

Allegato 2

GRADE PROFILE: <https://gdt.gradepro.org/app/handbook/handbook.html#h.dce0ghnajwsm>

HUTFLESS, Susan, et al.

Risk factors for infections after endoscopic retrograde cholangiopancreatography (ERCP): a retrospective cohort analysis of US Medicare Fee-For-Service claims, 2015–2021. BMJ open, 2022, 12.9: e065077

Quality assessment						N° of patient		Effect		Quality	Importance
Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Group A	Group B	Relative (95% CI)	Absolute (95% CI)		
OUTCOME - ERCP urgente											
Studio di coorte retrosp.	serious ¹	not applicable	not serious	not serious	none	Medicare N= 823.575	All-payer N=16.609	OR 3,3 95% CI (3,2-3,4)	//	⊕○○○ Very Low	IMPORTANT
OUTCOME - Ospedalizzazione per infezione entro 7 giorni											
Studio di coorte retrosp.	serious ¹	not applicable	not serious	not serious	none	Medicare N= 823.575	All-payer N=16.609	3,5% dei pazienti Medicare e 2,4% di tutti i pazienti	//	⊕○○○ Very Low	IMPORTANT
OUTCOME - Ospedalizzazione per infezione entro 30 giorni											
Studio di coorte retrosp.	Serious ¹	not applicable	not serious	not serious	none	Medicare N= 823.575	All-payer N=16.609	7,7%	//	⊕○○○ Very Low	IMPORTANT

¹ La raccolta dati di tipo retrospettivo ha comportato la perdita di una serie di dati a causa della documentazione incompleta

Shanthini Kuduva Rajan, et al.

Burdens of Postoperative Infection in Endoscopic Retrograde Cholangiopancreatography Inpatients

Cureus. 2019 Jul; 11(7): e5237. Published online 2019 Jul 25. doi: 10.7759/cureus.5237

Quality assessment						N° of patient		Effect		Quality	Importance
Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Group A	Group B	Relative (95% CI)	Absolute (95% CI)		
OUTCOME – Infezioni post ERCP (POI) in paz. di 36-50 anni											
Studio trasvers retrop.	serious ²	not applicable	not serious	serious ³	none	28.525 procedure di ERCP	//	OR 2,65 vs età 18-35 anni p <0,001	1,69-4,12	⊕○○○ Very Low	IMPORTANT
OUTCOME - Infezioni post ERCP (POI) in paz. di 51-65 anni											
Studio trasvers retrop.	serious ¹	not applicable	not serious	serious ³	none	28.525 procedure di ERCP	//	OR 2.26 vs età 18-35 p <0,001	//	⊕○○○ Very Low	IMPORTANT
OUTCOME – HIV+											
Studio trasvers retrop.	serious ¹	not applicable	not serious	serious ³	none	28.525 procedure di ERCP	//	1,40% p 0,023	//	⊕○○○ Very Low	IMPORTANT
OUTCOME – Diabete											
Studio trasvers retrop.	serious ¹	not applicable	not serious	serious ³	none	28.525 procedure di ERCP	//	1,40% p 0,003	//	⊕○○○ Very Low	IMPORTANT

² La raccolta dati di tipo retrospettivo ha comportato la perdita di una serie di dati a causa della documentazione incompleta

³ Il follow up per la raccolta dati relativa alle infezioni si è fermata al periodo di ricovero

Merchan MFS, et al.

Antibiotic prophylaxis to prevent complications in endoscopic retrograde cholangiopancreatography: A systematic review and meta-analysis of randomized controlled trials.

World J Gastrointest Endosc. 2022 Nov 16;14(11):718-730. doi: 10.4253/wjge.v14.i11.718. PMID: 36438881; PMCID: PMC9693690.

Quality assessment						N° of patient		Effect		Quality	Importance
Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Group A	Group B	Relative (95% CI)	Absolute (95% CI)		
OUTCOME – Batteriemia											
Systematic review	none	none	none	(-1) ⁴	none	371 pz.	387 pz.	RD -0,07	IC 95% (-0,14, -0,01) P =	⊕⊕⊕○ High	CRITICAL
OUTCOME – Colangite post ERCP											
Systematic review	none	none	none	(-1) ⁴	none	794 pz.	864 pz.	RD -0,02	IC 95% (-0,05, 0,02) P = 0,32	⊕⊕⊕○ High	CRITICAL
OUTCOME – Colangite n pazienti con sospetta ostruzione biliare											
Systematic review	none	none	none	(-1) ⁴	none	302 pz.	536 pz.	RD -0,02	IC 95% (-0,08, 0,13) P = 0,66	⊕⊕⊕○ High	CRITICAL
OUTCOME – Colangite in profilassi antibiotica per via endovenosa											
Systematic review	none	none	none	(-1) ⁴	none	pz.	pz.	RD -0,02	IC 95% (-0,05, 0,01) P = 0,25	⊕⊕⊕○ High	CRITICAL

⁴⁴ Presente I²

OUTCOME – Setticemia

Systematic review	none	none	none	(-1) ⁴	none	568 pz.	584 pz.	RD -0,02	IC 95% (-0,06, 0,01) P = 0,25	⊕⊕⊕⊕ High	CRITICAL
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OUTCOME – Pancreatite

Systematic review	none	none	none	none	none	371 pz.	427 pz.	RD -0,02	IC 95% (-0,06, 0,01) P = 0,19	⊕⊕⊕⊕ High	CRITICAL
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OUTCOME – Mortalità

Systematic review	none	none	none	none	none	804 pz.	834 pz.	RD -0,00	IC 95% (-0,01, 0,01) P = 0,71	⊕⊕⊕⊕ High	CRITICAL
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Anasua Deb et al.

Gastrointestinal Endoscopy-Associated Infections: Update on an Emerging Issue

Digestive Diseases and Sciences (2022) 67:1718-1732 <https://doi.org/10.1007/s10620-022-07441-8>

Quality assessment						N° of patient	Effect		Quality	Importance
Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Procedure di endoscopia	Relative (95% CI)	Absolute (95% CI)		
OUTCOME – Infezioni post ERCP										
Systematic review	none	none	(-1) ⁵	(-1) ⁶	none	3.115 pz.	0,123%	//	⊕⊕○○ Moderate	MODERATE

⁵ Alcuni outcome sono surrogati

⁶ Non condotta metanalisi e calcoli scorporati delle procedure eseguite con endoscopio monouso

Bang JY, Hawes R, Varadarajulu S.

Equivalent performance of single-use and reusable duodenoscopes in a randomised trial.

Gut. 2021 May;70(5):838-844. doi: 10.1136/gutjnl-2020-321836. Epub 2020 Sep 7. PMID: 32895332; PMCID: PMC8040157.

Quality assessment						N° of patient		Effect		Quality	Importance
Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Group A Monouso	Group B Pluriuso	Relative (95% CI)	Absolute (95% CI)		
OUTCOME – Successo dell'incannulamento											
RCT	none	none	none	none	none	46/48 (95.8%)	50/50 (100.0%)	p=0,237		⊕⊕⊕○ High	CRITICAL
OUTCOME – Manovrabilità dello strumento (punteggio medio complessivo)											
RCT	none	none	none	(-1) ⁷	none	1.2	1.06	p=0.065		⊕⊕⊕○ High	CRITICAL
OUTCOME – Qualità dell'immagine											
RCT	none	none	none	(-1) ⁷	none	33/48 (68.8%)	50/50 (100.0%)	p=<0.001		⊕⊕⊕○ High	CRITICAL
OUTCOME – Tasso di passaggio nello stomaco											
RCT	none	none	none	(-1) ⁷	none	42/48 (87.5%)	49/50 (98.0%)	p=0.047		⊕⊕⊕○ High	CRITICAL
OUTCOME – Funzionamento aspirazione-insufflazione											
RCT	none	none	none	(-1) ⁷	none	30/48 (62.5%)	49/50 (98.0%)	p=<0.001		⊕⊕⊕⊕ High	CRITICAL
OUTCOME – Stabilità dell'immagine											
RCT	none	none	none	(-1) ⁷	none	34/48 (70.8%)	50/50 (100.0%)	p=<0.001		⊕⊕⊕⊕ High	CRITICAL

⁷ Outcome surrogato

OUTCOME – Eventi avversi

RCT	none	none	none	none	none	2/48 (4.2%)	4/50 (8.0%)	p=0.429		⊕⊕⊕⊕ High	CRITICAL
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OUTCOME – Necessità di cross over dello strumento

RCT	none	none	none	none	none	2/48 (4.2%)	0/50 (0.0%)	p=0,237		⊕⊕⊕⊕ High	CRITICAL
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AGREE II

A critical appraisal of: RCP-related adverse events: ESGE Clinical Guideline using the AGREE II Instrument

Created with the AGREE II Online Guideline Appraisal Tool.

No endorsement of the content of this document by the AGREE Research Trust should be implied.

Appraiser: 1

Date: 22 March 2023

Email://

URL of this appraisal: <http://www.agreetrust.org/appraisal/106149>

Guideline URL:

<https://www.thieme-connect.com/products/ejournals/abstract/10.1055/a-1075-4080>

Overall Assessment

Title: RCP-related adverse events: ESGE Clinical Guideline

Overall quality of this guideline: 5/7

Guideline recommended for use? Yes.

Domain	Total
1. Scope and Purpose	19
2. Stakeholder Involvement	7
3. Rigour of Development	39
4. Clarity of Presentation	20
5. Applicability	10
6. Editorial Independence	14

1. Scope and Purpose

1. The overall objective(s) of the guideline is (are) specifically described.

Rating: 6

2. The health question(s) covered by the guideline is (are) specifically described.

Rating: 6

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Rating: 7

2. Stakeholder Involvement

4. The guideline development group includes individuals from all relevant professional groups.

Rating: 2

5. The views and preferences of the target population (patients, public, etc.) have been sought.

Rating: 1

6. The target users of the guideline are clearly defined.

Rating: 4

3. Rigour of Development

7. Systematic methods were used to search for evidence.

Rating: 3

8. The criteria for selecting the evidence are clearly described.

Rating: 5

9. The strengths and limitations of the body of evidence are clearly described.

Rating: 6

10. The methods for formulating the recommendations are clearly described.

Rating: 4

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

Rating: 6

12. There is an explicit link between the recommendations and the supporting evidence.

Rating: 7

13. The guideline has been externally reviewed by experts prior to its publication.

Rating: 7

14. A procedure for updating the guideline is provided.

Rating: 1

4. Clarity of Presentation

15. The recommendations are specific and unambiguous.

Rating: 7

16. The different options for management of the condition or health issue are clearly presented.

Rating: 6

17. Key recommendations are easily identifiable.

Rating: 7

5. Applicability

18. The guideline describes facilitators and barriers to its application.

Rating: 2

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

Rating: 2

20. The potential resource implications of applying the recommendations have been considered.

Rating: 5

21. The guideline presents monitoring and/or auditing criteria.

Rating: 1

6. Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.

Rating: 7

23. Competing interests of guideline development group members have been recorded and addressed.

Rating: 7

Created online at www.agreetrust.org 22 March 2023



AGREE II

A critical appraisal of: RCP-related adverse events: ESGE Clinical Guideline using the AGREE II Instrument

Created with the AGREE II Online Guideline Appraisal Tool.

No endorsement of the content of this document by the AGREE Research Trust should be implied.

Appraiser: 2

Date: 25 March 2023

Email://

URL of this appraisal: <http://www.agreetrust.org/appraisal/106149>

Guideline URL:

<https://www.thieme-connect.com/products/ejournals/abstract/10.1055/a-1075-4080>

Overall Assessment

Title: RCP-related adverse events: ESGE Clinical Guideline

Overall Assessment

Title: ERCP-related adverse events: European Society of Gastrointestinal Endoscopy (ESGE) Guideline

Overall quality of this guideline: 5/7

Guideline recommended for use? Yes.

Domain	Total
1. Scope and Purpose	20
2. Stakeholder Involvement	9
3. Rigour of Development	35
4. Clarity of Presentation	20
5. Applicability	9
6. Editorial Independence	13

1. Scope and Purpose

1. The overall objective(s) of the guideline is (are) specifically described.

Rating: 6

Lo scopo della LG è chiaro ("riesaminare definizioni, epidemiologia, fattori di rischio, misure di profilassi e gestione degli eventi avversi correlati all'ERCP") e facilmente reperibile.

2. The health question(s) covered by the guideline is (are) specifically described.

Rating: 7

La LG specifica le situazioni cliniche trattate ed anche le situazioni non affrontate nel documento. Sono inoltre chiaramente reperibili ed interpretabili le raccomandazioni espresse.

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Rating: 7

La LG si applica a tutti i pazienti sottoposti a ERCP, individuando, a seconda della condizione, le categorie a maggior rischio di sviluppare eventi avversi. Sono inoltre specificati gli eventi avversi non presi in considerazione nel documento.

2. Stakeholder Involvement

4. The guideline development group includes individuals from all relevant professional groups.

Rating: 3

Vengono specificati i nomi dei partecipanti, e l'istituzione/ente di affiliazione, l'area geografica di provenienza e nel materiale supplementare a quale gruppo di lavoro hanno collaborato, mancano tuttavia le relative professioni. Non è possibile quindi desumere la competenza in materia

5. The views and preferences of the target population (patients, public, etc.) have been sought.

Rating: 3

Il documento è stato inviato a revisori esterni e poi alle Società Nazionali ESGE, non è possibile reperire informazioni relative al coinvolgimento dei pazienti o altri stakeholder.

6. The target users of the guideline are clearly defined.

Rating: 3

Gli utilizzatori sono desumibili ma non chiaramente indicati.

3. Rigour of Development

7. Systematic methods were used to search for evidence.

Rating: 2

Vengono specificate le banche dati consultate ed i filtri utilizzati. Vi è inoltre il riferimento esplicito alla revisione sistematica della letteratura. Non sono indicate tuttavia le keywords utilizzate, né le stringhe di ricerca, né l'utilizzo e la combinazione degli operatori booleani.

8. The criteria for selecting the evidence are clearly described.

Rating: 4

Viene specificata la selezione degli studi sulla base del disegno ma non altri criteri di esclusione.

9. The strengths and limitations of the body of evidence are clearly described.

Rating: 7

Le prove sono state valutate con il metodo GRADE ed i dettagli riportati nel materiale supplementare.

10. The methods for formulating the recommendations are clearly described.

Rating: 2

Non è reperibile nel documento il metodo utilizzato per esprimere la forza delle raccomandazioni.

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

Rating: 6

12. There is an explicit link between the recommendations and the supporting evidence.

Rating: 6

13. The guideline has been externally reviewed by experts prior to its publication.

Rating: 7

14. A procedure for updating the guideline is provided.

Rating: 1

Non viene specificato.

4. Clarity of Presentation

15. The recommendations are specific and unambiguous.

Rating: 7

16. The different options for management of the condition or health issue are clearly presented.

Rating: 6

17. Key recommendations are easily identifiable.

Rating: 7

5. Applicability

18. The guideline describes facilitators and barriers to its application.

Rating: 1

Nel documento non sono reperibili tali informazioni.

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

Rating: 1

20. The potential resource implications of applying the recommendations have been considered.

Rating: 6

21. The guideline presents monitoring and/or auditing criteria.

Rating: 1

6. Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.

Rating: 6

23. Competing interests of guideline development group members have been recorded and addressed.

Rating: 7

Created online at www.agreetrust.org 25 March 2023