

# Complicanze in endoscopia digestiva formazione, qualità e percorsi

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LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

Transoral therapeutic endoscopy - Endolumenal surgery

Resection / ablation of mucosal lesions

Submucosal space therapeutic endoscopy Full thickness resection

Trans-oral treatment of motor functional disorders

Trans-oral treatment of gastro-esophageal reflux disease

Trans-oral treatment of obesity

Therapeutic ERCP

Trans-oral EUS-guided interventions



LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

Efficacy of endoscopic resection of large benign colorectal neoplasia

50 studies included in the meta-analysis; 6,442 patientsEndoscopic resection:Complication rate 8.0%Recurrence rate 13.8%Surgical resection:

Adverse events 17%- 30% (2-fold increase compared to endoscopic resection) Mortality rate 1% - 1.6% (10-fold increase compared to endoscopic resection)

Cost of colorectal polyp treatment:

- endoscopic resection = \$ 5,570 per patient
- surgical resection = \$ 18,717 per patient

Endoscopic resection is a cost-effective strategy for removal of colorectal neoplasia. The effectiveness depends on the high technical success, low adverse event rates, and better quality of life

Hassan C, et al. Efficacy and safety of endoscopic resection of large colorectal polyps: a systematic review and meta-analysis. Gut 2016; 65: 806-820



### LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

50 80 Age, yrs Cost of surveillance colonoscopy \$ 722 \$ 1,500 Cost of LR of polyp \$ 17,260 \$ 20,000 Cost of surgical intervention for \$ 27,364 \$ 35,000 complication Cost of colonoscopic resection of \$ 1,381 \$ 2,500 large colon polyp Loss of utility, for colonoscopy (2 .0055 .0082 days) Loss of utility, for LR .0178 .0274 (6.5 days) Loss of utility, for surgical .0271 .0384 intervention for adverse events (9.9 days)

All cost data derived from Centers for Medicare & Medicaid Services reimbursement and mean cost for respective CPT codes in 2012-2013.

All loss of utility data derived from 2012 Healthcare Cost and Utilization Project data using a national inpatient sample for all patients admitted with respective CPT codes

Overall costs of surgical vs endoscopic resection of large colorectal polyps

> Law R et al. Gastrointest Endosc 2016; 83:1248-57



# LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

# Esophageal POEM outcomes: efficacy

Study name	Statistic	cs for each	study		Std diff in means and 95% (	
	Std diff in means	Lower limit	Upper limit	Total		Relative weight
Ling et al.; 2014	-0.357	-0.640	-0.074	51		12.71
Minami et al.; 2014	-0.812	-1.240	-0.385	28	-	10.88
Familliari et al.; 2013	-13.985	-25.232	-2.738	3	$\leftarrow$	0.06
Chui et al.; 2013	-0.933	-1.520	-0.346	16		8.86
Lee et al.; 2013	-1.090	-1.776	-0.404	13	— <b>B</b>	7.74
Onimaru et al.; 2013	-1.717	-2.646	-0.787	11	<b></b>	5.55
Verlaan et al.; 2013	-1.028	-1.794	-0.262	10		6.93
Li et al.; 2013	-0.259	-0.389	-0.129	234		14.18
Cai et al.; 2013	-0.406	-0.609	-0.202	100		13.57
Zhou et al.; 2013	-1.709	-2.597	-0.822	12		5.87
Costamagna et al.; 2012	-1.901	-2.939	-0.862	10	<b></b>	4.81
Inoue et al.; 2010	-1.033	-1.622	-0.444	17		8.84
Total effect (95% CI) [Random]	-0.851	-1.129	-0.573		◆	
Heterogeneity: Tau <sup>2</sup> = 0.13 Test of overall effect: Z= -5	7; Q= 51.38 5.99; p< 0.00	; df=11; l²= 001	1			
					-4.00 -2.00 0.00 2.00	4.00

Talukdar R, Inoue H, Reddy N. Surg Endosc 2014



### LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

### Operative time of esophageal POEM vs Laparoscopic Heller Myotomy (LHM) for Achalasia : Meta-analysis

Authors		HM		POEM	Weig	hted	MD [95% CI]
	Ν	Mean [SD]	N	Mean [SD]	Mean Di	ifference	[]
Chan et al	23	127 [ 30.1 ]	33	97 [ 40.8 ]			30.00 [ 11.42 , 48.58 ]
Kumagai et al	41	108.7 [ 21 ]	42	130.5 [ 39.6 ]	⊢∎⊣		-21.80 [ -35.39 , -8.21 ]
Kumbhari et al	26	261.9 [ 43.5 ]	49	148.9 [ 94 ]			→ 113.00 [ 81.82 , 144.18 ]
Bhayani et al	64	175.2 [ 53.9 ]	37	129 [ 46.9 ]		<b>⊢</b> −−1	46.20 [ 26.13 , 66.27 ]
Hungness et al	55	133.9 [ 31.6 ]	18	134.6 [ 43.4 ]	, <b></b> -		-0.70 [ -22.42 , 21.02 ]
Ujiki et al	21	154.5 [ 8.3 ]	18	155.8 [ 12.8 ]	•		-1.30 [ -8.20 , 5.60 ]
POOLED WMD	230		197			-	26.28 [ -11.20 , 63.76 ]
Test for Overall Effect Test for Heterogeneity	Z = 1 Q = 8	37, P = 0.17 7.63, P = 0, I-sq.=	97.11	_			
				-70 Favou	-24.25 rs HM	67.2 Favo	25 113 Durs POEM

Awaiz et al. Surg Laparosc Endosc Percutan Tech 2017



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Trans-oral treatment of obesity

# Space occupying devices

Balloon:

- Orbera
- Obalon
- Reshape balloon
- Spatz

Non balloon:

- Trans-pyloric shuttle

# Aspiration

- AspireAssist

# **Gastric restriction**

- Sleeve gastroplasty
  - Apollo Overstich
  - GERDX
  - Endolumina
  - Primary obesity surgery endoluminal (POSE)

# Malabsorption

Gastrointestinal by pass sleeve

- Endobarrier
- EUS-guided magnetic by pass

Duodenal resurfacing

Weight reduction Type 2 diabetes control



How to prevent and manage complications of endoscopy ?

# - adequate training / experience

- learning curve
- case volume (longlife / per year)
- simulators
- retraining

# adequate technology / facilities

- imaging
- devices
- endoscopy room
- adequate reprocessing
- adequate supporting team



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Skills currently required for endoscopy practice

Learning to perform an endoscopic procedure or technique requires acquisition of:

- cognitive (knowledge and recognition) skills
- technical (psychomotor) skills
- non-technical (expertise and behavior) skills

An explicit understanding of the competencies required for performance of high-quality endoscopic procedures and techniques is essential to the development of a framework for endoscopy training and assessment.

Cognitive and non-technical skills often are underemphasized early in the training process, although these are critically important attributes of a competent endoscopist.

Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE) Gastrointest Endosc 2019;90:13-26



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Skills currently required for endoscopy practice

Cognitive skills encompass knowledge and the application of endoscopically derived information to clinical practice

Technical skills are the psychomotor activities required to carry out a procedure

Non-technical skills include core skills decision making that "allow individuals to integrate their knowledge and technical expertise to function effectively within a healthcare team, adapt to varied contexts, tolerate uncertainty, and ultimately provide safe and effective patient care" Non-technical skills also include safety-related competencies such as knowing when not to proceed, when to call for help, and crisis management skills

> Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE) Gastrointest Endosc 2019;90:13-26



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Non-technical skills

Non-technical skills are an essential component of competent endoscopic practice and a key contributor to patient safety and clinical outcomes

Procedure-related adverse events are more likely to stem from behavioral failures, such as a communication error, as opposed to a lack of technical skill

The vast majority of recommendations originating from the 2004 investigation into deaths occurring within 30 days of adult therapeutic endoscopy procedures in the United Kingdom, underscored deficits in non-technical skills, such as situation awareness, rather than technical

> Hitchins CR, Ward C, Edworthy J, et al. Non-technical skills and gastrointestinal endoscopy: a review of the literature. Frontline Gastroenterol 2018;9:129-34



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Definition of competence levels

# **Efficiency:**

The point in the learning curve in which the operator starts engaging in performance refinements that lead to increase in technical goals and decrease in procedure time and complications

# **Mastery:**

The point in the learning curve at which procedure time becomes consistent, and no further improvement is expected

# **Competency / Proficiency:**

The understanding the cognitive aspects of procedures and reliably achieving the procedure-related technical goals



### Colorectal polypectomy and endoscopic mucosal resection (EMR): European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline

### Endoscopy 2017; 49: 270–297





# LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

Endoscopic submucosal dissection of lateral spreading tumor of the colon





Curriculum for endoscopic submucosal dissection training in Europe: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement



ESGE discourages the starting of initial ESD training in humans. Practice on animal and/or ex vivo models is useful to gain the basic ESD skills. Beginning human practice in the colon is not recommended.

At least 20 ESD procedures in these models before human practice, with the goal of at least eight en bloc complete resections in the last 10 training cases, with no perforation.



Curriculum for endoscopic submucosal dissection training in Europe: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement



Performance of ESD in humans should start on lesions < 30mm, located in the antrum or in the rectum for the first 20 procedures, in tertiary referral centers.

The first 10 human ESD procedures should be done under the supervision of an ESD-proficient endoscopist.

In order to maintain proficiency in ESD, ESGE recommends a minimum case load of 25 ESD procedures per year

En bloc resection rates should be above 90 %, and the perforation rate should be below 3%, with a lower than 1% need for surgery because of complications.



Curriculum for endoscopic submucosal dissection training in Europe: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement

Endoscopists performing ESD should:

- have specific knowledge of the instrumentation, technique, and electrosurgical equipment
- be able to correctly estimate the probability of performing a curative resection based on the characteristics of the lesion and
- know the benefit/risk relationship of ESD when compared with other therapeutic alternatives
- know how to interpret the istopathology findings of the ESD specimen: criteria for low risk resection ("curative"), local risk resection, and high risk resection ("non-curative"), as well as their implications

ESD should be performed only in a setting where early and delayed complications can be managed adequately

Non-technical skills

Endoscopy, 2019



Wide-field endoscopic mucosal resection versus endoscopic submucosal dissection for laterally spreading colorectal lesions: a costeffectiveness analysis

Farzan F Bahin,<sup>1,2</sup> Steven J Heitman,<sup>1,3</sup> Khalid N Rasouli,<sup>1</sup> Hema Mahajan,<sup>4</sup> Duncan McLeod,<sup>4</sup> Eric Y T Lee,<sup>1</sup> Stephen J Williams,<sup>3</sup> Michael J Bourke<sup>1,2</sup>

Strategy	Cost (US\$)	Incremental cost (US\$)	Number of surgeries avoided	Additional surgeries avoided	Incremental C/E
S-ESD	4 224 464		925		
WF-EMR	4 334 561	110 097	906	-19	\$ than S-ESD <surgeries avoided="" s-esd<="" td="" than=""></surgeries>
U-ESD	6 911 797	2 687 333	938	13	210112 (compared with S-ESD)
C/E_cost effectiveness: ESI	) ondoccopic cubmucocol -	discostion: C CCD coloction D	CD: II CCD universal CCD:	WE EMD wide field and a	conic musered recetion

re, cost enectiveness, coo, endoscopic submicosar dissection, o coo, o coo, dinversar coo, wir chin, wide neid endoscopic indcosar resection.

In presence of large lesions, routine piecemeal EMR and selective ESD are cost effective approach compared to routine ESD

Gut, 2018; 67: 1965-1973



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# Endoscopic resection: hybrid ESD





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Endoscopic submucosal dissection: Orise (Boston Inc.)

Lesion in the rectum and distal sigmoid colon > 5 cm in size

Stabilizes the device on the lesion Permits triangulation Facilitates submucosal dissection Reduces time of resection







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The third space

A new concept to approach submucosal lesion and full thickness resection maintaining the integrity of the mucosa

"The third space"





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Third space endoscopy

Submucosal Tunneling endoscopic resection of Submucosal Tumors (STER)

Submucosal Tunneling Mucosal Dissection (ST-ESD)

Esophageal Peroral Endoscopic myotomy (E-POEM)

Gastric Peroral Endoscopic pyloromyotomy (G-POEM)

Submucosa Tunneling septotomy for Zenker and epiphrenic diverticula (D-POEM)

Per-rectal Endoscopic Myotomy (PREM)

Trans-rectal/Trans-gastric endoscopic cholecystolitotomy



# LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

Tunneling technique for full thickness resection of large gastric GIST





# LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

# Esophageal POEM: tunneling technique





# LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

# Gastric POEM: tunneling technique and muscle section



### ORIGINAL ARTICLE: Clinical Endoscopy



# Peroral endoscopic esophageal myotomy: defining the learning curve

Ashwin A. Kurian, MD,<sup>1</sup> Christy M. Dunst, MD,<sup>2</sup> Ahmed Sharata, MD,<sup>2</sup> Neil H. Bhayani, MD,<sup>1</sup> Kevin M. Reavis, MD,<sup>2</sup> Lee L. Swanström, MD<sup>2</sup>

Portland, Oregon, USA



Gastrointest Endosc 2013;77:719-25



Consecutive procedures: line demonstrates the trend of decreasing length of procedure (LOP).

Consecutive procedures: each dot defines the number of mucosotomies per case along the timeline of experience.

Mastery of operative technique in POEM is evidenced by a decrease in length of procedure, variability of minutes per centimeter of myotomy, and incidence of inadvertent mucosotomies and plateaus in about 20 cases for experienced endoscopists.

#### ORIGINAL ARTICLE: Clinical Endoscopy



### The light at the end of the tunnel: a single-operator learning curve analysis for per oral endoscopic myotomy

Kumkum Sarkar Patel, MD, MPH,<sup>1</sup> Rose Calixte, PhD,<sup>2</sup> Rani J. Modayil, MD,<sup>3</sup> David Friedel, MD,<sup>3</sup> Collin E. Brathwaite, MD, FACS,<sup>4</sup> Stavros N. Stavropoulos, MD<sup>3</sup>

Mineola, New York, USA

Gastrointest Endosc 2015;81:1181-7



Sequential grouping of procedure time. Median (interquartile range) procedure times (minutes) for each sequential group showing overall decrease in procedure time. Plots of procedure time with a locally weighted scatter plot smoothing regression curve. CUSUM analysis showing efficiency after 40 procedures and mastery after 60 procedures



### The Per Oral Endoscopic Myotomy (POEM) technique: how many preclinical procedures are needed to master it?

### Endoscopy International Open 2015; 03: E559–E565

Authors

Oscar Víctor Hernández Mondragón<sup>1</sup>, Dulce Maria Rascón Martínez<sup>2</sup>, Aracely Muñoz Bautista<sup>3</sup>, Maria Lourdes Altamirano Castañeda<sup>3</sup>, Gerardo Blanco-Velasco<sup>1</sup>, Juan Manuel Blancas Valencia<sup>1</sup>

Institutions

Institutions are listed at the end of article.





Control chart of speed behavior in subsequent procedures of ex vivo model

Control chart of speed behavior in subsequent procedures of porcine model



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ESD should be performed only in a setting where early and delayed complications can be managed adequately







# LE COMPLICANZE IN ENDOSCOPIA DIGESTIVA

ESD should be performed only in a setting where early and delayed complications can be managed adequately





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Current methods of endoscopy skill acquisition

# Endoscopic simulators:

- inanimate static models or mechanical simulators
- computer-generated (virtual reality) models
- ex vivo (explanted organ) animal models
- in vivo (live) animal models
- hybrid simulations (attaching a simulator to a simulated patient)

A 2014 ASGE survey revealed that less than half of adult gastroenterology programs in the United States use simulation, and it is mandated in only 15% of programs



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Current methods of endoscopy skill acquisition

The use of virtual reality endoscopy simulation training for novice endoscopists aimed at developing basic endoscopic skills can improve subsequent clinical performance

A simulation curriculum that incorporates mentored training and instructional feedback has been shown to provide a distinct advantage compared with self-regulated learning in the acquisition of endoscopic skills

Randomized controlled trials have indicated measurable transfer of skills to the clinical environment and possible potential benefit in shortening the learning curve to competency in some circumstances such as in the early part of training

A reduction in the learning curve of more than 25%, as proposed in the ASGE PIVI document as a threshold for widespread adoption of their use, has yet to be demonstrated



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Ex-vivo porcine model for POEM training at HSR: "POMOD"







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# Learning curve for POEM by "POMOD" – 15 procedures





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Learning curve to achieve competency in ERCP

Recent performance measures suggest  $a \ge 90\%$  selective cannulation rate is an appropriate metric for a native ampulla, but a "competent" ERCP operator should attain  $a \ge 95\%$  rate (with precut maneuvers)

# 1996

Minimal threshold of 100 ERCPs, with a > 85% biliary cannulation rate

# 2002

Minimal threshold of 180-200 ERCPs, including 120 gallstone extractions, and 60 stent deployments. ASGE Standards of Practice Committee

# 2007

Minimal threshold of 350 ERCPs performed on a native papilla. Mayo Clinic **2015** 

Minimal threshold ranges from 79 to 300  $\operatorname{ERCPs}$  .



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Learning curve to achieve competency in ERCP Joint Advisory Group (JAG) British Society of Gastroenterology (BSG) Endoscopy Committee

# Knowledge

- To include working clinical knowledge of the underlying diseases, the clinical indications for ERCP and the contra-indications to ERCP.
- Knowledge of safe sedation and informed consent.
- Full knowledge of the guidelines for managing specific risks e.g. antibiotics, anticoagulation etc and identifying high risk patients.
- Passing a knowledge assessment e.g the endoscopic section of the "MRCP Gastro" exit examination



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Learning curve to achieve competency in ERCP

Joint Advisory Group (JAG)

British Society of Gastroenterology (BSG) Endoscopy Committee





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# Criteria for training ERCP endoscopists to act as trainers

Joint Advisory Group (JAG) British Society of Gastroenterology (BSG) Endoscopy Committee

- Personal experience of and participation in an average of 75 procedures per year as per non-trainers
- Continuous audit certifying complication rates of < 5%; > 90% completion of intended therapy on level 1 patients.
- Attendance as Faculty or Observer at ERCP Training Events outside their own network as a minimum once every 5 years.
- Working in a network with a workload averaging over 150 procedures per year in order to provide sufficient breadth of experience for trainees.



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Quality

# Safety

An agreed minimum workload (procedure type/volume) per endoscopist For each case, a minimum of A minimum of 2 ERCP-trained Staffing 3 endoscopy assistants with endoscopists within a centre or local appropriate competences network, to enable continuous service provision Sphincterotomy bleeding requiring >90% of ERCPs intended as transfusion < 2%therapeutic Perforation rate < 2%Quality Completion of the intended therapeutic Clinically symptomatic pancreatitis standards procedure at initial ERCP in at least < 5% 80% of cases Procedure related mortality <1%

# Performance measures for ERCP and endoscopic ultrasound: a European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative

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# Endoscopy 2018; 50: 1116-1127



### Domains and performance measures chosen by the ESGE pancreatobiliary working group



# Endoscopy 2018; 50: 1186-1204

#### Authors

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Performance measures for endoscopy services:

**Quality Improvement Initiative** 

a European Society of Gastrointestinal Endoscopy (ESGE)



# Endoscopy room = operatory room

2<sup>nd</sup> – 3<sup>rd</sup> level structures

Adequate instrumentation

- X-ray support
- EUS support
- CO 2 availability
- devices specific for procedures

Anaesthesiologist assistance

- deep sedation
- general anaesthesia Adequate nurse assistance

### Performance measures for endoscopy services: a European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative





### Endoscopy 2018; 50: 1186–1204

Leadership and organization	Facilities & equipment	Quality	Safety	Appropriate- ness	Information, consent, further care	Comfort, privacy, dignity	Staffing	Patient involvement
Leadership roles & responsi- bilities	Review of facilities and equipment	System to capture procedural indicators	Policies in place to mitigate known risks	Referral guidelines for all procedures	Informed consent complies with national requirements	Patient comfort assessment undertaken	Review of staffing in relation to activity	Patient feedback is collected
Annual operational plan	Program of inspection, calibration, and maintenance Shortfalls of facilities and	Performance data fed back to endo- scopists Action is taken for	Known adverse events are captured Root cause analysis	Compliance with guidelines is assessed	Patient information available for all procedures Compre- hensive	Action taken to improve patient comfort Environment suitable	New staff have an induction Staff are adequately	Patient complaints and suggestions reviewed All patient feedback
	<ul> <li>equipment are addressed</li> <li>Compliance with national decontami- nation re- quirements</li> </ul>	<ul> <li>persistent underperfor- mance</li> <li>Register of who can perform which procedures</li> </ul>	<ul> <li>of major adverse events</li> <li>Stop pro- cedure(s) when the balance of benefits/ risks is unfavorable</li> </ul>		discharge information given to patients	to preserve patient privacy	<ul> <li>trained for their role(s)</li> <li>Methods in place to motivate staff</li> <li>Confidential reporting is available to staff</li> </ul>	reviewed and acted upon



Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018





Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018



Endoscopy 2018; 50: 1205-1234

The documentation of the reprocessing procedure should include:

- The patient on whom the endoscope was last used;
- The endoscope identification;
- The whole reprocessing cycle including all manual cleaning steps, and identification of the EWD/ADD and storage cabinet used;
- The time-frame for reprocessing and storage;
- Identification of the staff member involved in reprocessing of that endoscope;
- Identification of the staff who check the correct performance of the reprocessing cycle and release the endoscope for use on the next patient.

	In the endoscopy procedure room	Bedside cleaning rinsing and flushing of all channels function control         Transport from endoscopy room to reprocessing area and start of manual cleaning steps within approximately 30 minutes						
		external a	Manual cleaning including manual leakage test, external and internal cleaning, including brushing         Waiting time between manual cleaning and reprocessing in the EWD should not exceed the duration of one EWD cycle					
		Waiting time the EWD sho						
			Cleaning and	l disinfection				
	In the separated reprocessing room	Manual reprocessing	EV	VD	ADD			
	Dirty side	Rinsing	All reprocessir performed in	ng steps are the EWD:	Rinsing may be included some ADDs			
		Disinfecting	<ul> <li>cleaning</li> <li>rinsing</li> <li>disinfection</li> <li>final rinsing</li> <li>drying</li> </ul>		Disinfection and final rinsing are included in all ADDs			
		Drying or direct use			Drying is an additional option in some ADDs			
			Drying or direct use?					
			Drying		Direct use			
	In the separated reprocessing room	Sterilization in the case of medical indication only	Automated drying	Manual drying with com- pressed air				
	Clean side		Storage					
			Storage cabinet with drying function	Endoscope cabinet without drying function				
			Transport to	next natient				



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How to prevent and manage complications of endoscopy ?

Please, don't forget

- appropiateness
- adherence to guidelines
- patient information