Learning Curve in ESD

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Concept of ESD

- **Organ Preservation: Oesophagus, Rectum, Stomach, Colon.**

  Alternatives: Aggressive surgery (such as oesophagectomy, gastrectomy, Colectomy, perminant stoma).

- **En-Block Resection: for flat, surperficial mucosa, Subepithilial lesions.**
- **Avoid Surgery: (Hospitalization time, Surgical comorbidities, scaring).**
- **Cost: Feasabilities (in Western Country).**

I) Skills/ Competence to start ESD

- **Advanced endoscopy diagnostic practice** is advised before initiating ESD training.
- Training in ESD should be considered only by **fully trained endoscopists**.
- **Proficiency in EMR and adverse event management** is recommended before starting ESD training.
- Knowledge of the **“ESD theory”** is necessary before and during training.

II) Training

- **Live conferences and meetings** are suggested before and during ESD training.
- D**iscourages** the starting of initial ESD training in **humans**.
- **Practice on animal** and/or ex vivo models is useful to gain the basic ESD skills.

Live Conferences

Don’t start in human

Practice on animal

II) Training

- At **least 20 ESD procedures in these models** before human practice

  The goals are:

  ✓ **at least 8 En-bloc complete resections**

  ✓in the **last 10 training cases**

  ✓**with no perforation**.

- **Supervision during training** as it seems effective in improving the skills of trainees.

II) Training

- To **understand strategies and risk management**, ESGE recommends observation of experts performing ESD in tertiary referral centers. **At least 20 ESD procedures observed** and **5 procedures as assistant**, ideally within a **short period** of time, are recommended.
- Performance of ESD in humans should start on carefully selected lesions,

  ideally small (< 30 mm),

  located in the antrum or rectum (first 20 procedures – initial period).
- Beginning **human practice** in the **colon is not recommended**
- At least the **first 10 procedures in humans** should be done **under the supervision** of an ESD-proficient endoscopist.

III) Knowledge and maintaining competence

- Endoscopists involved in ESD should have specific **knowledge of the instrumentation, technique, and electrosurgical equipment.**
- Endoscopists performing ESD **should be able to correctly** estimate the probability of performing a curative resection based on the characteristics of the lesion and **should know the benefit/risk relationship of ESD** when compared with other therapeutic alternatives.

III) Knowledge and maintaining competence

- Endoscopists performing ESD should **know how to interpret the histopathology findings of the ESD specimen**, namely the criteria for resection, as well as their implications:
  - Low-risk resection.
  - Local risk resection.
  - **High-risk resection.**

III) Knowledge and maintaining competence

All procedures should be registered in a **prospective database covering items** such as:

- Endoscopic classification.
- Location.
- Size.
- Technique used.
- En-bloc resection rate.
- Complication rates.
- Procedure time.
- R0 resection rate.
- Final histopathology (including type of resection).

Optimum Features:

✓ En-block rate 90%.

✓ Perforation rate <3%.

✓ Surgery <1%.

Summary

25 + 55 = 80 cases

- ✓25 Observer
- ✓>20 Animal
- ✓>10 Human cases
- ✓> 25 Human/ year

(20 see + 5 assist)

(last 8/10) enblock without perforation

(Easy sites) 8 R0, no perforation

(90% enblock, <3% perforation, <1% surgery)

UEGW 2015

ESGE Learning Session

Therapeutic Approach to GI Lesions –
ESD Open Hands-On Training

Trainers:
Dr. Ken Ohata, Tokyo, Japan
Dr. Yousuke Tsuji, Tokyo, Japan

Location:
Fira de Barcelona

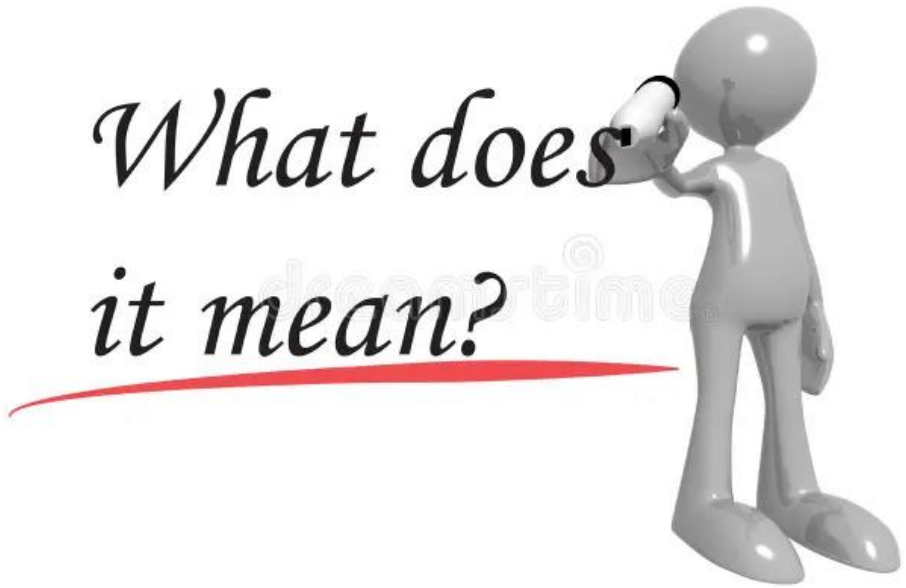
ESD Milestones for Endoscopist Learning Curve: Japan vs. Western World

- **Endoscopic Submucosal Dissection (ESD)** is an advanced, minimally invasive endoscopic resection technique.
- ESD allows for **en bloc resection** of superficial neoplasms regardless of size or presence of fibrosis, yielding high curative resection rates and low local recurrence rates compared to (EMR).
- Acquiring proficiency in ESD is **technically challenging** and requires a **high level of technical expertise** due to its inherent complexity and long procedure times.

Important Concepts and Definations of Resection

In the context of **(ESD)**, several terms are used to describe the quality and outcome of the resection.

- **Endoscopic Resection**.
- **En-Block** Resection.
- **R0** Resection.
- **Curative** Resection.
- **Low-risk** resection.
- **Local risk** resection.
- **High-risk** resection.



ESD Milestones for Endoscopist Learning Curve: Japan vs. Western World

- The learning curve for ESD is often described as **"very flat"**.
- The learning curve progression is typically measured by metrics such as:

1. **Procedure time.**
2. **Resection speed.**
3. **En bloc resection rate.**
4. **R0** (complete) resection rate.
5. **Complication rates** (perforation and bleeding).

Contextual Differences in Training Environments

Japan (East Asia)	Western World (ESGE/US)
High incidence of Early Gastric Cancer (EGC) provides ample/enough training case volume.	Low incidence of EGC means less opportunity to practice initially on the safest organ.
Training focuses initially on gastric ESD (considered easier/safer location).	Training typically focuses on colorectal or esophageal lesions.
Established structured, step-by-step training systems are widespread.	Historical lack of standardized training pathways and lack of local experts/highly qualified mentors.
Apprenticeship model where direct supervision by experts is readily available.	Training often relies heavily on external courses, animal labs, and observerships.

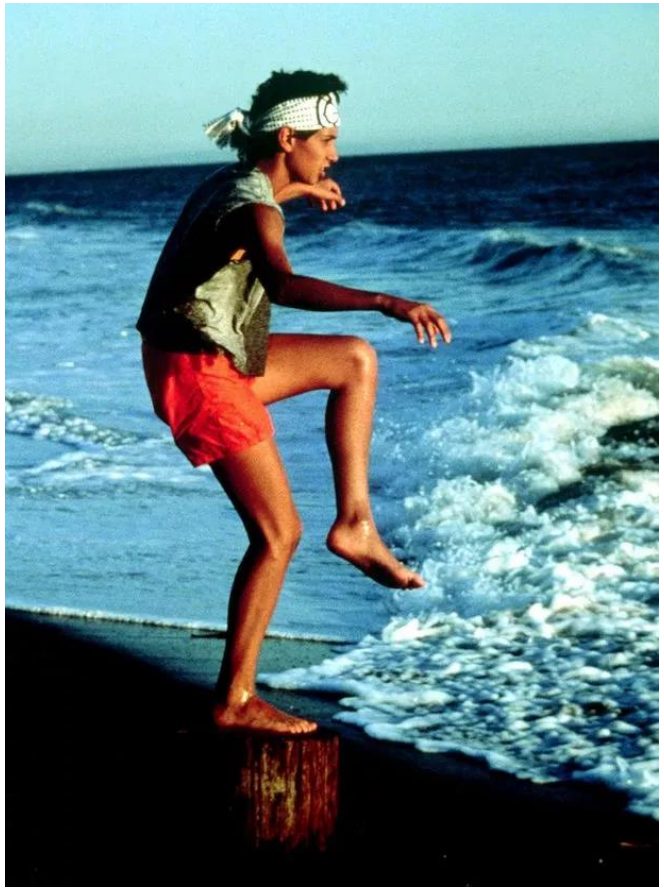
Prerequisite Skills and Knowledge Checkpoints

- **Trainee Status:** Training should only be considered by **fully trained endoscopists**.
- **Procedural Experience (Japan Objective Indicators):** Prior to performing the first ESD, trainees should have performed:
  - More than **1,000 cases** of (EGD) for acquiring **gastric ESD** skills efficiently.
  - A minimum of **500 cases** of colonoscopy for **colorectal ESD**.

- **Core Endoscopic Skills:** Proficiency in **EMR** and expertise in **hemostatic techniques** are crucial, as uncontrolled bleeding is a major difficulty during ESD.

Prerequisite Skills and Knowledge Checkpoints

- **Adverse Event Management:** Required expertise in managing adverse events such as active bleeding and perforations using clips, OTSC (over-the-scope clips), or endoscopic suturing.
- **Diagnostic Mastery:** Essential prerequisite includes; mastering
  - ✓ Diagnostic practice (virtual or dye-based chromoendoscopy+/- magnification)
  - ✓ Accurately diagnose the lesion.
  - ✓ Predict invasion depth
  - ✓ Delineate margins (e.g., using classifications like Paris, JNET, NICE).



Training Phase: Simulation and Observation

Japanese Model Checkpoints	Western/ESGE Model Checkpoints
Phase 1: Knowledge Acquisition	**ESGE Checkpoint: Theory**
▪ Accumulate basic knowledge about ESD technique, indications, limitations, ESU operation, and adverse event management.	▪ Knowledge of the "ESD theory" is necessary before and during training.
Phase 2/3: Observation & Assistance	**ESGE Checkpoint: Observation & Assistance**
▪ Observe experts and assist them to understand strategy, tools, and risk management.	▪ Observe at least 20 ESD procedures in tertiary referral centers.
▪ Recommended observation/assistance: 20 procedures observed and 5 procedures as assistant.	▪ Assist in 5 procedures.
Phase 4: Hands-on Models (Variable)	**ESGE Checkpoint: Simulation**
▪ Training using ex vivo animal models (e.g., pig stomach) occurs, but the necessity is debated due to high availability of expert supervision.	▪ Discourages starting initial ESD training in humans.
▪ Typical minimum: Approximately 5 or less ex vivo training sessions before starting human cases.	▪ Recommended: Perform at least 20 ESD procedures in animal/ex vivo models before human practice.

Hands-on Model Proficiency Checkpoint (Western)

Checkpoint for Readiness to Transition to Human Cases

- ESGE recommends defining a trained student based on achieving a performance objective rather than just a minimum number of cases.
- **Minimum Procedures:** At least **20 ESD procedures** performed in animal or *ex vivo* models (with supervision encouraged).
- **Quality Threshold Metric:** The trainee should achieve a quality goal:
  - ✓ **At least 80% en bloc complete resections** (all margins visible)
  - ✓ **No perforation**
  - ✓ In the **last 10 consecutive training procedures**.

JAPAN

Hands-on Model Proficiency Checkpoint (Japan)

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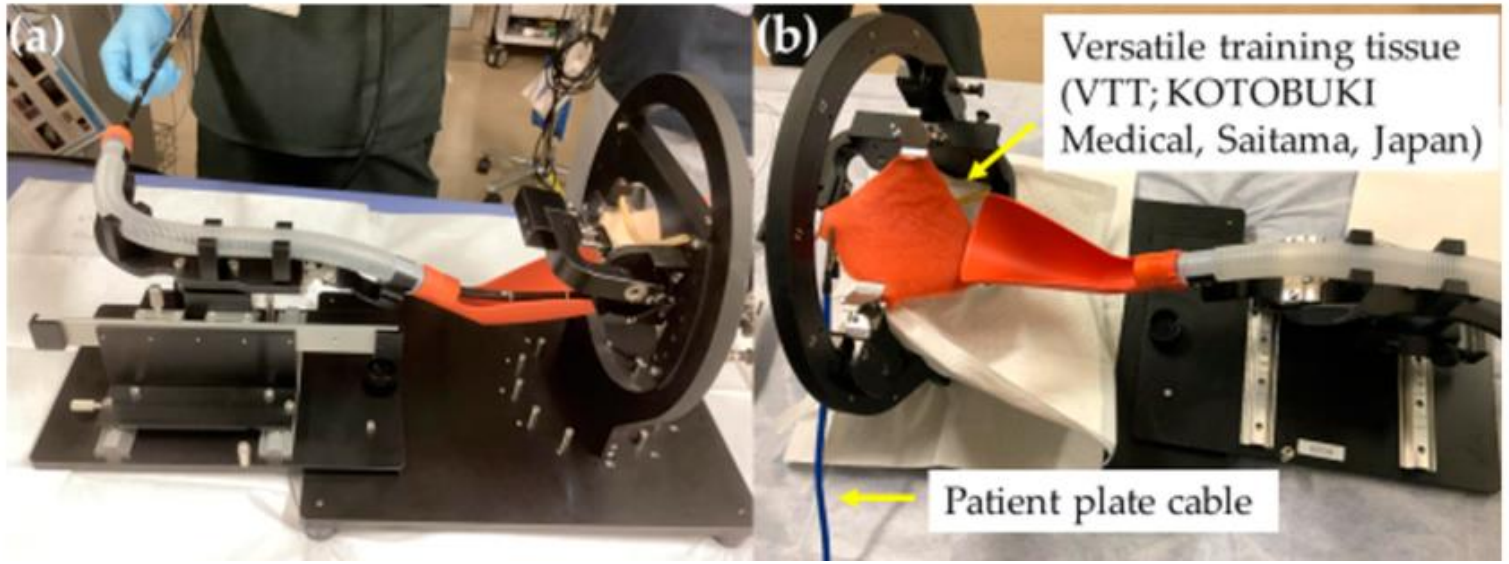
Checkpoint for Readiness to Transition to Human Cases

- **Japanese Example (G-Master ex vivo model):** Studying a novel Japanese model, 4 trainees achieved 100% en-bloc resection without perforation across 30 sessions, indicating the model is highly effective for pre-ESD practice. The transition point from the initial growth phase (Phase 1) to the plateau phase (Phase 2) occurred after a median of **10 sessions**.



Initiating in Human: Lesion Selection & Supervision

- **Supervision is Mandatory:** At least the **first 10 procedures in humans** (ideally per organ) should be done under the **supervision of an ESD-proficient endoscopist**.
- **Japan: Initial Cases (Gastric Focus)**

  - Lesions should be **small (≤ 20 mm)**, located in the **lower third (antrum) of the stomach**, and without ulceration or scarring.
  - Lesions in the antrum are suitable for beginners because antegrade endoscopic manipulation is possible and lesion elevation is usually good.
  - Trainees receive hands-on support by experts during the **first 10 ESD procedures**.

Initiating in Human: Lesion Selection & Supervision

- **Western/ESGE: Initial Cases (Organ Selection)**
  - Performance of ESD in humans should start on carefully selected lesions, ideally **small (< 30 mm)**, located in the **antrum or in the rectum** for the first 20 procedures (initial period).
  - The **rectum** is preferred over the colon due to better maneuverability and lower morbidity associated with perforations.
- **Progression Checkpoint:** As techniques improve, trainees are gradually assigned to perform ESD on lesions located in the middle and upper thirds of the stomach and lesions larger in size.

Gastric ESD Learning Curve Milestones (Japan)

Learning Phase	Cases Completed	Checkpoint/Outcome
Initial Supervised Phase	1–10 cases (Period A)	Hands-on support by experts; low complication rate achieved.
Early Development	11–20 cases (Period B)	Hands-on support mostly replaced by verbal guidance. En-bloc rate 100%; Procedure time (lower third): 90 min.
Acquisition of Basic Technical Skills (Competency)	30 cases (Period C)	Learning curve point for acquiring basic technical skills for ESD in the lower third of the stomach. Procedure time (lower third): 70 min.
Improved Efficiency	31–40 cases (Period D)	Procedure time for lower third lesions significantly shorter than Period B (60 min vs 90 min). Proportion of easy lesions (lower third) decreases Statistically significant.
Minimum for Proximal Location	40 cases	Estimated minimum learning curve point for performing ESD in the middle and upper thirds of the stomach.
Proficiency/ Expertise	50–100 cases	Consensus level of experience required for a competent or proficient ESD operator.

Colorectal ESD Learning Curve Milestones (Japan)

- **Prerequisite (Common Strategy):** Trainees should start colorectal ESD *after* performing at least **30 cases of gastric ESD** due to technical difficulty.
- **Learning Phase Checkpoints (for those experienced in Gastric ESD):**
  - **Avoiding Perforations:** Performance of approximately **40 procedures** was sufficient to acquire the skill to avoid causing perforations during the procedure.
  - **Competency Milestone:** Trainees could reach a stable level of technical competency after an average of **30 cases** of colorectal ESD.
  - **Proficiency Milestone (Large Tumors):** Approximately **80 procedures** must be carried out to acquire adequate skill to successfully remove large colorectal tumors.

Western Learning Curve (Colorectal/Mixed Sites)

Case Load	Endoscopist/Setting	Checkpoint/Outcome
Initial Competency (Europe)	Experienced endoscopists (Germany) after formal training (observation, animal model, supervised ESD)	R0 resection rate started at 86.7% for the first 15 lesions and peaked at 100% for the last 15 lesions (gastric/rectal focus).
Mid-Volume Improvement (Europe, Colorectal)	Specialized center (Sweden)	Improvement in R0 rate from 60% (first 60 cases) to approximately 80% by 300 cases.
Colonic Plateau (Untutored US Operator)	Single operator, large tertiary center (US)	Learning plateau for en-bloc and R0 resection in the colon reached after 185 cases.
Proficiency (Untutored US Operator, Mixed Sites)	Single operator, large tertiary center (US)	Competency achieved for en-bloc, R0, and curative resection rates between 250 and 350 procedures.
High Effectiveness Plateau (Europe, Colorectal)	Specialized center (Europe)	Required 120 colorectal ESD procedures to reach a plateau of high effectiveness and low morbidity.

Case Complexity: A Major Western Obstacle

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- **Lesion Selection Bias:** In Japan, training starts on easy, unmanipulated lesions (small EGC in the antrum).
- **Western Referral Patterns:** In the US and Europe, ESD endoscopists often encounter cases referred as a "last resort" before surgery.
- **Increased Difficulty:** Approximately **17%** of lesions in a US single-operator analysis were previously manipulated (incomplete resection or tattooing extending to the base).
- **Fibrosis Checkpoint:** Severe submucosal **fibrosis** (F2/F3) is common in these complex Western referrals, found in **17%** of lesions in one US cohort.
- **Impact:** Fibrosis significantly increases technical difficulty, procedure time, and negatively affects R0 resection rate, thereby **steepening the learning curve** in the West compared to Asia.

Defining Expertise: Objective Outcome Checkpoints

- **Need for Standards:** Objective standardized markers are needed to define ESD expertise.
- **Three Key Measures (Oyama et al. / ESGE goals):**

Metric	Target Value	ESGE Recommendation	Japanese Trainee/Expert Data (Colorectal)
En Bloc Resection Rate (Technical Success)	≥90%	Recommended goal for all endoscopists.	Experts achieved 95.6%; Trainees achieved 94.7%.
Perforation Rate (Safety)	≤3%	Recommended upper limit.	Japanese studies often report lower rates (e.g., US/Europe report higher pooled rates, 8.6%).
Curative Resection Rate (Efficacy/Oncology)	>75%	Recommended goal.	Experts achieved 81.3%; Trainees achieved 81.1%.
Dissection Speed (Efficiency)	≥9 cm^2/h	Acknowledged mark for expertise.	Experts achieved 10.3 cm^2/h; Trainees achieved 6.7 cm^2/h.

Technical Aids for Western Trainee Progression

Traction Methods: Use of traction methods (e.g., clip-and-line, dental floss, double-clip traction) is strongly recommended, particularly in esophageal and colorectal ESD.

- **Benefit:** Traction consistently **decreases procedure time** and **adverse events** in the esophagus and colorectum.
- **Learning Curve Impact:** Traction techniques can shorten the learning curve for trainees and improve early results.

Scissor-Type Knives (SB Knife Jr, Clutch Cutter): These devices enable grasping the target tissue, facilitating controlled dissection.

- **Benefit:** Scissor-type knives allow for safe and easy colorectal ESD during the introductory period compared to conventional tip-type knives.
- **Adoption:** Using these knives may encourage widespread adoption of Colorectal ESD in general hospitals and non-Asian countries.

Summary of ESD Learning Curve Contrast

The ESD learning curve path differs significantly based on regional disease prevalence and available mentorship:

Characteristic	Japan (Gastric Focus)	Western World (Colorectal Focus)
Initial Lesion	Small, non-fibrotic EGC in Gastric Antrum.	Small lesions in Rectum or Gastric Antrum.
Hands-on Model	Typically 5 sessions or less, supplementary to mentorship.	Mandatory: 20 sessions/80% success before human cases.
Supervision Intensity	Direct hands-on support for first 10 gastric cases.	Direct supervision for first 10 human procedures (ideally per organ).
Competency Milestone (Lower third gastric)	30 cases (Acquisition of basic technical skills).	Undefined by case number for stomach, but early high R0 rates possible with training (e.g., 15-20 cases).
Expertise Milestone (Gastric/Colorectal)	80 cases (Colorectal proficiency) 50–100 cases (Gastric expertise).	250–350 cases for untutored expert proficiency in mixed sites (US data).
Key Technical Aid	Expert mentorship and diagnostic skill development.	Traction methods, specialized knives, and animal models.

Support ☺

Thank You