prevalent in the Indian population but poorly predictive of NAFLD specifically. The high referral rate (70% positive screens) combined with low diagnostic accuracy creates a "screening trap" where most positive results are false positives, overwhelming secondary healthcare facilities with unnecessary referrals while missing significant numbers of patients with actual NAFLD. High false-positive rates strain secondary healthcare capacity and reduce patient confidence in screening programs. Furthermore, there is a limited correlation with actual NAFLD risk in validation studies, demonstrating a disconnect between screening tool design and disease pathophysiology. This gap between community-level screening and tertiary care capabilities creates opportunities for commercial exploitation that may not optimally serve patient interests. The expansion of elastography into corporate wellness programs raises questions regarding patient selection, follow-up care, and clinical oversight [88, 89]. These programs often operate outside the healthcare system, potentially compromising care quality. India's regulatory framework has limitations in addressing the inappropriate commercialization of medical technologies [90, 91]. Although the CDSCO has improved the device approval process, post-market surveillance remains inadequate. The integration of NAFLD screening into national health programs represents positive policy development; however, implementation challenges require better risk stratification approaches [92, 93]. The limitations of primary screening tools necessitate evidence-based alternatives between primary and tertiary care. Elastography screening raises ethical concerns regarding informed consent and resource allocation [94, 95]. Patients often misunderstand test limitations, especially in commercial settings, where financial incentives affect communication. Partnerships between diagnostic and pharmaceutical companies may compromise clinical decisions [96, 97], creating pressure to maximize positive findings over conservative approaches. Based on the analysis, several key recommendations emerge for optimizing elastography implementation in India: *a) Strengthening Primary Screening:* Development and validation of improved primary screening tools specifically for Indian populations, potentially incorporating simple biomarkers such as FIB-4 alongside clinical risk factors [98, 99]. *b) Establish Clear Clinical Pathways:* Standardized protocols for elastography referral should be created to ensure appropriate patient selection and comprehensive follow-up care [100, 101]. *c) Enhanced Regulatory Oversight:* Stronger supervision of commercial screening programs should be implemented, including mandatory disclosure of financial relationships and independent medical oversight requirements [102, 103]. *d) Improve Training Standards:* Develop national competency standards for elastography interpretation and establish certification requirements for healthcare providers across different practice settings [105, 104].

Several research priorities emerge from this analysis: a) Large-scale studies validating elastography cutoff values in diverse Indian populations, considering genetic, dietary, and environmental factors specific to different regions [106, 107]. b) Comprehensive cost-effectiveness analyses of different screening strategies in the Indian healthcare context, considering both clinical outcomes and resource utilization [108, 109]. c) Research optimal approaches for integrating elastography with existing healthcare infrastructure and workforce capabilities, particularly at the primary and secondary care levels [110, 111]. d) Need for a comprehensive policy framework that addresses elastography implementation while preventing inappropriate commercialization: a) *Professional Guidelines:* Development of India-specific guidelines for

elastography use that account for local disease prevalence, healthcare infrastructure, and resource constraints [112, 113]. *b) Quality Assurance:* Implementation of systematic quality control measures and appropriate use criteria that ensure clinical standards while preventing commercial exploitation [114, 115]. *c) Educational Initiatives:* Comprehensive training programs for healthcare providers at all levels, emphasizing both technical competency and appropriate clinical application [116, 117].

Limitations and Future Directions

This study has several limitations. Commercial practice data may be incomplete because of limited public disclosure requirements. Long-term outcome data for elastography-based screening in the Indian population remain limited. The rapidly evolving regulatory environment may affect the relevance of the current findings. Future research should focus on prospective studies evaluating clinical outcomes from different elastography implementation strategies, health economic analyses specific to Indian healthcare settings, and the development of appropriate regulatory frameworks for emerging medical technologies [118-121].

5. Conclusions

The commercialization of elastography represents both a medical advance and caution regarding rapid technology adoption challenges. While elastography has proven utility in liver fibrosis assessment and breast lesion characterization, its commercial success has led to inappropriate expansion into mass screening. The elastography market is expected to grow to USD 2.28 billion in 2024 with a 7.32% CAGR (1), reflecting clinical demand but raising overutilization concerns. The medical community must balance the benefits of technology while avoiding inappropriate screening and overdiagnosis. Key recommendations include strict adherence to evidence-based guidelines, enhanced regulatory oversight requiring robust evidence, professional education about appropriate use and limitations, and research investment in standardization and outcome studies. The future success of elastography depends on balancing commercial interests with evidence-based medicine, ensuring that the technology serves patient interests through appropriate use criteria, training, and evidence standards. The commercialization of elastography demonstrates both medical progress and challenges in the adoption of healthcare technology. While proven useful for liver fibrosis and breast lesion assessments, its success has created pressure for inappropriate screening applications. Market growth indicates clinical demand but raises concerns regarding overutilization.

Abbreviations

NPCDCS	National Programme for Prevention & Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke
NPPA	National Pharmaceutical Pricing Authority
NSSO	National Sample Survey Office
OECD	Organisation for Economic Co-operation and Development
ORF	Observer Research Foundation
PHFI	Public Health Foundation of India
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
pSWE	Point Shear Wave Elastography
PvPI	Pharmacovigilance Programme of India
QCI	Quality Council of India
RSSDI	Research Society for Study of Diabetes in India
SRU	Society of Radiologists in Ultrasound
SRMIP	Society of Radiologists and Medical Imaging Professionals of India
SWE	Shear Wave Elastography
TE	Transient Elastography
USD	United States Dollar
WFUMB	World Federation for Ultrasound in Medicine and Biology

Author Contributions

Atul Kapoor is the sole author. The author read and approved the final manuscript.

Conflicts of Interest

The author declares no conflicts of interest.

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