

MARKET UNDERSTANDING OF ENDOSCOPIC ULTRASOUND

Dissertation Submitted to



IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

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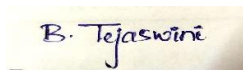
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DECLARATION

I hereby declare that this dissertation titled Market Understanding of Endoscopic Ultrasound is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



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COMPLETION CERTIFICATE

This is to certify that Tejaswini Bathala (IIHMR-U/02/2020-22/0232) in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed her/his internship at Cetas Healthcare during March 22, 2022, to June 19, 2022.

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CERTIFICATE

This is to certify that dissertation titled Market Understanding of Endoscopic Ultrasound is a record of the research work undertaken by Tejaswini Bathala (IIHMR-U/02/2020-22/0232) in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

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ABSTRACT

The global ultrasound endoscope market is expanding at a quicker rate than the endoscope market as a whole. The main purpose of this project is in interest of learning more about the flexible endoscope market, particularly optical endoscopes with ultrasound (EUS), as well as customer dynamics when it comes to purchasing (ultrasound) endoscopic systems.

The objective is to Provide insights on Current unmet needs and customer expectations of flexible endoscope systems, especially ultrasound endoscopes and Purchase dynamics like process followed, key decision makers, factors considered, etc. The research objectives are-To assess the challenges and expectations with current ultrasound endoscopes used in endoscopic ultrasound (EUS); To explore key innovations expected in the area of endoscopy and EUS in particular; To evaluate customer perceptions of key competitors in this space; To understand the purchase process for flexible endoscope systems and EUS systems; To determine the key decision makers involved in the purchase of flexible endoscope systems and EUS systems and To identify the factors driving purchase of flexible endoscope systems and EUS systems. A 60-mins (qualitative) and 45-mins (competitive intelligence) web assisted in-depth-interview (IDI) using a comprehensive discussion guide is the methodology used in the process. The unmet needs and expectations in the usage of EUS, Current brand usage and perception with the Purchase process and purchase dynamics are gathered to get insights on the challenges and expectations with current ultrasound endoscopes used in endoscopic ultrasound. The Fusion EUS imaging/electromagnetic navigational bronchoscopy followed by single-use endoscopes and incorporation of AI/ML are the key innovations that will have the most impact in the future usage of Ultrasound Endoscopes helping in better detection and characterization of polyps/lesions, adenoma, early carcinomas, and dysplastic changes, which tend to get missed in present type of endoscopes.

Key words: Ultrasound endoscope, stakeholder, purchase, availability, CAPEX, AI, ML

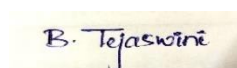
ACKNOWLEDGEMENT

It is great pleasure for me to acknowledge all those who have contributed towards the conception, origin, and nurturing of this project.

It gives me immense pleasure to thank my Industry mentor, **Meghavi Mehta, Manager, Cetas Healthcare** for all her support and constant encouragement during this study. Under her constant guidance, encouragement and positive attitude towards work have instilled more confidence in me than before.

I would also thank my esteemed guide **Dr. Surya Prakash, Associate Professor, IIHMR University** and mentor, **Dr. Saurabh Kumar Banerjee, Dean, School of Pharmaceutical Management, IIHMR University**, for their valuable suggestions, and constant encouragement during this study. It is with warmth and reverence that I acknowledge my indebtedness to them and their outstanding dedication, often far beyond the call of duty.

I am sincerely grateful to **all family members** for their blessing, constant encouragement to educate me to this level. There are countless other names flashed across my mind when I enlisted those who have been grateful to us. It would rather be impracticable to mention each of them separately, but I am conscious of our obligation and thank them collectively.



Tejaswini Bathala

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CONTENTS

Chapter	Title	Page no.
1	Introduction	11
	1.1 About Endoscopy and Endoscope	11
	1.2 Types of endoscopies	12
	1.3 Latest techniques in endoscopy technology	13
	1.4 Why is Endoscopic Ultrasound (EUS) used?	14
	1.5 Components of ultrasound endoscope	15
	1.6 Types of Endoscopic Ultrasound	18
	1.7 Advantages of ultrasound endoscopes over optical endoscopes	21
	1.8 Limitations of endoscopic ultrasound	21
	1.9 Additional information	22
	1.10 New techniques/recent innovations in Ultrasound Endoscopes	24
	1.11 Current Competitive Landscape in the Endoscopic Ultrasound Market	28
	1.12 Ultrasound Endoscope market	29
2	Literature review	31
3	Methodology	35
4	Results	37
	4.1 Current Practice	37
	4.1.1 Current EUS practice and future outlook – gastroenterology	37
	4.1.2 Current EBUS practice and future outlook – pulmonology	37
	4.1.3 Reasons to prefer E(B)US over traditional optical endoscopes- Clinicians/HODs (Users)	38
	4.1.4 Drivers for adoption of an E(B)US system- Clinicians/HODs (Intenders)	39
	4.1.5 Barriers for adoption of an E(B)US system- Clinicians/HODs (Intenders)	39
	4.2 Unmet Needs	40
	4.2.1 Challenges with currently used E(B)US- Clinicians/HODs (Users)	40
	4.2.2 Challenges with currently used gastroscope/bronchoscope- Clinicians/HODs (Intenders)	40
	4.3 Purchase Considerations	41
	4.3.1 Key purchase factors for flexible endoscopes/E(B)US (Unaided)- Clinicians/HODs & Purchasers	41
	4.3.2 Key purchase factors for flexible endoscopes/E(B)US (Aided)- Clinicians/HODs & Purchasers	41

	4.3.3 Impact of cost of maintenance/service contracts on purchase decision- Purchasers	42
	4.3.4 Key stakeholders involved in purchase decisions- Clinicians/HODs & Purchasers	42
	4.3.5 Preferred Payment Model for flexible endoscopes/E(B)US- Purchasers	43
5	Discussion	44
	5.1 Awareness about the product	44
	5.2 Challenges	44
	5.3 Brand Satisfaction, Likes and Dislikes and Areas of Improvement	45
	5.4 Purchase process	47
	5.5 Preferred Payment Model for flexible endoscopes/E(B)US	50
	5.6 Key innovations in flexible endoscopes that will be impactful in future	50
6	Conclusion	52
7	References	54
8	Annexure	56

LIST OF FIGURES

1. Figure 1.1: Rigid endoscope.....	11
2. Figure 1.2: Flexible endoscope.....	11
3. Figure 1.3: Responsive Insertion Technology (RIT) Endoscope.....	12
4. Figure 1.4: Picturing Endoscopy.....	15
5. Figure 1.5: Ultrasound Gastroscope.....	16
6. Figure 1.6: Fine Needle Aspiration.....	17
7. Figure 1.7: Ultrasound processor.....	17
8. Figure 1.8: Radial Scanning Endoscope.....	18
9. Figure 1.9: Linear array Endoscope.....	19
10. Figure 1.10: Ultrasound Miniprobe.....	20
11. Figure 1.11: B-Mode Imaging.....	23
12. Figure 1.12: Forward viewing angle in Ultrasound Endoscope.....	27
13. Figure 1.13: Current Competitive Landscape in the Endoscopic Ultrasound Market.....	28
14. Figure 4.1: Graph representing the Current EUS practice.....	37
15. Figure 4.2: Graph representing the Current EBUS practice and future outlook – pulmonology.....	38
16. Figure 4.3: Graph representing the Reasons to prefer E(B)US over traditional optical endoscopes- Clinicians/HODs (Users).....	38
17. Figure 4.4: Graph representing the Drivers for adoption of an E(B)US system- Clinicians/HODs (Intenders).....	39
18. Figure 4.5: Graph representing the Barriers for adoption of an E(B)US system -Clinicians/HODs (Intenders).....	39
19. Figure 4.6: Graph representing the Challenges with currently used E(B)US- Clinicians/HODs (Users).....	40
20. Figure 4.7: Graph representing the Challenges with currently used gastroscope/bronchoscope- Clinicians/ HODs (Intenders).....	41
21. Figure 4.8: Graph representing the Key purchase factors for flexible endoscopes/E(B)US (Unaided)- Clinicians/HODs & Purchasers.....	41
22. Figure 4.9: Graph representing the Key purchase factors for flexible endoscopes/E(B)US (Aided)- Clinicians/HODs & Purchasers.....	42
23. Figure 4.10: Graph representing the Impact of cost of maintenance/service contracts on purchase decision- Purchasers.....	42
24. Figure 4.11: Graph representing the Key stakeholders involved in purchase decisions- Clinicians/HODs & Purchasers.....	43
25. Figure 4.12: Graph representing the Preferred Payment Model for flexible endoscopes/E(B)US- Purchasers.....	43

ABBREVIATIONS

E(B)US: Ultrasound Endoscope

GI: Gastrointestinal

RIT: Responsive Insertion Technology

ERCP: Endoscopic Retrograde Cholangiopancreatography

EMR: Endoscopic Mucosal Resection

NBI: Narrow Band Imaging

FNA: Fine Needle Aspiration

FNB: Fine Needle Biopsy

JAG: Joint Advisory Group

CE-EUS: Contrast-Enhanced endoscopic ultrasound

THE: Tissue harmonic echo

n-CLE: Needle-based confocal laser endomicroscopy

FV-EUS: Forward viewing EUS

CAGR: Compound Annual Growth Rate

OGD: Esophagogastroduodenoscopy

IDI: In-depth-interview

CI: Competitive Intelligence

CAPEX: Capital Expenditure

AI: Artificial Intelligence

ML: Machine Learning

1. INTRODUCTION

1.1 About Endoscopy and Endoscope:

Endoscopy is a minimally invasive diagnostic medical procedure directly visualizing any part of the inside of the body. It is a long, tube-like optical viewing instrument with a lens and light source, used to view the internal body organs. It may be inserted through the mouth, anus, or small cut in the skin, which the endoscope can then be passed through. ^[1]

Endoscopic procedures are used to diagnose ailments, to screen for diseases such as colorectal cancer, to remove foreign bodies, and to treat many diseases and conditions of the GI tract, bile duct and pancreas ^[2]

An endoscope consists of following components:

- Rigid or flexible endoscope
- A light delivery system to illuminate the organ or object under inspection. The light source is normally outside the body and the light is typically directed via an optical fibre system
- A lens system transmitting the image to the viewer from the fiberscope an additional channel to allow entry of medical instruments or manipulators

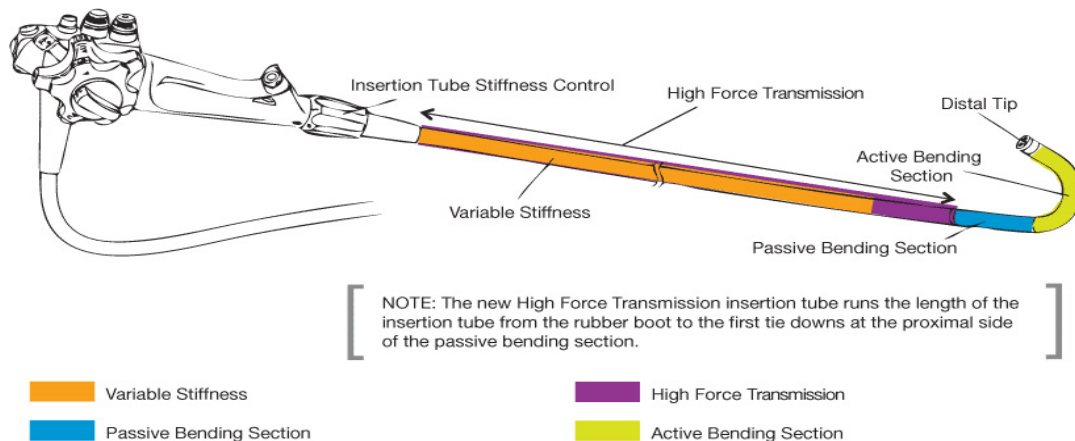
Figure 1.1: Rigid Endoscope



Figure 1.2: Flexible endoscope



Figure 1.3: Responsive Insertion Technology (RIT) Endoscope



1.2 Types of endoscopies: [3]

Type	Area examined	Where scope is inserted	Speciality (Uses)
Arthroscopy	Joints	Through a small incision near the examined joint	Orthopedic surgeon
Bronchoscopy	Lungs	Into the nose or mouth	Pulmonologist or thoracic surgeon
Colonoscopy	Colon	Through the anus	Gastroenterologist or proctologist
Cystoscopy	Bladder	Through the urethra	Urologist
Enteroscopy	Small intestine	Through the mouth or anus	Gastroenterologist
Hysteroscopy	Inside of the uterus	Through the vagina	Gynecologists or gynecological surgeons
Laparoscopy	Abdominal or pelvic area	Through a small incision near the examined area	Various types of surgeons
Laryngoscopy	Larynx	Through the mouth or nostril	Otolaryngologist, also known as an ear, nose, and throat (ENT) doctor
Mediastinoscopy	Mediastinum, the area between the lungs	Through an incision above the breastbone	Thoracic surgeon
Sigmoidoscopy	Rectum and the lower part of the large intestine, known as the sigmoid colon	Into the anus	Gastroenterologist or proctologist
Thoracoscopy, also known as a Pleuroscopy	Area between the lungs and the chest wall	Through a small incision in the chest	Pulmonologist or thoracic surgeon
Upper gastrointestinal endoscopy, also known as an Esophagogastroduodenosc	Esophagus and upper intestinal tract	Through the mouth	Gastroenterologist

opy or gastroscopy			
Ureteroscopy	Ureter	Through the urethra	Urologist

1.3 Latest techniques in endoscopy technology: ^[4]

1. Capsule endoscopy

- When other tests are inconclusive, a novel procedure known as a capsule endoscopy may be done. A capsule endoscopy involves swallowing a tiny camera-filled pill. The capsule creates millions of photos of the intestines as it goes through your digestive system painlessly and without causing you any discomfort.

2. Endoscopic retrograde cholangiopancreatography (ERCP)

- For diagnosing or treating issues with the bile and pancreatic ducts, ERCP combines X-rays with upper GI endoscopy.

3. Chromoendoscopy

- In chromoendoscopy, the lining of the intestine is stained or dyed specifically for use during an endoscopic treatment. The color makes it easier for the doctor to see if the intestinal lining is abnormal.

4. Endoscopic mucosal resection (EMR)

- EMR is a method that aids medical professionals in removing malignant tissue from the digestive system. In EMR, a liquid is injected beneath the aberrant tissue using a needle that is inserted through the endoscope. This makes it easier to remove the malignant tissue by separating it from the surrounding layers.

5. Narrow band imaging (NBI)

- To aid increase contrast between the arteries and the mucosa, NBI employs a specific filter. The mucosa is the digestive system's interior lining.

6. Endoscopic ultrasound (EUS)

- EUS combines an endoscopy with an ultrasonography. This enables medical professionals to view organs and other structures that are typically hidden during a standard endoscopy.
- Traditional ultrasound images must be transmitted from outside the body, while EUS images are often more accurate and detailed.
- The tissue can then be removed from the organ or structure and examined under a microscope using a fine needle. The term for this process is fine needle aspiration.

- An ultrasound transducer has been added to the endoscope used for EUS, making it like a standard endoscope.
- Endoscopic ultrasonography has been shown to be more accurate than a CT scan in detecting chronic pancreatitis. It is also the most sensitive imaging method.
- Endoscopic ultrasound (EUS) also called echoendoscopes

1.4 Why is Endoscopic Ultrasound (EUS) used?

EUS is used to detect the origin of symptoms like chest pain or abdominal pain, to assess the severity of lung and digestive tract disorders, and to assess the results of imaging tests like a CT or MRI.

EUS may help in the evaluation of:

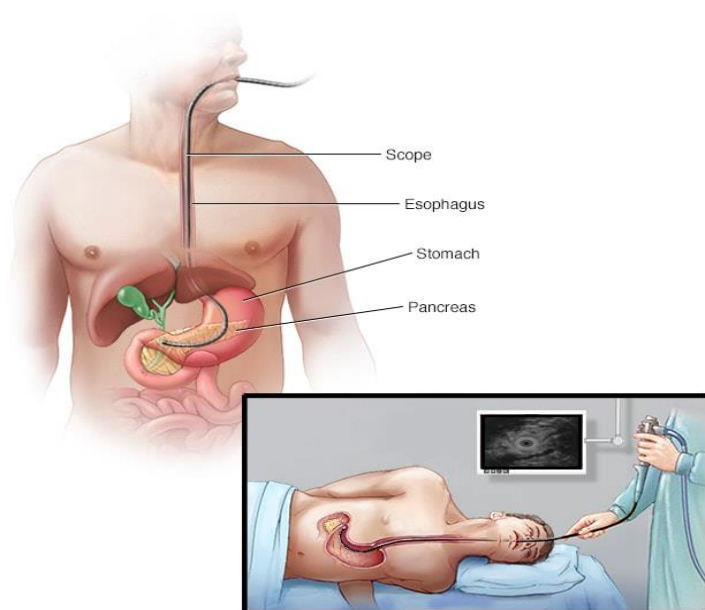
- Cancer of the colon, esophagus, lung, pancreas, or stomach, and ampullary and rectal cancers
- Lymphoma
- Barrett's esophagus
- Neuroendocrine tumors
- Pancreatitis and pancreatic cysts
- Bile duct stones
- Sarcoidosis

An EUS can:

- Assess how deeply a tumor penetrates your abdominal wall.
- Determine the extent (stage) of the disease.
- Determine whether the disease has spread (metastasized) to your lymph nodes or other organs.
- Provide precise information about non-small cell lung cancer cells, to guide treatment.
- Assess abnormal findings from imaging tests, such as pancreatic cysts.

EUS is performed on an outpatient basis and is well-tolerated by most people.

Figure 1.4: Picturing Endoscopy



1.5 Components of ultrasound endoscope: ^[5]

Ultrasound endoscope (EUS) consists of ultrasound processor, connected to specific echoendoscopes, either with radial or linear transducer design coupled at the tip of an endoscope. Scopes are also connected to a standard video processor.

1. Echoendoscopes

- Timed, high-amplitude voltages from the transmitter activate the transducer components. Piezoelectric crystals in this transducer respond to applied voltage by changing form.
- Sound waves are produced by crystals using electrical energy (mechanical energy). The specific tissue under assessment will be exposed to sound waves, which will then be reflected and picked up by the transducer and transformed into electrical signals by the reverse piezoelectric effect.
- Different amplitudes of sound wave signals reflected from the tissues or organs being studied are the cause of the differences in picture glare.
- The transducers' crystal content is tunable, allowing them to change the focal distance and apply tissue harmonic augmentation to boost the image's resolution.
- As the number of piezoelectric elements rises, so does the image's lateral resolution.

- The most popular range for echoendoscope frequencies is between 5 and 12 MHz. Higher frequencies improve resolution while limiting the ultrasonic beam's ability to penetrate.
- Three major manufacturers are (both radial and linear echoendoscopes) –
 - Fujifilm Endoscopy (Fujifilm Europe GmbH, Germany),
 - Olympus (Olympus Europa SE and Co., KG), and
 - Pentax (Pentax Europe GmbH, Hamburg, Germany)

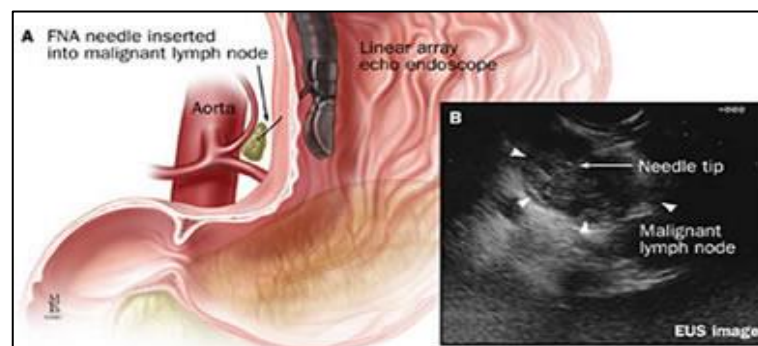
Figure 1.5: Ultrasound Gastroscope



2. **Fine Needle Aspiration (FNA) / Fine Needle Biopsy (FNB)** ^[6]

- The clinical utility of FNA/FNB is the cytological identification of local and distant tumor metastasis, through the acquisition of tissue or fluid to diagnose and stage the extent of GI disorders, which can determine tumor stage and affect treatment choices.
- Cysts can be shrunk, tumors can be sampled, and biopsies can be taken using needles and a linear scope.

Figure 1.6: Fine Needle Aspiration



3. **Ultrasound processor**

- To produce the ultrasound image on the monitor, the ultrasound processors decode the electrical signals produced by the echoendoscopes.

- The basic image acquired is what is known as the B-mode, which is a two-dimensional representation of the reflected sound waves.
- New processors have increased the resolution and enabled the use of newer contrast agents, tissue elastography, Doppler/power flow, and other imaging features.
- Contrast-enhanced EUS, which evolved from straightforward power Doppler evaluation with contrast injection to a wideband dedicated transducer and is now commonly referred to as contrast-enhanced harmonic EUS, is made possible with the introduction of contrast agents.
- With the help of harmonic technology, microbubbles in slow-flowing micro vessels can be detected without the use of Doppler-related artifacts.
- Three major manufacturers –
 - Fujifilm Endoscopy (Fujifilm Europe GmbH, Germany),
 - Olympus (Olympus Europa SE and Co., KG), and
 - Hitachi (Hitachi Medical Systems Europe, Zug, Switzerland)

Figure 1.7: Ultrasound processor



1.6 Types of Endoscopic Ultrasound (EUS):

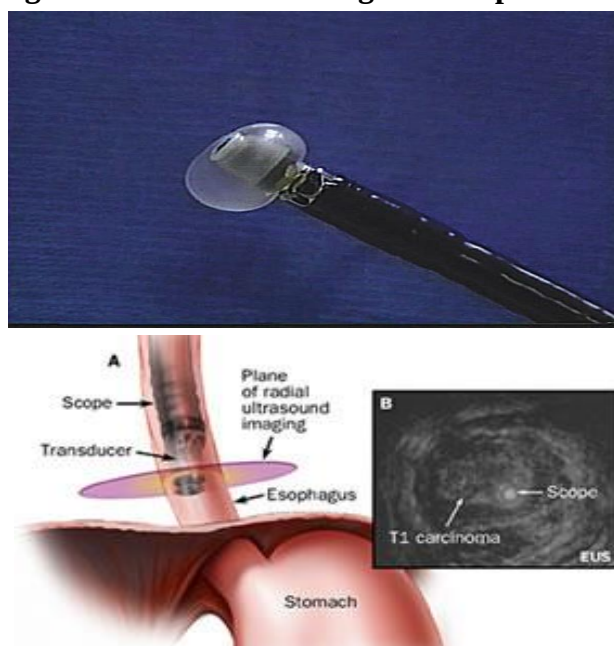
Echoendoscopes are designed using either a radial or curvilinear array system. The format may be mechanical or electronic. The electronic echoendoscope is now more favoured as it contains no moving parts and is thus more durable. The design is essentially that of a modified gastroscope, having both optical video views as well as ultrasound capability. ^[7]

The two types of EUS scopes are as follows: ^[8]

1. Radial scanning echoendoscope:

- The radial type scans in a plane perpendicular to the axis of the scope to produce 360° images like a CT “slice.” The transducer appears as a “bull’s-eye” within the image.
- An oblique viewing lens at the endoscope's tip is located distally to a rotating ultrasonic transducer with a frequency range of 5–20 MHz. A balloon with water inside enables acoustic coupling. Similar to the "slices" produced by CT scanning, the images are cross-sectional in shape and taken perpendicular to the endoscope shaft.
- Radial echoendoscopes are equipped with Doppler technology.
- Although it is possible to evaluate almost identical structures with the linear or curvi-linear EUS, such as the pancreaticobiliary systems and the mediastinum, radial EUS is mostly used for luminal imaging and evaluation of the wall layers of the gastrointestinal tract (division of the thoracic cavity; it contains the heart, thymus gland, portions of the oesophagus and trachea, and other structures)

Figure 1.8: Radial Scanning Endoscope



2. **Linear array or curvi-linear echoendoscope:**

- In the linear array images, one wall of the oesophagus is visible, and the hypoechoic linear structure is parallel to the axis of the scope.
- The scanning plane of electronic linear echoendoscopes is oriented in the same plane as the scope shaft and accessory channel.
- A needle can be inserted through the endoscope's accessory channel, and its path through the oesophagus wall and into lesions can be seen in real time.

- Linear EUS provides a significant added value since it enables real-time tissue sampling and therapeutic applications.
- It has also proven to be a more effective tool for pure diagnostic imaging.

Figure 1.9: Linear array Endoscope



Difference between radial and linear or Curvi-linear ultrasound endoscope:

- The capacity to do fine needle aspiration with the linear echoendoscope is the key distinction between radial and linear echoendoscopes.
- The radial echoendoscope cannot be used for fine needle aspiration (FNA) because the ultrasound beam would pass through the needle at an angle and make it seem as a "dot."
- However, with the linear echoendoscope, the needle travels along the same axis as the ultrasound beam and is therefore fully visible as it is inserted into the desired lesion.

3. Ultrasound Miniprobe: ^[9]

- The Miniprobe high ultrasonic frequency (7.5–30 MHz) and small calibre are what give it exceptional resolution but at the sacrifice of penetration depth.
- The Miniprobe is put into the working channel of a regular endoscope, allowing endoscopy and EUS to be performed simultaneously. The instrument's tiny size enables intraductal biliary or pancreatic ultrasonography as well as the exploration of narrow tumor stenoses. Miniprobe typically produce a radial 360° picture and operate mechanically.
- Advantages - Miniprobe ultrasonography's undeniable benefit is that it enables endoscopy and EUS to be performed in the same session.
- Disadvantages - The poor penetration depth of high frequency Miniprobe ultrasonography is a drawback. Therefore, although it has been done successfully in a few instances, systematic examination of the pancreas and lymph-node areas or other tissues farther from the gut wall is typically not practicable. The Miniprobe inability to

do real-time controlled fine-needle aspiration biopsy (FNAB) is its second drawback. Their application is consequently restricted when the focus of the examination is on the environs of the gastrointestinal wall, such as for investigating lymph nodes and the pancreas. The main drawback of these devices is their small penetration depth (2-3 cm) at frequencies of 20–30 MHz.

- The lifespan of a Miniprobe is significantly influenced by the examiner's level of expertise, the instrument's care, and the uses to which it is put (e.g., esophageal applications versus intraductal ultrasonography).
- Estimates of the typical number of exams each probe range from 10 to 90.
- A mini probe costs between \$2000 and \$4000.

Figure 1.10: Ultrasound Miniprobe



1.7 Advantages of ultrasound endoscopes over optical endoscopes: ^[10]

- Accurate photos and findings - In contrast to standard ultrasound, where a transducer is placed on the skin far from the organs of interest, EUS uses a transducer that is much closer to the organ(s) of interest, resulting in images that are higher quality and precise.
- For assessing GI malignancies and lesions that lie below the mucosal surface, EUS has been found to be superior to conventional abdominal ultrasound, barium studies, CT scans, and even MRI.
- Providing comprehensive information that would typically only be possible through CT, MRI, or even surgical intervention concerning the layers of the intestinal wall as well as nearby structures including lymph nodes and blood arteries.

1.8 Limitations of endoscopic ultrasound:

- Maximum focus length of only 4 cm (small field of view)
- Criteria used to differentiate between diseases overlap and features of many pancreatic disorders and lymph nodes can look identical.

- Currently, it is equally challenging to distinguish focal chronic pancreatitis from carcinoma.
- Higher cost of the instrument and lack of expertise limits its widespread use ^[11]
- Long learning curve
- Uncertain ultrasound interpretation
- Difficult navigation
- Failing to understand the anatomical structure of the pancreato-biliary region
- It has been demonstrated that the accuracy of EUS depends on the operator.
- The number of procedures a unit performs is also important.
- The Joint Advisory Group (JAG) on GI endoscopy suggests that training take place in a unit that performs at least 200 operations annually in routine EUS examinations.
- Trainees should attend regular weekly sessions for at least 6 months, but no specific ‘number’ of cases is required to complete training. ^[12]

Challenges with FNA/FNB:

- Amount of sample collected is in-sufficient
- Needle can miss a tumour and take a sample of normal cells instead
- Enough cells from the tumour location are not removed for the diagnosis ^[13]
- Lesions located further than 7 cm into the gastrointestinal tract may not be reachable ^[14]

1.9 Additional information:

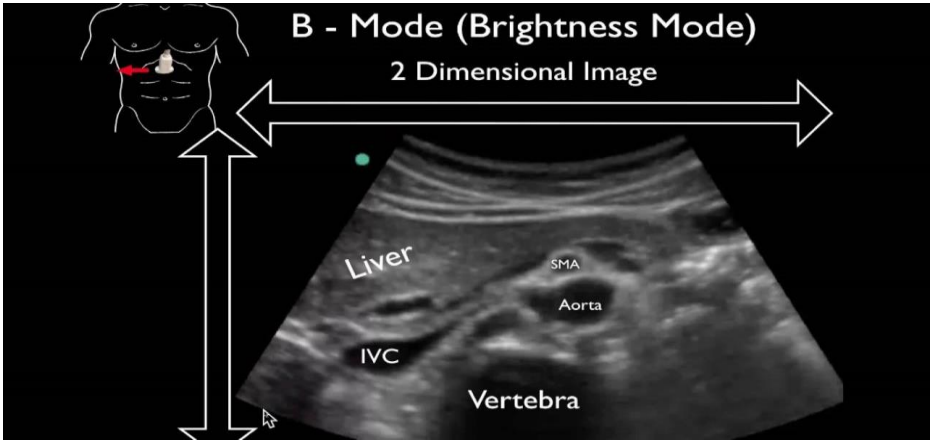
- Both types of scopes can be used to perform all new advanced image technologies, including elastography and contrast-enhanced imaging.
- The ultrasonic tip design, flexibility, balloon insufflation control design, and bend points at the distal end of the echoscopes vary amongst manufacturers.
- All the EUS transducers have a curved design and are located distal to the oblique-viewing endoscopic camera lens ^[15]
- The initial expenses for starting an EUS program are not insignificant. An entire system might cost between 200,000 and 300,000 euros.
- Maintenance costs for an EUS program is mainly due to damage that may occur from needle punctures of the echoendoscope, breaking of the elevator, and other general repairs.
- Data available in the literature estimated a mean maintenance cost of \$41 per procedure
- It is economically necessary for the basic ultrasound unit to be usable for transabdominal, vascular, and cardiac ultrasonography in facilities with low annual examination volumes. Now, all manufacturers of EUS equipment provide variable-use systems.

- A typical echoendoscope starts off costing between \$60 000 and \$90 000. Experience indicates that an instrument's lifespan is 3 years or less when utilized 500 times annually.
- Purchasing a second echoendoscope is profitable above a frequency of three or four examinations per day ^[16]
- However, considering the usefulness of the results obtained from the EUS, it has proven to be a cost-effective method.
- The vast international community of gastroenterologists and pulmonologists still uses EUS infrequently despite consistent efforts to improve the learning curve using supervised human procedures in reference centers, computer-based simulators, or live animal models ^[17]
- Although having a considerable clinical influence on patient care, notably in pancreaticobiliary and mediastinal illnesses, the use of EUS-FNA is still restricted to tertiary referral facilities.
- Because EUS heavily depends on the education, expertise, and experience of the endoscopist, it is still essential to improve navigational methods and identify anatomical landmarks if this technology is to be adopted more widely.

What is b-mode (brightness mode) imaging:

- Bright dots that indicate the ultrasound echoes make up the two-dimensional B-Mode ultrasound image display. The strength of the returning echo signal determines the brightness of each dot.
- This enables the visualization of diagnostic and therapeutic methods for small animal investigations, as well as the quantification of anatomical features.
- This universal imaging mode is great for:
 - Image-guided injections for needle placement of an injection or aspiration procedure
 - Identification of lesions, cysts, or tumors
 - Locating structural anomalies
 - Visualizing cardiac and vascular movement across the cardiac cycle ^[18]

Figure 1.11: B-Mode Imaging



What is high resolution b-mode (brightness mode):

- The SU-1 significantly improved high-resolution B-mode images with the invention of a unique ultrasonic wave transmission and reception design, a patented image processing technique, and high-sensitivity transducers. Small veins and pancreatic ducts can be seen clearly, allowing for precise pinpointing of the afflicted location and high accuracy ultrasonographic results. ^[19]

What is harmonic imaging:

- The resonance properties of tissue are used in the method known as harmonic imaging. Harmonic imaging is presently the primary method used in echocardiography because the images it produces have a greater resolution and are linked with less artefacts than traditional (fundamental) imaging.
- Because the tissue resonates, when an ultrasound wave travels through it, "harmonic ultrasonic waves" are produced. The original frequency (transmission frequency) at which the tissue was insonated is normally multiplied by the resonance frequency (to expose to or treat with ultrasound).
- The transducer receives the harmonic frequencies after they have been reflected, and the transducer uses them to produce the image. The second harmonic frequency is employed specifically. Modern transducers have a reception frequency that is two times greater than their sending frequency.
- The advantages of harmonic imaging are its fewer artifacts and better image quality ^[20]

What is doppler ultrasound:

- Using high-frequency sound waves (ultrasound) that are reflected off moving red blood cells, a Doppler ultrasound is a noninvasive diagnostic that can be used to gauge the blood flow via your blood arteries.
- Regular ultrasounds produce images using sound waves but are unable to depict blood flow.
[21]

1.10 New techniques/recent innovations in Ultrasound Endoscopes: [22]

- **Ultrasound endoscope (EUS) real-time tissue elastography:**
 - Real-time elastography (RTE), a relatively recent technology used in endoscopic ultrasonography (EUS), allows for the assessment of tissue stiffness with the goal of better defining lesions during EUS exams.
 - Real-time EUS elastography can help distinguish between benign and malignant tumors by providing qualitative and semi-quantitative data about tissue stiffness.
 - The ability to employ the RTE-EUS approach in multiple areas that are accessible from the GI tract is one of its benefits.
 - Future developments in real-time tissue elastography are a tissue characterizing technique that will certainly not replace biopsy but will rather be an adjunct during EUS examinations, due to its ease of use and low cost [23]
- **Contrast enhanced ultrasound endoscope (EUS):**
 - A recently developed technique called contrast-enhanced endoscopic ultrasonography (CE-EUS) combines the benefit of high-resolution ultrasound (US) of internal organs with the delivery of ultrasonic contrast agents (UCAs)
 - Two alternative technical variants have been used to characterise the method with comparable outcomes: Contrast-enhanced low-MI endoscopic ultrasound (CELMI-EUS) employing the contrast-specific mode, the technique for which is the same as the transabdominal approach, and contrast-enhanced endoscopic Doppler ultrasound with high-mechanical index (MI) (CEHMI-EUS), which does not require special software.
 - In CEHMI-EUS the Doppler frequency should be as high as possible, depending on the distance to the tumor. The flow velocity range (pulse repetition frequency, PRF) should be between 4 and 6 cm/s and the gain should be as high as possible without inducing artefacts [24]

- Standard B-Mode imaging makes it simple to identify the major vasculature structures, and the inclusion of color and power Doppler aids in the confirmation of vascular flow as well as the direction and velocity of flow inside the vessel.
- Capillary flow with low volume and very slow velocities cannot be seen with this standard imaging. The addition of “contrast” amplifies microvasculature flow to help define the vascular architecture, and hence to characterize the nature of a specific lesion ^[25]

Novel techniques in Ultrasound Endoscopes:

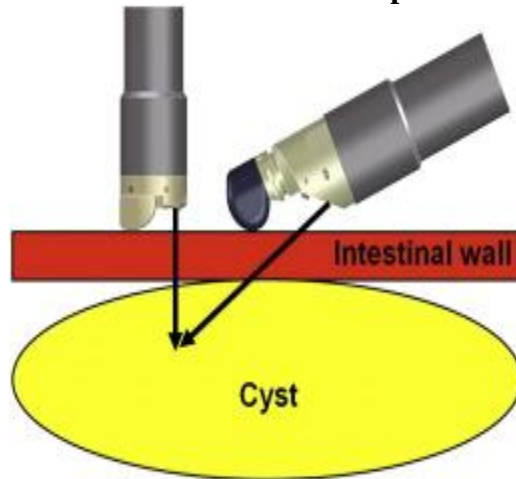
- **Fusion Ultrasound Endoscope (EUS) imaging:** ^[26]
 - The goal of EUS imaging is to reduce the challenging learning curve of EUS while simultaneously boosting diagnostic confidence and better orienting multiple target lesions. EUS imaging is a combination of EUS and CT/MRI, which is currently in development.
 - In the pancreaticobiliary and mediastinal (the region of the chest between the sternum and the spinal column, and between the lungs) areas, FI procedures may improve the selection and targeting of lesions for EUS-guided FNA.
 - - In addition to navigation, the three-dimensional (3-D) anatomical reconstruction may improve EUS examinations by improving the spatial relationship of studied lesions (targets), allowing for future offline interrogations of the acquired data volume.
 - Due to the intricate anatomy and tiny size of the probes, linear EUS and EUS-FNA are particularly challenging to perform. However, a prototype 3-D visualization of the linear EUS improved the assessment of vascular involvement in pancreatic lesions.
 - Therefore, compared to the currently existing free-hand procedures, the addition of an automated 3-D acquisition methodology may be desirable for future linear EUS transducers.
- **Tissue harmonic echo (THE)**
 - A new imaging technique called tissue harmonic echo (THE) imaging offers yet another way to characterize pancreatic cystic lesions.

- THE mode imaging is more accurate than traditional B mode pictures. The sonogram is created by higher harmonic frequencies as ultrasonic rays travel through tissues, according to the theory.
 - It has only ever been applied to abdominal ultrasonography, but EUS may one day use it as well. ^[27]
- **Needle-based confocal laser endomicroscopy (n-CLE)**
 - The method known as needle-based confocal laser endomicroscopy (n-CLE) enables in-vivo "optical" histology utilising fluorescence contrast. N-CLE can therefore be used to identify the areas that are most likely to be cancerous and need biopsy.
 - Initial findings from trials using n-CLE are very encouraging, and in the future, n-CLE may serve as a backup method for detecting pancreatic cysts when EUS-FNA is equivocal.
 - Following inconclusive results from EUS-FNA on solid pancreatic masses, n-CLE may soon be utilized frequently.
 - Despite n-accuracy, CLE's its expensive cost and the difficulties of diagnosing disease from surface characteristics will probably prevent it from taking off quickly.
 - Though traditional tissue acquisition will continue to offer diagnostic advantages such the capacity to conduct molecular testing, flow cytometry, and PCR, N-CLE has the potential to replace it one day.
 - **Forward viewing ultrasound endoscope (FV-EUS)**
 - Some experts consider EUS (FV-EUS), a relatively new tool, to be an improvement over the traditional curved linear array (CL-EUS).
 - The endoscopist has greater, steadier access to cysts thanks to FV-EUS. Additionally, due to its small, firm tip, it is simpler to handle, allowing for greater dexterity during interventional operations.
 - This enables the endoscopist to access more challenging areas of the GI tract, particularly the lower GI tract where FV-EUS has been demonstrated to facilitate simpler cecal intubation.
 - In addition, FV-EUS allows for quicker training, which could make it more widely used than the traditional curved linear array EUS. Studies have revealed that FV-

EUS can identify more gastrointestinal lesions in addition to having technical advantages over CL-EUS.

- The EUS view is decreased from 180 to 90 degrees, which is a disadvantage, but it is claimed that skilled endo sonographers are unaffected by this.

Figure 1.12: Forward viewing angle in Ultrasound Endoscope



- **Artificial Intelligence and EUS Elastography**

- EUS elastography (EUS-E) can enhance traditional EUS information while lowering examination costs without affecting patient morbidity or mortality.
- Endoscopic physicians can identify potential pathological alterations of corresponding tissues or organs based on EUS-E images because of the ability of EUS-E to transform the characteristics of tissue into visual images made up of colour pixels. ^[28]

- **Artificial intelligence, contrast-enhanced EUS and guided fine-needle aspiration**

- Since its discovery in 1992, EUS-FNA has been routinely used to diagnose and treat both intramural and extramural gastrointestinal tract lesions.
- The multistep nature of EUS-FNA and the potential impact of various uncertainty are well understood. Differentiating benign from malignant tumours and developing subsequent treatment plans based only on clinical/imaging characteristics and sample EUS-FNA results might be challenging at times.
- These factors have led to the development of certain AI-related algorithms in the last five years that are intended to increase the diagnostic efficacy and accuracy of EUS-FNA.

- Because to the development of NOTES, endoscopy is turning into an increasingly interventionist procedure (natural orifice transluminal endoscopic surgery).
- Under the supervision of EUS, endoscopic gastrojejunostomy has been successfully completed in pig models.
- After an unsuccessful ERCP, it has been reported that EUS-guided biliary drainage is safe, practical, and efficient. As well as EUS-guided pancreaticogastrostomy, without any major issues, EUS has been employed in swine models to successfully recover whole nodes by a trans gastric route, enabling thorough pathological analysis.
- In the upcoming years, it appears likely that EUS's therapeutic options will dramatically expand.^[29]

1.11 Current Competitive Landscape in the Endoscopic Ultrasound Market

Olympus, Pentax Medical, Fujifilm Healthcare and Boston Scientific are the leading players in the global Endoscopic Ultrasound System.

Figure 1.13: Current Competitive Landscape in the Endoscopic Ultrasound Market

Endoscopic Ultrasound System Players	
	• Provides superior flexible EUS-FNB/FNA needles aid in obtaining tissue from difficult scope positions and improved echogenicity help with controlled sampling • Improved B-mode image quality technology aiding in localization of tumors and accurate identification of tissue abnormalities • Arrietta 850 offers enhanced sensitivity towards tumors and other abnormal growth detection with the help of Contrast Harmonic EUS mode • Tissue Harmonic Echo mode reduces artifacts by image signal processing and achieves a clearer image
	• EUS system have Hitachi HI Com which combines frequency and spatial compounding resulting in an exceptional contrast and detailed resolution and Hitachi HI Rez+ high-resolution, real-time tissue adaptive filter technique which enhances real tissue echoes, delineation and depth of imaging, whilst reducing noise to improve diagnosis. • Offers Contrast Enhanced-EUS for characterization of micro vascularization, to differentiate benign from malignant lesions with higher diagnostic accuracy of pancreatic mass by sensitivity of 94% and a specificity of 89%
	• Fujifilm 580 Series have Color Doppler that obtains hemodynamic information to locate an observation site and blood flow • Pulse Wave Doppler Mode measures the velocity of blood flow by the doppler shift and gives a spectral display and audio of blood flow • Equipped with ergonomically designed G7 scope grip to enhance comfort with a rounded handle surface
	• EXALT™ Model D Single-Use Duodenoscope first single-use duodenoscope, allowing doctors to perform endoscopic retrograde cholangiopancreatography (ERCP) operations to diagnose and treat a variety of pancreatic and biliary disorders • Its SpyGlass™ DS Direct Visualization System allows doctors to obtain high-resolution images from inside the biliary, hepatic, and pancreatic ducts during ERCP

1.12 Ultrasound Endoscope market:

- The global endoscopic ultrasound market size stood at USD 830.6 Million in 2018 and is projected to reach USD 1,375.6 Million by 2026, exhibiting a CAGR of 6.5% during the forecast period^[30]

- North America accounts for largest share of EUS market, owing to the high incidence rate of chronic digestive diseases, growing number of endoscopy surgeries, better healthcare infrastructure, and favorable reimbursement policies
- This is mostly due to the high incidence rate of chronic digestive illnesses among the senior population in the US.
- The market in Europe will be fueled by established healthcare systems and pro-active healthcare policies.
- In Asia-Pacific, rising cancer rates are anticipated to increase demand for echo-endoscopy equipment, which is encouraging for this market.
- There has been a general drop in colonoscopy utilisation over the past 20 years, among other general trends in persons aged 75 years or older but a gradual increase in persons aged 50 to 74 years.
- The overall trend in upper endoscopy use has increased slightly in most age groups. Flexible sigmoidoscopy use decreased dramatically in the first decade of this century, with stable low rates since then.
- ERCP volumes have been generally stable across all age groups. The biggest increases in volume were in upper endoscopic ultrasound (EUS) procedures, with volumes increasing more than 6-fold in some older age groups since 2002.
- On the other hand, lower EUS use has declined somewhat in the past decade. ^[31]

The estimated numbers of endoscopic procedures performed in 2019 are as follows:

- o US Total endoscopic procedures: 22,162,641
- o UK Total endoscopic procedures: 11,323,022
- o JAPAN Total endoscopic procedures: 59514

Solution/ Outcome expected revolves around the following

Unmet need, brand preference evaluation, identification, and willingness to adopt new technologies in EUS

- The top unmet needs faced by Surgeons, Purchasers and IT dept. heads were identified and key expectations from manufacturers were mapped
- From these, key solutions for Surgeons and Purchasers were prioritized and communicated
- Brand perceptions, satisfaction, and reasons for preferences were evaluated, and from these top drivers of brand choice were identified to come up with key differentiators

- New technologies in EUS were identified; Surgeon and KOL perception and their likely future trends were evaluated to identify the key areas of investment
- The purchase process of EUS systems in different markets was clearly mapped and provided, especially pain points and expectations of Purchasers from manufacturers was provided

2. LITERATURE REVIEW

1. EBME and Clinical Engineering Articles, Endoscopic operations are used to identify illnesses, screen for problems including colon cancer, remove foreign objects, and treat a variety of GI tract, bile duct, and pancreatic diseases and conditions.
2. <https://www.ebme.co.uk/articles/clinical-engineering/endoscopy>, Endoscopy is a minimally invasive diagnostic medical treatment that allows for direct visualization of any inside organ. It is an optical viewing device that looks like a long tube and has a lens and light source for examining the internal human organs.
3. <https://www.healthline.com/health/endoscopy#types>, types of endoscopies where scope is inserted with usage specialty on the areas examined is seemingly captured and made as a table.
4. <https://www.healthline.com/health/endoscopy#new-endoscopy-techniques>, Latest techniques in endoscopy technology are Capsule endoscopy, ERCP, Chromoendoscopy, EMR, NBI, EUS Like most technologies, endoscopy is constantly advancing. Newer generations of endoscopes use high-definition imaging to create images in incredible detail. Innovative techniques also combine endoscopy with imaging technology or surgical procedures.
5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5331841/>, The ultrasound endoscope (EUS) is made up of an ultrasound processor that is attached to echoendoscopes that have either radial or linear transducers built into the endoscope's tip. A common video processor is also connected to the scopes.
6. <http://educationaldimensions.com/eLearn/aspirationandbiopsy/fna.php>, EUS-guided fine-needle aspiration (FNA) is performed in many large medical centers as part of routine esophageal cancer staging.
7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5024835/>, Both radial and curvilinear array systems can be used in the design of echoendoscopes. Both mechanical and electronic formats are possible. Since it has no moving parts and is therefore more durable, the electronic echoendoscope is currently more popular. With both optical video views and ultrasound capability, the design is essentially that of a modified gastroscope.
8. <http://educationaldimensions.com/eLearn/aspirationandbiopsy/radvslin.php#:~:text=There%20are%20two%20types%20of,%2Deye%E2%80%9D%20within%20the%20image,> There are two types of EUS scopes: radial scanning and linear array. The radial type scans in a plane perpendicular to the axis of the scope to produce 360° images like a CT “slice.”

The transducer appears as a “bull’s-eye” within the image.

9. https://radiologykey.com/radial-eus-linear-eus-or-ultrasound-miniprobe-which-is-the-most-suitable-device-in-gastrointestinal-eus/#c006_r3; The miniprobe's small calibre and high ultrasonic frequency, which provide high resolution but at the sacrifice of penetration depth, are its defining characteristics.
10. https://www.researchgate.net/publication/303815570_Endoscopic_Ultrasound_A_New_Hope_for_Patients, Advantages of ultrasound endoscopes over optical endoscopes: When compared to other methods, such as CT, MRI, or even surgery, it can provide detailed information on the layers of the intestinal wall as well as nearby structures like the lymph nodes and blood veins.
11. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4770620/#:~:text=To%20improve%20navigation%20of%20medical,magnetic%20resonance%20imaging%20\(MRI\),](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4770620/#:~:text=To%20improve%20navigation%20of%20medical,magnetic%20resonance%20imaging%20(MRI),) Limitations of endoscopic ultrasound includes the instrument's higher price and lack of experience prevent broad use.
12. <https://academic.oup.com/bmb/article/84/1/81/381499#5585874>, It has been demonstrated that the operator affects EUS accuracy. Another crucial factor is how many procedures a unit conduct.
13. <https://www.komen.org/breast-cancer/diagnosis/biopsies/fine-needle-aspiration/>, Challenges with FNA/FNB are- A needle may miss a tumour and instead collect a sample of healthy cells. Not enough tumor-related cells are eliminated for the diagnosis.
14. <https://www.gastroenterologyandhepatology.net/archives/august-2017/endoscopic-ultrasound-guided-fine-needle-aspiration-vs-fine-needle-biopsy/>, Another Challenge with FNA/FNB is, more than 7 cm inside the gastrointestinal tract, lesions might not be accessible.
15. [https://www.giejournal.org/article/S0016-5107\(01\)70388-4/abstract](https://www.giejournal.org/article/S0016-5107(01)70388-4/abstract), Persons who are required to perform endoscopy are required to attend adequate training.
16. https://radiologykey.com/radial-eus-linear-eus-or-ultrasound-miniprobe-which-is-the-most-suitable-device-in-gastrointestinal-eus/#c006_r3, Variable-use systems are currently provided by all manufacturers of EUS equipment.
17. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4770620/#:~:text=To%20improve%20navigation%20of%20medical,magnetic%20resonance%20imaging%20\(MRI\),](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4770620/#:~:text=To%20improve%20navigation%20of%20medical,magnetic%20resonance%20imaging%20(MRI),) Despite persistent efforts to reduce the learning curve utilizing supervised human procedures in reference centers, computer-based simulators, or live animal models, the huge global community of gastroenterologists and pulmonologists still underutilizes EUS.

18. <https://www.visualsonics.com/product/software/b-mode-imaging#:~:text=Get%20High%20Resolution%20Anatomical%20Data%20with%20B%20DMode%20Ultrasound!&text=This%20allows%20for%20visualization%20and,procedures%20for%20small%20animal%20studies.>, Bright dots that indicate the ultrasound echoes make up the two-dimensional B-Mode ultrasound image display. The strength of the returning echo signal determines the brightness of each dot.
19. https://asset.fujifilm.com/www/uk/files/2021-05/e594d7f1b9a1a651c3635db133dd499c/EUS_Brochure_3_2016_72dpi.pdf, The SU-1 significantly improved high-resolution B-mode images with the invention of an unique ultrasonic wave transmission and reception design, a patented image processing technique, and high-sensitivity transducers.
20. <https://123sonography.com/content/165-harmonic-imaging#:~:text=Harmonic%20imaging%20is%20a%20technique,principal%20technique%20used%20in%20echocardiography.>, Harmonic imaging is presently the primary method used in echocardiography because the images it produces have a greater resolution and are linked with less artefacts than traditional (fundamental) imaging.
21. <https://www.mayoclinic.org/doppler-ultrasound/expert-answers/faq-20058452#:~:text=A%20Doppler%20ultrasound%20is%20a,can't%20show%20blood%20flow.>, By reflecting high-frequency sound waves (ultrasound) off moving red blood cells, a Doppler ultrasound is a noninvasive diagnostic that can be used to gauge the blood flow via your blood arteries.
22. <https://www.sciencedirect.com/topics/medicine-and-dentistry/endoscopic-ultrasound>, Real-time tissue elastography (EUS) and contrast-enhanced ultrasound endoscopes are new methods/recent breakthroughs in ultrasound endoscopes.
23. <https://www.sciencedirect.com/science/article/pii/B9780323547239000051>, The ability to distinguish between benign and malignant tumors may be made possible by real-time EUS elastography, which gives qualitative and semi-quantitative data about tissue stiffness.
24. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4062228/#:~:text=Contrast%20Enhanced%20endoscopic%20ultrasound%20\(CE,ultrasound%20contrast%20agents%20\(UCAs\)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4062228/#:~:text=Contrast%20Enhanced%20endoscopic%20ultrasound%20(CE,ultrasound%20contrast%20agents%20(UCAs)).
25. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2998834/>, Depending on the distance to the tumour, the Doppler frequency in CEHMI-EUS should be as high as possible. The gain should be as high as feasible without creating artefacts, and the flow velocity range (pulse repetition frequency, PRF) should be between 4 and 6 cm/s.
26. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4770620/#:~:text=To%20improve%20na>

vigation%20of%20medical,magnetic%20resonance%20imaging%20(MRI)., Fusion EUS imaging is an ongoing research project that combines EUS and computed tomography/magnetic resonance imaging (CT/MRI) to reduce the challenging learning curve of EUS while simultaneously improving diagnostic certainty and the direction of multiple target lesions.

27. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5648992/>, A novel tool called tissue harmonic echo (THE) imaging offers yet another way to image pancreatic cystic lesions.
28. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8098839/>, In the past five years, a few AI-related algorithms have evolved that attempt to improve the diagnostic efficacy and accuracy of EUS-FNA.
29. <https://academic.oup.com/bmb/article/84/1/81/381499#5585874>, With the advent of NOTES, endoscopy is becoming more interventional (natural orifice transluminal endoscopic surgery). Under the supervision of EUS, endoscopic gastrojejunostomy has been successfully completed in pig models.
30. <https://www.globenewswire.com/news-release/2019/11/28/1953612/0/en/Endoscopic-Ultrasound-EUS-Market-Size-to-Touch-USD-1-375-6-Million-by-2026-Increasing-Number-of-Medical-Professionals-to-Stimulate-Growth.html>, The size of the global market for endoscopic ultrasound was USD 830.6 million in 2018 and is anticipated to increase to USD 1,375.6 million by 2026, demonstrating a CAGR of 6.5 percent over the forecast period.
31. <https://www.endoscopy-campus.com/en/ec-news/u-s-gi-endoscopy-volumes-biggest-change-is-increases-in-upper-endoscopic-ultrasound/>, In most age categories, there has been a small increase in the overall trend for upper endoscopy use. The first ten years of this century saw a sharp decline in flexible sigmoidoscopy usage, which has subsequently stabilized at low levels.

3. METHODOLOGY

Research instrument: A 60-mins (qualitative) and 45-mins (competitive intelligence) web assisted in-depth-interview (IDI) using a comprehensive discussion guide is taken. The draft of the interview is based on readings, previous studies, and professional literature.

Research questions

- To provide insight on Current unmet needs and customer expectations of flexible endoscope systems, especially ultrasound endoscopes
- To provide insight on Purchase dynamics like process followed, key decision makers, factors considered, etc.

Research objectives

- To assess the challenges and expectations with current ultrasound endoscopes used in endoscopic ultrasound (EUS).
- To explore key innovations expected in endoscopy and EUS.
- To evaluate customer perceptions of key competitors in this space.
- To understand the purchase process for flexible endoscope systems and EUS systems.
- To determine the key decision makers involved in the purchase of flexible endoscope systems and EUS systems.
- To identify the factors driving purchase of flexible endoscope systems and EUS systems.

Collection of data: Data was collected via a comprehensive discussion guide from the respondents with their consent. The respondents are people from the medical industry and people with little or more exposure to usage of Ultrasound Endoscopes.

Discussion guide administration: The discussion guide was administered to respondents via web assisted in-depth-interview through Double-blinded Qualitative Interviews and Pilot Interviews.

Sample design: The study was a Qualitative Research approach, and the respondents were people from the medical industry and people with little or more exposure to Ultrasound Endoscopes.

Analysis: Analysis was done by using Microsoft Excel

Sample size: 66

Exclusion and inclusion criteria:**Respondent criteria: Qualitative**

- All respondents must purchase/use/perform procedures with flexible endoscopes (not necessarily limited to endoscopic ultrasound)
- Have 5+ years of total experience and 2+ years of experience at current facility
- All respondents must be involved in purchase decision-making process of (ultrasound) endoscopes
- Have knowledge about current landscape and trends in (ultrasound) endoscopes market
- US: Hospitals with 250+ beds, ASCs, OBLs; China: Level 3 Hospitals; Other Countries: Hospitals with 250+ beds

Respondent criteria: Competitive Intelligence

- All respondents have worked as Business Unit Head/Marketing Manager/Sales Manager managing portfolio of flexible endoscopes/echoendoscopes
- Have 2+ years of total experience managing a portfolio of flexible endoscopes/echoendoscopes
- Have worked for 1+ years at Olympus/Fujifilm/Pentax managing a portfolio of flexible endoscopes/echoendoscopes
- Have knowledge about current landscape and trends in flexible endoscopes/echoendoscopes

4. RESULTS

The study included 66 respondents belonging to the purchase/use/perform procedures with flexible endoscopes (not necessarily limited to endoscopic ultrasound). The data was collected using a discussion guide and evaluated appropriately under the designated sub-heads. A discussion guide, with the help of industry experts, was made to understand the awareness of ultrasound endoscopes among users, purchasers, and their usage.

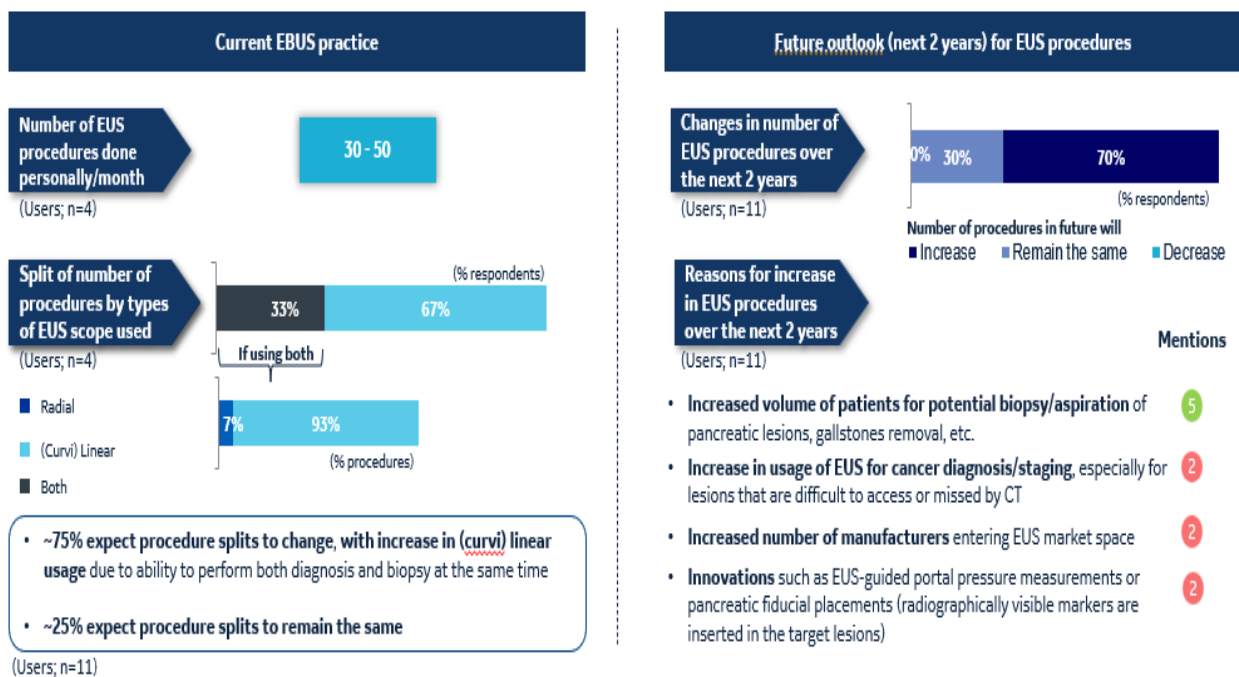
It included different parameters like awareness of the product, their preference, and usage, risk factors, and limitations.

4.1 Current Practice

4.1.1 Current EUS practice and future outlook – gastroenterology

This includes Gastros/Gastro Surgeons and HODs (User).

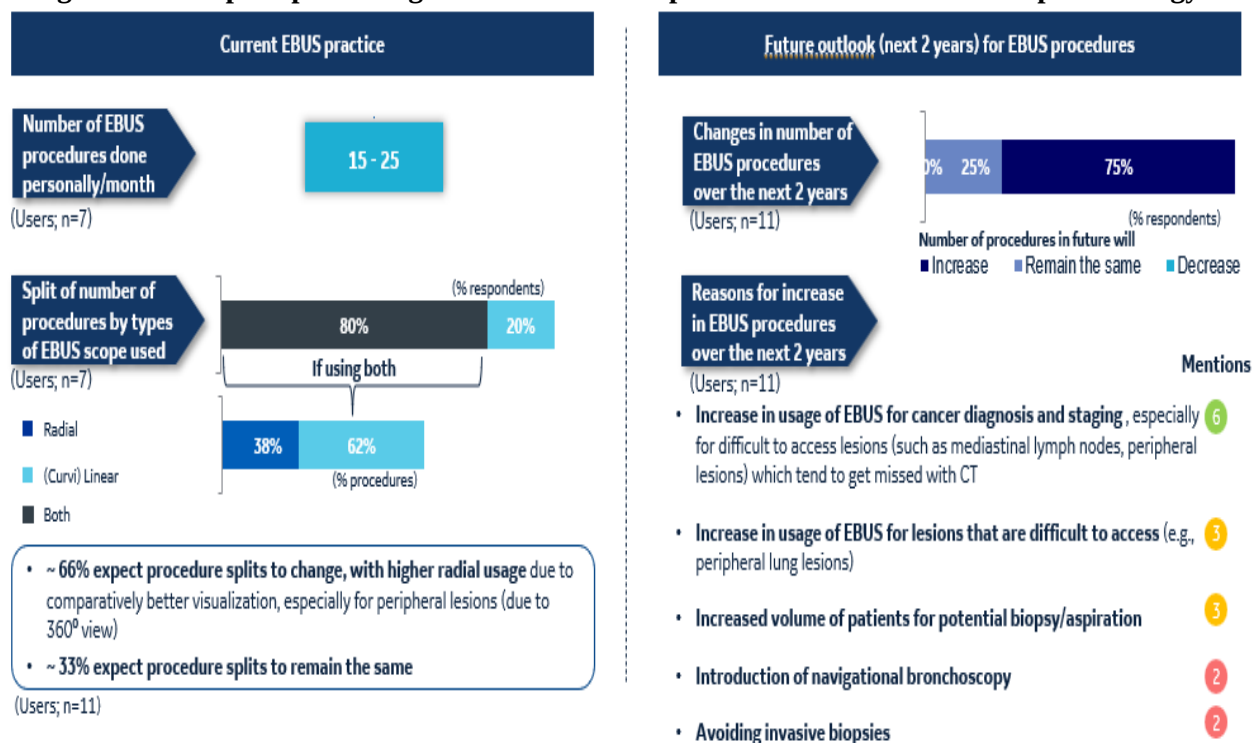
Figure 4.1: Graph representing the Current EUS practice and future outlook – gastroenterology



4.1.2 Current EBUS practice and future outlook – pulmonology

This includes Pulmos/Interv. Pulmos and HODs (User)

Figure 4.2: Graph representing the Current EBUS practice and future outlook – pulmonology.



4.1.3 Reasons to prefer E(B)US over traditional optical endoscopes- Clinicians/HODs (Users)

Single procedure for diagnosis and biopsy and better cancer staging are the key factors driving E(B)US usage over traditional endoscopes

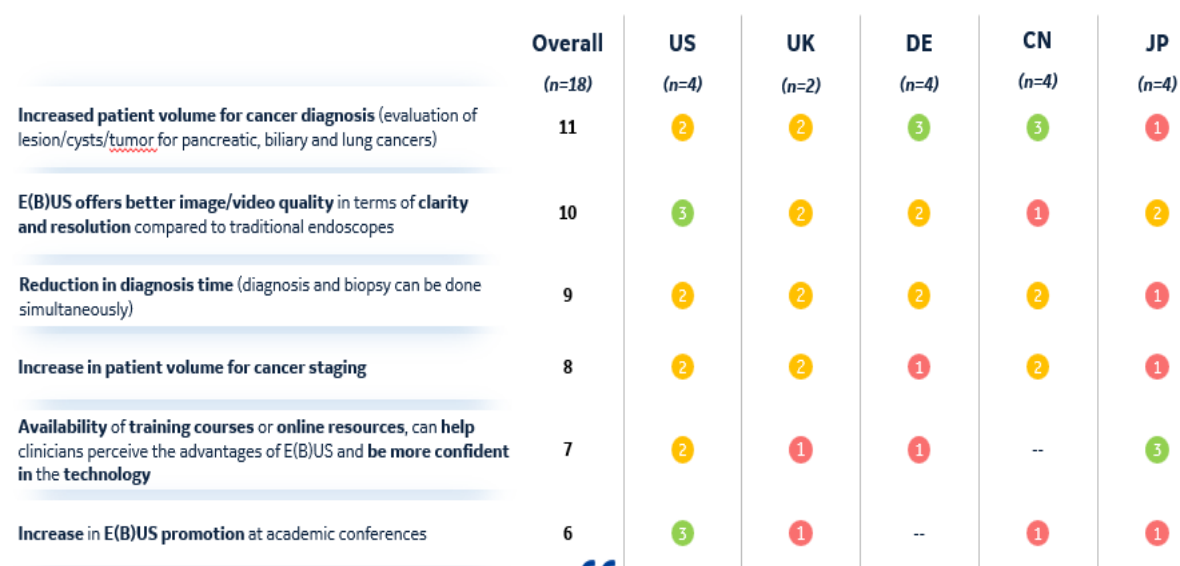
Figure 4.3: Graph representing the Reasons to prefer E(B)US over traditional optical endoscopes- Clinicians/HODs (Users).

	Overall (n=22)	US (n=4)	UK (n=6)	DE (n=4)	CN (n=4)	JP (n=4)
Ability to diagnose and perform biopsy simultaneously (Single procedure for diagnosis and biopsy vs. multiple procedures with traditional endoscopes)	9	3	3	--	1	2
Better staging of cancer , because extra luminal swellings, mucosal texture changes, and nodules can be detected better with echoendoscopes (vs. regular endoscopes)	9	2	2	3	1	1
Better visualization of the anatomy behind folds (precise location and size of deep-seated lesions/tumours)	8	1	--	3	1	3
Easier biopsy with less possibility of artery puncture/bleeding (better visualization of artery microstructure using ultrasound)	5	--	1	2	1	1
Precise and targeted sampling of soft tissues	4	1	2	1	--	--

4.1.4 Drivers for adoption of an E(B)US system- Clinicians/HODs (Intenders)

Increased patient volume for cancer evaluation, better image quality and quicker diagnosis are the key drivers of the adoption of E(B)US.

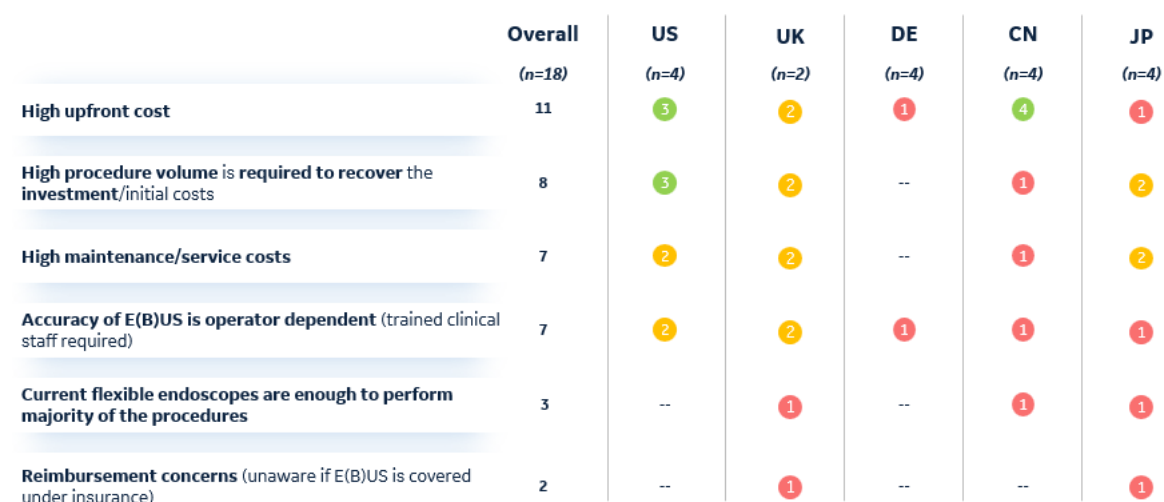
Figure 4.4: Graph representing the Drivers for adoption of an E(B)US system- Clinicians/HODs (Intenders).



4.1.5 Barriers for adoption of an E(B)US system- Clinicians/HODs (Intenders)

High upfront costs and high patient volume to recover initial investment are the barriers to adopt E(B)

Figure 4.5: Graph representing the Barriers for adoption of an E(B)US system - Clinicians/HODs (Intenders).



4.2 Unmet Needs

4.2.1 Challenges with currently used E(B)US- Clinicians/HODs (Users)

Limited angulation of distal scope tip, high cost of maintenance/repair, sub-optimal characterization of lesions and large diameter of the echoendoscope are the key challenges with E(B)US.

Figure 4.6: Graph representing the Challenges with currently used E(B)US- Clinicians/HODs (Users)

Challenge (Unaided+Aided)	Mentions					
	Overall (n=22)	US (n=4)	UK (n=6)	DE (n=4)	CN (n=4)	JP (n=4)
Limited angulation of distal scope tip (Aided)	11	2	3	3	2	1
High cost of maintenance/repair (Unaided + Aided)	10	1	2	2	1	4
Sub-optimal characterization of lesions (Aided)	9	-	2	2	4	1
Large diameter of the echoendoscope (Unaided + Aided)	8	2	3	1	-	2
Improper/inefficient depth perception (Aided)	8	3	1	1	1	2
Sub-optimal cleaning or improper reprocessing of scope (Aided)	7	2	1	1	1	2
Fragile scope lens/ probe (Unaided)	2	-	1	1	-	-

4.2.2 Challenges with currently used gastroscope/bronchoscope- Clinicians/ HODs (Intenders)

Sub-optimal characterization of lesions and sub-optimal cleaning or improper reprocessing, are the key challenges with gastroscope/bronchoscope.

Figure 4.7: Graph representing the Challenges with currently used gastroscope/bronchoscope- Clinicians/ HODs (Intenders)

Challenge (Unaided+Aided)	Mentions					
	Overall (n=18)	US (n=4)	UK (n=2)	DE (n=4)	CN (n=4)	JP (n=4)
Sub-optimal characterization of lesions (Aided)	9	2	2	1	3	1
Sub-optimal cleaning/reprocessing of scope and long reprocessing TAT (Unaided + Aided)	8	2	2	1	2	1
High cost of maintenance/repair (Aided)	7	2	1	1	2	1
Diameter of the endoscope (Unaided + Aided)	6	1	1	1	1	2
Restricted field of view (Unaided + Aided)	5	-	1	-	3	1
Fragile scopes (Unaided)	2	-	2	-	-	-

4.3 Purchase Considerations

4.3.1 Key purchase factors for flexible endoscopes/E(B)US (Unaided)- Clinicians/HODs & Purchasers

Image quality, ease of use and competitive upfront cost are key drivers influencing purchase decisions for flexible endoscopes/E(B)US.

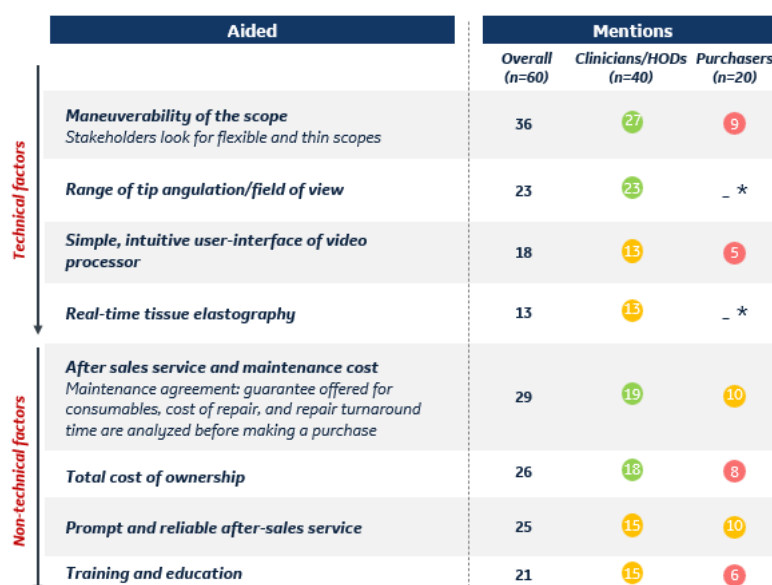
Figure 4.8: Graph representing the Key purchase factors for flexible endoscopes/E(B)US (Unaided)- Clinicians/HODs & Purchasers

Unaided		Mentions		
		Overall (n=60)	Clinicians/HODs (n=40)	Purchasers (n=20)
Technical factors	Image quality • Good image quality in terms of resolution, video clarity, focus, saturation and availability of contrast enhancement option to help with better diagnosis	22	14	8
	Ease of use • Adequate scope flexibility/ maneuverability to accurately target area of interest • Better scope ergonomics for easier handling	18	12	6
	Sturdy scopes that are easy to clean and reprocess • The scope lens/ultrasound probe should be sturdy and not prone to damage when cleaning and reprocessing	13	7	6
Non-technical factors	Competitive upfront cost • Stakeholders prefer a device with competitive upfront cost, but would not compromise on quality	21	11	10
	Prompt and reliable service • Inclusions in the service/maintenance contract, and prompt technical support from the vendors	15	8	7
	Maintenance cost and repair turnaround time • Low cost of repair with quick repair turnaround time for endoscopes	14	7	7
	Training • Regular training with continuous medical education for clinicians • Robust training on device reprocessing during early phase of device installation for support staff	7	3	4

4.3.2 Key purchase factors for flexible endoscopes/E(B)US (Aided)- Clinicians/HODs & Purchasers

Maneuverability of the scope, range of tip angulation/field of view, after sales service and maintenance cost and total cost of ownership are key purchase factors.

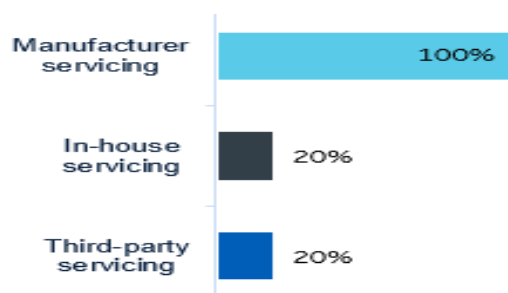
Figure 4.9: Graph representing the Key purchase factors for flexible endoscopes/E(B)US (Aided)- Clinicians/HODs & Purchasers.



4.3.3 Impact of cost of maintenance/service contracts on purchase decision- Purchasers

Overall, there is an impact of cost of maintenance/service on purchase decision because high cost of maintenance leads to an overall high total cost of ownership.

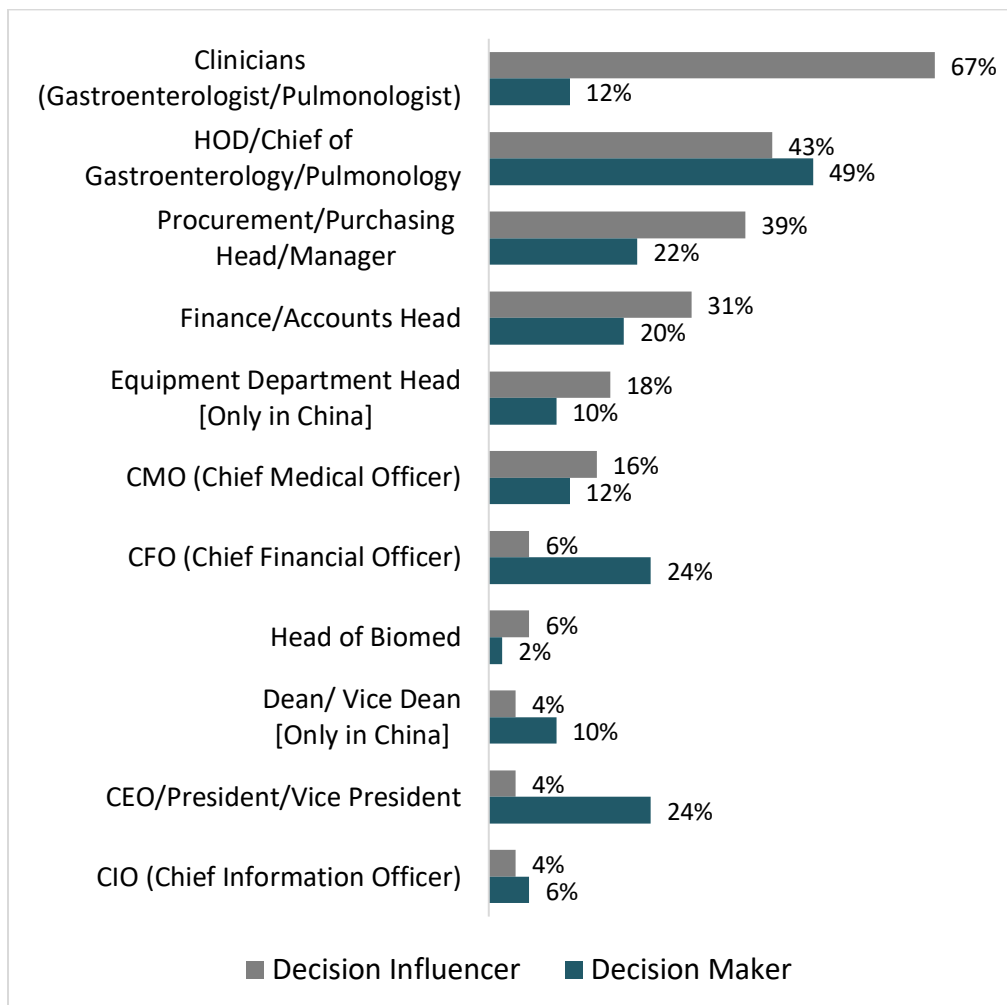
Figure 4.10: Graph representing the Impact of cost of maintenance/service contracts on purchase decision- Purchasers.



4.3.4 Key stakeholders involved in purchase decisions- Clinicians/HODs & Purchasers

HODs, Procurement/ Purchasing Head/Manager and Finance/Accounts Head are the key stakeholders involved in the purchase

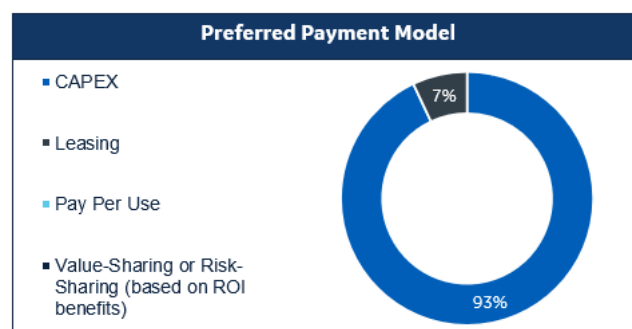
Figure 4.11: Graph representing the Key stakeholders involved in purchase decisions- Clinicians/HODs & Purchasers.



4.3.5 Preferred Payment Model for flexible endoscopes/E(B)US- Purchasers

CAPEX is the preferred payment model for flexible endoscopes/E(B)US.

Figure 4.12: Graph representing the Preferred Payment Model for flexible endoscopes/E(B)US- Purchasers.



5. DISCUSSION

5.1 Awareness about the product:

66 respondents were taken in 5 countries, USA, UK, Germany, Japan, China who are the total E(B)US users and intenders who are purchasers/users performing procedures with flexible endoscopes (not necessarily limited to endoscopic ultrasound). The users and intenders have 5+ years of total experience and 2+ years of experience at current facility. All respondents are involved in purchase decision-making process of (ultrasound) endoscopes and have knowledge about current landscape and trends in (ultrasound) endoscopes market for Qualitative Analysis. For Competitive Intelligence, all respondents have worked as Business Unit Head/Marketing Manager/Sales Manager managing portfolio of flexible endoscopes/echoendoscopes and have 2+ years of total experience managing a portfolio of flexible endoscopes/echoendoscopes and worked for 1+ years at Olympus/Fujifilm/Pentax managing a portfolio of flexible endoscopes/echoendoscopes. All have knowledge about current landscape and trends in flexible endoscopes/echoendoscopes.

Many clinicians and purchasers were aware of the Ultrasound endoscopes. Going in-depth, few of them knew how to use it and few of them need training and demo sessions to understand the product. A negligible number of purchasers did not know about current updated endoscopes and were using in older version usage. Proper training would help the users in understanding the benefits of the product.

5.2 Challenges

Challenges with currently used E(B)US:

Due to limited angulation, there is inefficient visualization of the target site, e.g., areas like the entrance of the stomach or the duodenum are difficult to get a good view of target. Difficult to visualize lesions, tumors, or lymph nodes due to limited angulation.

High incidence of scope damage coupled with high repair costs, add up to a significant maintenance burden. Limited durability also adds up to high maintenance cost, one respondent using Pentax endoscope said.

In certain cases, it is difficult to interpret the type of lesion and characterize it accurately; clinicians expect an improvement in the resolution and focus. Sub-optimal illumination can sometimes result in missing blood vessels, which can cause internal bleeding. Ultrasound artifacts make characterization of lesions more difficult.

As the diameter of an echoendoscope is comparatively bigger than an endoscope, it is difficult to penetrate further into the anatomic site like lungs. Due to sub-optimal optics depth perception is a challenge, especially with smaller lesions.

Cleaning an endoscope is cumbersome and often leads to damage, sub-optimal infection control, or quality degradation of the scope. The echoendoscope lens/ultrasound probe is fragile, and prone to damage especially during reprocessing.

Challenges with currently used gastroscope/bronchoscope:

Due to sub-optimal illumination, it is difficult to accurately characterize masses like lymph nodes and tumors; Locate and mark small peripheral lesions for biopsy.

Reprocessing the scope is cumbersome and the scope is prone to damage. Inefficient cleaning can degrade the quality of the lens, resulting in sub-par image quality. Long reprocessing turnaround time. Sub-optimal cleaning may lead to inefficient infection control.

High incidence of scope damage coupled with high repair costs, add up to a significant costly maintenance burden. Large diameter of the scope makes it difficult to penetrate further into the anatomic site. Due to restricted field of view, there is a high chance to miss a mass which may lead to incorrect diagnosis. Endoscopes are fragile, hence prone to damage, which in turn impacts the procedure volume.

5.3 Brand Satisfaction, Likes and Dislikes and Areas of Improvement

Echoendoscope brand satisfaction and brand likes:

Of 22 respondents of Olympus users, the brand satisfaction is 5.8 out of 7. They said, the new Olympus video processors yield better image quality, has Optimal image color and saturation with excellent image clarity of lesions. Echoendoscopes are thin and flexible, hence easy to maneuver with good integration capabilities with EHR. Good training workshops provided via Olympus Academy and Prompts revert to technical queries

Of 12 respondents of Pentax users, the brand satisfaction is 5.6 out of 7. They said, it has good image resolution and quality of ultrasound image with Quick repair turnaround time.

Of 8 respondents of Fujifilm users, the brand satisfaction is 5.0 out of 7. They said, it has good image resolution. Echoendoscopes are thin; hence, they enable access to difficult to reach anatomy. Good training support provided during device installation with Prompt and reliable service support.

Echoendoscope brand dislikes:

Olympus has high upfront cost of the device. Training for support staff is not proactive and there are Infrequent visits from the sales representative during the early phase of equipment installation. High cost of repair with High turnaround time for device repair and replacement is seen the respondent added.

Pentax Echoendoscopes are thick and rigid; hence they lead to more patient discomfort and the Scopes are fragile and less sturdy. Inadequate training provided to clinicians and support staff with High cost of repair.

Fujifilm has High image saturation which may sometimes be mistaken as internal bleeding with Inadequate training provided to the new clinicians and support staff.

Areas of improvement:

Incorporate artificial intelligence to help with a better and quicker diagnosis. In some cancers where the anatomy/site is difficult to access, there is a need for thinner and flexible echoscopes. There is need to Improve user interface for some complicated functionalities, need for regular visits from the sales representative to understand physicians' unmet needs and keep them updated about the current innovations in echoendoscopes. Need to Provide simulation-based training to practice cases and ensure quick learning for new physicians.

Gastroscope/ bronchoscope brand satisfaction and brand likes:

Of 39 respondents of Olympus users, the brand satisfaction is 6.2 out of 7. They said, it has good image quality, especially of new generation devices in terms of resolution, focus, balance of color, saturation, and TXI (Texture and Color Enhancement Imaging), NBI mode is superior as compared to other brands with good quality and durable device. Superior ergonomics of the scope is seen, and Endoscopes are flexible/ easy to maneuver. High brand familiarity is seen due to being trained on the Olympus device during fellowship. Prompts revert to technical queries. Olympus representatives interact with the clinicians once every month to assist them with problems associated with device usage.

Of 16 respondents of Pentax users, the brand satisfaction is 4.5 out of 7. They said, it has good image quality in terms of resolution. Prompt and reliable customer service with quick repair turnaround time and Representatives are professional in conduct.

Of 16 respondents of Fujifilm users, the brand satisfaction is 6.2 out of 7. They said, it has good

image quality in terms of color, brightness, and resolution. It has Minimal breakdowns hence reliable device. Good training support provided during device installation and Prompt revert to technical queries.

Gastroscope/ bronchoscope brand dislikes and areas of improvement:

Olympus has Sub-optimal image magnification and is Expensive/ high upfront cost of the device. Training provided is technical, there is a need for regular simulation-based training and seminars for clinicians with High turnaround time for device repair and not all sales

representatives have a professional attitude.

Pentax has Limited maneuverability of endoscopes with Inadequate training provided to the new clinicians and support staff with High replacement turnaround time for damaged devices in warranty.

Of 16 respondents of Fujifilm users, 1 respondent said there is Sub-optimal image clarity, 2 respondents said there is High replacement turnaround time for damaged devices in warranty and 1 respondent said there is Limited presence in Germany leads to delay in service.

5.4 Purchase process

Purchase process of a new flexible endoscope/E(B)US:

	USA (n=4)	UK (n=4)	Germany (n=4)	China (n=4)	Japan (n=4)
Purchase triggers	• Equipment nearing end of life	• Equipment nearing end of life • High maintenance/ reprocessing cost	• Equipment nearing end of life • Upgrade to new technology	• Equipment nearing end of life	• Equipment nearing end of life • Upgrade to new technology • Clinician request/interest/complaints
Purchase initiators	• Clinicians (Gastroenterologists /Pulmonologists)			• HOD - Gastroenterology/ Pulmonology	• Clinicians (Gastroenterologists /Pulmonologists)
Purchase follow up/ discussion	• The initiator(s) identifies the need gathers information to make a case in front of VAC (value analysis committee)* • VAC post-evaluation will decide if they want to go ahead with the purchase or not	• In case of a new purchase, the Purchasing/ Procurement Head would step in to assess the vendors and help the clinicians build a business case	• The initiators make a business case outlining why there is a need for new equipment which is then evaluated by the Purchasing/Procurement Head	• The request initiated by the initiator is assessed by the Equipment Department Head to check if there is really a requirement and thus decide to move ahead for approval to the final decision maker or not	• The initiator(s) identifies the need and gathers information to make a case in front Procurement Department; which then evaluates the request and looks at the annual budget before making a decision
Resources used to research	• Sales representative	• Sales representative	• Colleague recommendation / Testimonials from users at other facilities • Group Purchasing Organization (GPO) • Online resources • Professional societies/conferences	• Colleague recommendation / Testimonials from users at other facilities • Professional societies/conferences • Online resources	• Sales representative • Colleague recommendation / Testimonials from users at other facilities
Purchase method	• Direct purchase/No competitive bidding • Group Purchasing Organizations (GPOs)	• NHS Supply Chain	• Direct purchase/No competitive bidding • Government-driven quotation/tender process	• Government-driven quotation/tender process • Hospital-specific quotation/tender process	• Direct purchase/No competitive bidding • Hospital-specific quotation/tender process
Time taken**	• 6 months	• 4 to 6 months	• 6 to 9 months	• 3 to 6 months	
Preferred payment model	• CAPEX				

*consisting of physicians, representatives from the infection control, maintenance, and reprocessing department

**from need initiation to final purchase

n=20

Reasons for impact of maintenance contract on purchase decision:

Maintenance cost along with the upfront cost is taken into consideration during purchase. Since the maintenance cost is high (vs. upfront cost) it has an impact on the total cost of ownership which in turn impacts the purchase decision. Preference is given to a vendor who provides maintenance services in their contract versus a vendor who has a lower upfront price. For maintenance/ service all depend on the manufacturer. Additionally in the US 3rd party servicing has opted especially for older equipment. Further in case of minor repairs hospitals in US, Germany and Japan cite using the in-house repair.

Impact of training on purchase decision:

Although training does not have a high impact on the decision, there is a preference for vendors that provide practical training/demonstration. Training is not a primary consideration; it is just an additional clause in the contract. Clinicians expect minimal training when switching brands, Given the years of experience performing endoscopy and since most of the features/controls are the same across brands the learning curve is not considered steep (high among Olympus users). Hence, extensive clinical training is not expected when switching brands. Training is a part of the service contract and is provided basis facility needs

Clinician training: Training is provided to clinicians on device and feature usage. While performing procedures in the endoscopy room, sales representatives are present during the initial training period.

Support staff/ physician assistants: On installation, support staff, and physician assistants are trained on device setup, maintenance, and troubleshooting.

Reprocessing staff: Training is provided on reprocessing, cleaning, and sterilization of scope. If necessary, training is provided to new support staff basis requirement.

Stakeholders prefer continuous training (at least twice a year) to ensure the new clinicians/ support staff are trained.

Training expectations with E(B)US:

Physician: Training should be provided during device installation. 2-3 days of comprehensive training should be provided when a new technology is introduced. Due to high physician turnover frequent on-site training should be provided to new physicians. Expected periodicity of training is biannually. Sales representatives from manufacturers should provide training on various intricacies associated with using the device. EUS experts/ experienced physicians

should train on the skills to perform a procedure. Training is provided on device and feature usage. Sales representative is present during the initial procedures to answer questions if needed. Additionally, clinicians expect: Funding for training conducted by physician societies: Regular and robust training courses are provided by physician societies such as the European Respiratory Society and Chinese Medical Association; physicians expect manufacturers to finance such courses. Organize medical conferences where experts speak about newer techniques and innovations in the area. Online courses like the one provided by Olympus Academy on technical skills and device usage, should be offered by other manufacturers. Manufacturers should provide virtual models to practice cases and ensure quick learning for new physicians.

Physician Assistants/ Support staff: Regular training should be provided to support staff on reprocessing to prevent frequent damages. New physician assistants should receive training on how to handle the device. Expected periodicity of training is triennially. Sales representatives from manufacturers should provide training on device handling and reprocessing. There is a need to train the support staff on how to use, reprocess, and handle the device. Clinician training is the focus, while support staff training is limited, more robust training should be provided for reprocessing and handling of scopes. Train support staff on optimal handling and reprocessing of scopes to prevent breakages as and reduce maintenance costs.

Key stakeholders involved in purchase decisions:

HODs, Procurement/ Purchasing Head/Manager and Finance/Accounts Head are the key stakeholders involved in the purchase.

Clinicians/HODs- Clinicians/HODs identify the need for the device and define its technical specifications. They gather information to make a case in front of VAC (value analysis committee). HODs play a key role in the final decision making.

Procurement/Purchasing Head/Manager- Identify and assess products basis facility budgets and recommend the most cost-effective option or a device with maximum return on investment fitting the facility requirement. Review competitive bids and carry out negotiations with vendors. Build business case along with clinicians. Procurement/Purchasing Head/Manager are key decision-makers in Germany.

Finance/Accounts Head- Approve budget for the device and finalize both upfront cost and maintenance cost.

In China, **Equipment Department Head** is the key decision influencer whereas Dean/Vice Dean is the key decision-maker.

5.5 Preferred Payment Model for flexible endoscopes/E(B)US:

Almost all prefer CAPEX. CAPEX is preferred for equipment with a longer average lifespan (~5 years or more). It is perceived to be a comparatively cost-effective option. It also enables the hospital to own the equipment, which is not the case with leasing (which is preferred only when the facility is short of capital). Stakeholders are skeptical of Pay Per Use and Value-Sharing models for scopes since they are not very sure how these will be tracked or calculated.

5.6 Key innovations in flexible endoscopes that will be impactful in future:

Fusion EUS imaging / Electromagnetic navigational bronchoscopy (Unaided + Aided)- Combining EUS with CT/MRI offers better visualization of lesions/tumors aiding diagnosis (especially early-stage cancers). Enables better handling of sudden spikes in patient volume (especially in ER/ICUs).

Single-use flexible endoscope (Unaided + Aided) - Helps avoid laborious process of sterilization and reprocessing (better infection control); however, costs and equipment quality are the concerns.

Incorporation of AI/ML in flexible endoscopy (Unaided + Aided) - AI/ML can help in better detection and characterization of polyps/lesions, adenoma, early carcinomas, and dysplastic changes, which tend to get missed. Application of AI can be further extended by combining endoscopy with CT/MRI images.

Forward viewing EUS (Unaided + Aided) - It provides direct view (instead of oblique view with conventional EUS), which leads to better precision during biopsy, thereby avoiding accidental artery puncture.

Capsule endoscopy (Unaided + Aided) - Non-invasive diagnosis of the complete GI tract (including colon) without procedure hassle (patient just must swallow a pill). Improved reach – access to narrow lumens that scopes cannot get into. However, biopsy is not possible.

Robot-assisted endoscopy (Unaided)- Robot assisted endoscopy will improve precision because of higher degrees of freedom.

Availability of thinner (echo)endoscopes (Unaided) - Thinner (echo)endoscopes will help reach difficult anatomy (narrow lumens) along with improving patient comfort for the procedure.

6. CONCLUSION

A 60-minute telephonic in-depth-interview (TDI) using a comprehensive discussion guide is done to the target group. The type of primary facility, experience, and professional function in the primary facility are considered when profiling respondents.

30 to 50 EUS procedures are carried out by gastro/gastro surgeons each month. Increasing patient volume for biopsy/aspiration is the main reason they anticipate an increase in EUS procedures. 15–25 EBUS operations are carried out by pulmonologists each month. Everyone anticipates an increase since there will be a greater demand for cancer staging, particularly for difficult-to-reach tumors and those that other imaging modalities overlook. E(B)US utilization over traditional endoscopes is primarily driven by a single procedure for diagnosis and biopsy and better cancer staging. The main factors influencing the adoption of E(B)US include an increase in the number of patients being evaluated for cancer, improved image quality, and quicker diagnosis. The hurdles to adopting E(B)US are expensive upfront costs and a high patient volume to recover initial investment.

The main issues with E(B)US include limited distal scope tip angulation, expensive maintenance and repair costs, inadequate lesion characterization, and a large echoendoscope diameter and with gastroscope/bronchoscope are inadequate characterization of lesions and inadequate cleaning or inappropriate reprocessing. Because of the training received during the fellowship, Olympus has higher image quality, agility and flexibility, and brand familiarity. The main reason people dislike Olympus is their high upfront and ongoing maintenance and servicing costs; some people also think Pentax echoendoscopes are bulky and rigid. Olympus' high customer satisfaction is fueled by its exceptional image quality and user-friendliness, whereas Pentax and Fujifilm's are fueled by their affordable prices.

The primary buy initiators and champions are clinicians (gastroenterologists/pulmonologists) and HODs. Users' recommendations and feedback are important sources of information before making a purchase.

Flexible endoscopes/E(B)US buying decisions are mostly influenced by three factors: image quality, usability, and affordable upfront cost. Key purchasing considerations include the scope's maneuverability, tip angulation/field of view range, cost of maintenance and after-sales services, and total cost of ownership.

Cost of service and maintenance has an overall impact on purchasing decisions since high

maintenance costs result in high total costs of ownership. The main suggestions include quick loaner availability, lower maintenance costs, and remote support for troubleshooting.

Since device controls and features are similar across brands, training is included in the purchase agreement, but it is not believed to have a significant influence on purchase decisions.

Clinicians anticipate that manufacturers will sponsor training programs run by medical associations, offer in-person instruction, and offer online courses. The principal stakeholders involved in the purchase are the HODs, the Procurement/Purchasing Head/Manager, and the Finance/Accounts Head. The preferred method of payment for flexible endoscopes and E(B)US is CAPEX.

The main advancements that will have the biggest impact are the combination of EUS imaging and electromagnetic navigational bronchoscopy, single-use endoscopes, and the utilization of AI and ML.

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ANNEXURE

DISCUSSION GUIDE

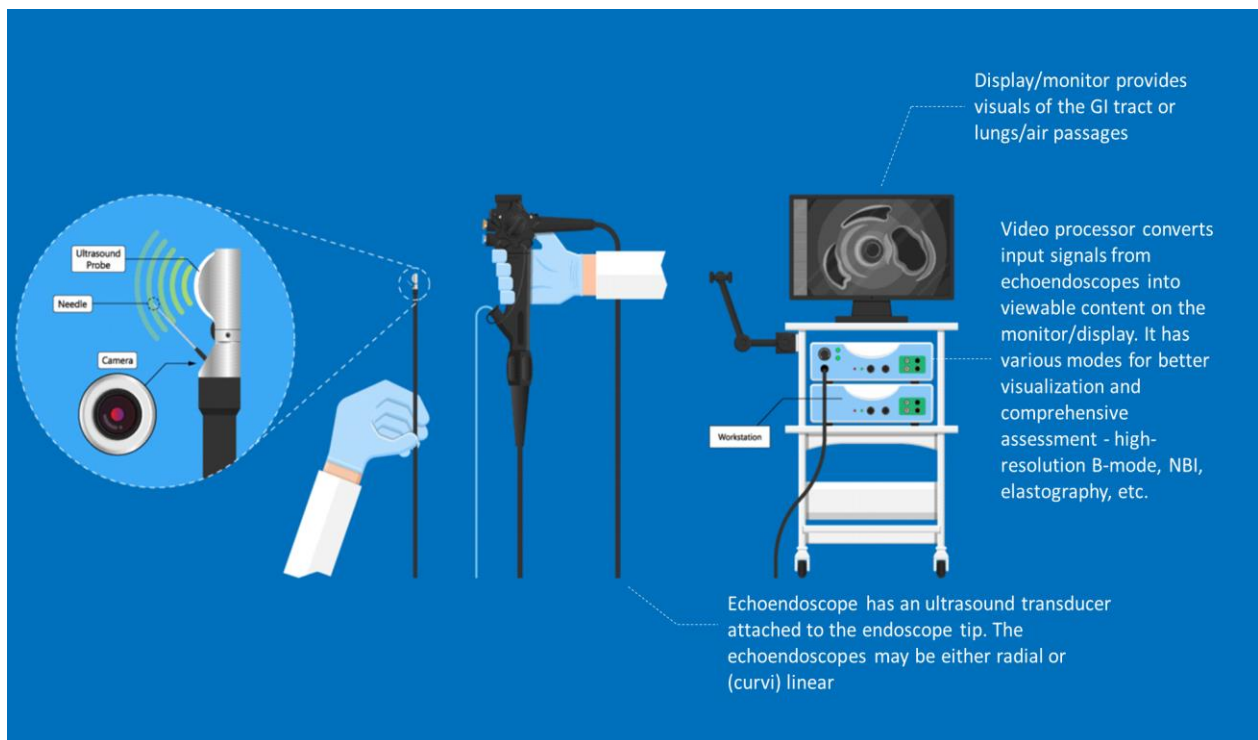
*Clinician/HOD users include all clinicians/HODs who currently use an E(B)US

*Purchase users include all purchasers who purchased an E(B)US in the last 2 years

*Clinician/HOD intenders include all clinicians/HODs who currently use a gastroscope/bronchoscope and are intending to purchase a E(B)US in the next 2 years

*Purchase intenders include all purchasers who have a gastroscope/bronchoscope installed in their facility and intend to purchase a E(B)US in the next 2 years

Q1. Moderator to show image and description of endoscopic ultrasound system (EUS)/endobronchial ultrasound (EBUS) along with its components and give enough time for the respondents to go through the same.



For Clinicians -

Q2. Of the total flexible endoscopic procedures, how many E(B)US procedures do you personally perform in a month?

Q3a. Why do you prefer E(B)US over traditional optical endoscopes? Please explain.

Q3b. Which type of echoendoscope is used at your facility – radial/(curvi) linear/both?

Q3c. What is the percentage split of procedures performed using radial vs. (curvi) linear echoendoscope?

Q3c i. Will the split by type of echoendoscope likely change?

Q3d. How will the current usage of E(B)US change over the next 2 years – increase/decrease/remain the same? Why do you say so?

Q4. How do you manage the maintenance/service of flexible endoscopes/EUS/EBUS used at your facility?

Q5. Are there any challenges that can be resolved through clinician training?

- a. If yes, please explain how training can help overcome the challenges faced?
- b. Who should best provide that training? **[PROBE IF ANY TRAINING EXPECTATIONS FROM OEMs]**
- c. Any thoughts on training periodicity/format?

Q6. What are the top 2 challenges, which, if resolved, will have the most impact on your current endoscopy practice (in improving patient outcomes, reducing procedure time, etc.)?

Q7. What would trigger or prompt the purchase of new flexible endoscopes/E(B)US?

Q8. What challenges, if any, do you currently face with your gastroscope/bronchoscope?

- a. Sub-optimal characterization of lesions due to lack of uniform illumination, contrast, or focus
- b. Restricted field of view, leading to improper adenoma detection
- c. Lack of triangulation and spatial orientation
- d. Improper/inefficient depth perception
- e. Limited angulation of distal scope tip
- f. Difficulty in visualizing mucosa behind folds
- g. Need for contrast enhancement options that are inexpensive and less time-consuming
- h. Lack of AI/ML algorithms to help with better polyp detection
- i. Low reliability of the echoendoscopes
- j. Sub-optimal cleaning or improper reprocessing leading to scope damage/quality degradation
- k. Long reprocessing turnaround time
- l. Lack of training to support staff leading to improper handling of scopes
- m. High cost of maintenance/repair
- n. Large diameter of the echoendoscope
- o. Any others?

Q9. How was the requirement/need request for a new flexible endoscope/E(B)US initiated?

Q9a. Who was the initiator of this request?

Q9b. Who within your facility has “championed” the adoption of flexible endoscopes/E(B)US?

Q10. What happened next, once the request for a new flexible endoscope/E(B)US was identified?

Q10a. Was there a need to create a business case to drive the purchase of a new flexible endoscope/E(B)US?

Q10a i) Who would be responsible for making a business case to purchase new flexible endoscopes/ E(B)US?

Q10a ii) What help would be needed when making a business case? Please explain.

Q11. What are the top 2 challenges, which, if resolved, will have the most impact on your current endoscopy practice (in improving patient outcomes, reducing procedure time, etc.)?

Q12. Who would be typically involved in the evaluation – researching, reviewing, compiling and presenting of the options?

Q12a. Which resources would be used to research/learn more about the flexible endoscopes/E(B)US available in the market?

Q12b. Which according to you is the most important source of information? Why do you say so?

Q13. What is the purchase method that is followed for flexible endoscopes/E(B)US at your facility? Why?

Q13a. Can you please elaborate on the procurement preferences/expectations for flexible endoscopes/E(B)US?

Q13a i) In what instances, would your facility opt for Direct purchase/No competitive bidding? Why?

Q13a ii) Is there a trend towards consolidating the number of suppliers? What is driving this trend?

Q13a iii) Is the purchasing aggregated across the network or is it an independent facility purchase?

Q14. If your facility is planning to purchase a new flexible endoscope/E(B)US, how do you decide whether to repurchase from existing vendors or to try new vendors?

Q14a. What are the key influencers that make you to consider new vendors over existing vendors?

Q15. How do you select the vendors from whom you request the bids?

Q15a. From how many vendors were bids requested? Is there any internal policy on the minimum number of bids required?

Q15b. Once the bids were received, how were they compared? What aspects of the bids were more important vs. less important in your evaluation?

Clinicians/HODs (Users) –

Q16. How would you rate your overall satisfaction with the currently used brand of gastroscope/bronchoscope? Please rate on a scale of 1 to 7 where 1 is not at all satisfied and 7 is very satisfied. **[IF MULTIPLE BRANDS OF GASTROSCOPE/BRONCHOSCOPE ARE BEING USED CURRENTLY, MODERATOR TO CAPTURE SATISFACTION RATING FOR MOST-USED BRAND]**

- a. What are some of the key features/likes?
- b. Are there any drawbacks?
- c. Are there any areas of improvement?

Purchasers (Intenders) –

Q16. How would you rate your overall satisfaction with the currently installed brand of gastroscope/bronchoscope? Please rate on a scale of 1 to 7 where 1 is not at all satisfied and 7 is very satisfied.

- a. What are some of the key features/likes?

Purchasers –

Q17. Who are the key stakeholders involved in purchasing a new flexible endoscope/EUS/EBUS?

Would you classify each as a DECISION MAKER and DECISION INFLUENCER

Decision MAKER: a person who makes the final decision either alone or in combination with others

Decision INFLUENCER: a person who would have the influence to affect or change the buying decisions

[LIST OF STAKEHOLDERS TO PROBE, IF RESPONDENT NEEDS GUIDANCE]

- a. Clinicians (Gastroenterologist/Pulmonologist)
- b. HOD/Chief of Gastroenterology/Pulmonology
- c. Procurement/Purchasing Head/Manager
- d. Equipment Department Head [INCLUDE ONLY FOR CHINA]
- e. Finance/Accounts Head
- f. CMO (Chief Medical Officer)
- g. CIO (Chief Information Officer)
- h. CFO (Chief Financial Officer)
- i. CEO/President/Vice President
- j. Head of Biomed
- k. Any others?

Purchasers -

Q18. What are the top 5 features taken into consideration during the purchase of flexible endoscopes/E(B)US for your facility?

Kindly select the top 5 ranks, from the list of the technical features and non-technical features list, 1 being the most important feature, 2 being the 2nd most important feature and so on.

[ALLOW FOR SPONTANEOUS RESPONSE THEN DISPLAY SHOWCARD FOR PROBE POINTS]

Technical features

- a. Maneuverability of the scope
- b. Ergonomically designed scope grip
- c. Range of tip angulation/field of view
- d. Simple, intuitive user interface of video processor

Non-technical features

- a. Clinician choice/preference [IF SELECTED, PROBE WHAT DRIVES

PREFERENCE – TRAINED ON THE BRAND DURING RESIDENCY, EASE OF USE, ETC.]

- b. Brand reputation
- c. Relationship with the sales team
- d. Flexible payment options
- e. Training and education
- f. Prompt and reliable after-sales service
- g. After-sales service and maintenance cost
- h. Total cost of ownership
- i. Any others

Purchasers-

Q19. What impact, if any, did the cost of maintenance/service contracts have on the purchasing decision for flexible endoscopes/EUS/EBUS? Please explain.

- a. What types of maintenance/service contracts are currently offered by manufacturers for flexible endoscopes/EUS/EBUS? [WAIT FOR RESPONSE, THEN PROBE ON BELOW POINTS]
 - a. Extended warranty
 - b. Comprehensive maintenance contract
 - c. Annual maintenance contract
 - d. Pay per fix (hourly rate)
 - e. Any others?
- b. Which is the most preferred service/maintenance contract model? Why?
- c. What could manufacturers of flexible endoscopes/EUS/EBUS do regarding maintenance/service contracts? Please explain. [WAIT OF RESPONSE AND THEN PROBE – QUICK RESPONSE TIME, PROVIDE REPLACEMENT MODELS, REMOTE TROUBLESHOOTING, SPECIAL DISCOUNTS, ETC.]

Clinicians/HODs (Intenders) –

Q20. How would you rate overall satisfaction with the currently used brand of gastroscope/bronchoscope? Please rate on a scale of 1 to 7 where 1 is not at all satisfied and 7 is very satisfied.

- a. What are some of the key features/likes?
- b. Are there any drawbacks?
- c. Are there any areas of improvement?

Q21. How would you rate your overall satisfaction with the maintenance/service support received from the currently used brand of gastroscope/bronchoscope? Please rate on a scale of 1 to 7 where 1 is not at all satisfied and 7 is very satisfied and explain your rating.

Q22. How would you rate your overall satisfaction with the clinical support/training received from the currently used brand of gastroscope/ bronchoscope? Please rate on a scale of 1 to 7 where 1 is not at all satisfied and 7 is very satisfied and explain your rating.

Purchasers –

Q23. When it comes to paying for flexible endoscopes/E(B)US, which of the following would be your preferred payment model? Why do you say so?

[SHOW BELOW OPTIONS AND IDENTIFY THE MOST PREFERRED OPTION AND REASONS]

- **CAPEX:** Acquire the equipment via a one-time upfront payment, with the option of ongoing payments for service, maintenance, upgrades, and updates
- **Leasing:** Acquire equipment for a specified time usually in return for a security deposit/down payment and periodic payments. Ownership rests in the hands of the leasing institution
 - **Operating lease:** Agreement to lease the equipment for a short period of time where it is the liability of the lessor to maintain the equipment
 - **Financial lease:** Agreement to lease the equipment for a long period of time where it is the liability of the lessee to maintain the equipment
- **Pay Per Use:** This is a pay as you go-based model, for example, based on the number of times the equipment has been accessed/utilized
- **Value-Sharing or Risk-Sharing (based on ROI benefits):** Vendor only gets paid (full or percentage of total) based on their performance against an agreed-upon metric

Q24. What are the key drivers that motivate your facility to invest in a E(B)US system?

Q25. What have been key barriers for your facility to invest in/adopt E(B)US in the past? **[WAIT FOR RESPONSE, THEN PROBE ON]**

- a. High upfront cost
- b. High maintenance/service costs

- c. Accuracy of E(B)US is operator dependent
- d. High procedure volume is required to recover the investment/initial costs
- e. FNA/FNB are more expensive than the standard needles increasing overall procedure costs
- f. Current flexible endoscopes are enough to perform the majority of the procedures
- g. Any others?
- h. Q6. What are the challenges you face with the E(B)US currently used at your primary facility?
- i. Sub-optimal characterization of lesions due to lack of uniform illumination, contrast, or focus
- j. Restricted field of view, leading to improper adenoma detection
- k. Lack of triangulation and spatial orientation
- l. Improper/inefficient depth perception
- m. Limited angulation of distal scope tip
- n. Difficulty in visualizing mucosa behind folds
- o. Need for contrast enhancement options that are inexpensive and less time-consuming
- p. Lack of AI/ML algorithms to help with better polyp detection
- q. Low reliability of the echoendoscopes
- r. Sub-optimal cleaning or improper reprocessing leading to scope damage/quality degradation
- s. Long reprocessing turnaround time
- t. Lack of training to support staff leading to improper handling of scopes
- u. High cost of maintenance/repair
- v. Large diameter of the echoendoscope
- w. Any others?

Clinicians/HODs –

Q26. What are the top 5 features taken into consideration during the purchase of **[FOR INTENDERS - gastroscope/bronchoscope; FOR USERS - E(B)US]** for your facility?

Kindly select the top 5, from the list of technical features and non-technical features list, 1 being the most important feature, 2 being the 2nd most important feature, and so on.

[ALLOW FOR SPONTANEOUS RESPONSE THEN DISPLAY SHOWCARD FOR PROBE POINTS]

Technical features

- a. Maneuverability of the scope
- b. Elevator locking assist
- c. Ergonomically designed scope grip
- d. Range of tip angulation/field of view
- e. High-resolution B-mode
- f. Narrow band imaging (NBI) mode
- g. Real-time tissue elastography
- h. Contrast-enhancement option
- i. Simple, intuitive user interface of video processor

Non-technical features

- a. Clinician choice/preference **[IF SELECTED, PROBE WHAT DRIVES PREFERENCE – TRAINED ON THE BRAND DURING RESIDENCY, EASE OF USE, ETC.]**
- b. Brand reputation
- c. Relationship with the sales team
- d. Flexible payment options
- e. Training and education
- f. Prompt and reliable after-sales service
- g. After-sales service and maintenance cost
- h. Total cost of ownership
- i. Any others?

Q27. Who are the key stakeholders involved in purchasing a new **[FOR INTENDERS - gastroscop/ bronchoscope; FOR USERS – EUS/EBUS]**? **[ASK OPEN-ENDED, AND THEN PROBE FOR THE BELOW ROLES IF NEEDED]**

- a. Would you classify each as a DECISION MAKER and a DECISION INFLUENCER

Decision MAKER: a person who makes the final decision either alone or in combination with others

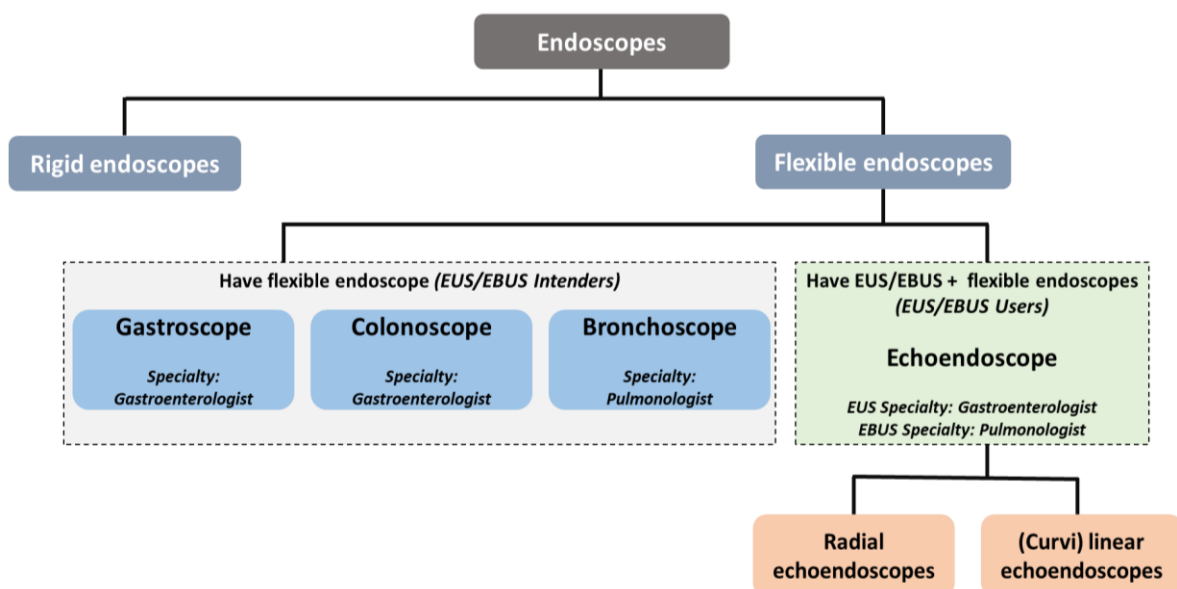
Decision INFLUENCER: a person who would have the influence to affect or change the buying decisions

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- d. Equipment Department Head **[INCLUDE ONLY FOR CHINA]**
- e. Finance/Accounts Head
- f. CMO (Chief Medical Officer)
- g. CIO (Chief Information Officer)
- h. CFO (Chief Financial Officer)
- i. CEO/President/Vice President
- j. Head of Biomed
- k. Any others?

Discussion Guide Flow:

FOR CLINICIANS & HODs



FOR PURCHASERS

