Il nuovo Handbook della IARC

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SPECIAL REPORT

The IARC Perspective on Colorectal Cancer Screening

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Lo screening per i tumori del colon-retto (CCR) ha l'obiettivo di

- ridurre il rischio di morte per cancro del colon-retto attraverso la diagnosi precoce e il tasso di complicanze associate con l'identificazione del cancro in una fase avanzata
- ridurre l'incidenza e mortalità del CCR attraverso l'identificazione e la rimozione delle lesioni precancerose.

Esistono diversi test disponibili

Test per la ricerca del sangue occulto nelle feci: il test al guaiaco (con o senza reidratazione) e il test immunochimico (FIT)

Metodi endoscopici, che esaminano direttamente il retto ed il colon: la sigmoidoscopia e la colonscopia (come test primario di screening e come follow-up per le persone positive con altri metodi di screening)

Colonscopia virtuale (CTC), un metodo di imaging, basato su tecnologia di scansione, sviluppato come tecnica di visualizzazione meno invasiva

Nuove tecniche recentemente emerse ma non ampiamente testate: videocapsula endoscopica o l'analisi dei biomarcatori nelle feci (DNA multitarget-stool), nel sangue (methylated septin 9 DNA) o nel respiro (ad esempio composti organici volatili e vari marcatori di proteine, RNA e DNA).

Metodologia

Revisione dell’ evidenza pubblicata da

- trial randomizzati controllati
- studi osservazionali
- studi di modellizzazione

che valutano

FOBT, Endoscopia, Colonscopia virtuale

valutati rispetto ad effetti preventivi, effetti avversi e la bilancia benefici e danni nelle popolazioni a rischio medio di uomini e donne combinati.

Nei casi in cui dati da studi randomizzati sull'effetto di un particolare test di screening su mortalità e l'incidenza non erano disponibili, è stata considerata l’evidenza relativa:

- a un test di screening simile per il quale è stata mostrata una riduzione della mortalità o dell’incidenza (FIT/test al guaiaco o colonscopia/sigmoidoscopia)
- o da studi di confronto delle performance dei test (colonscopia virtuale invece di colonscopia)

Prove riguardanti le nuove tecniche sono state considerate insufficienti per fare una valutazione

La maggior parte degli studi esaminati è stato condotta in ambienti con redditi medio-alti, con l'incidenza generalmente alta; in popolazioni asintomatiche, a rischio medio (in genere, tra 50 e 70 anni di età); in condizioni in cui lo screening, compresi follow-up e trattamento successivi, possono essere di alta qualità.

L'estrapolazione delle conclusioni a setting diversi deve prendere in considerazione questi e altri aspetti correlati alle specificità del contesto (ad esempio, il livello di sviluppo del sistema sanitario).

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Single screening with CT colonography	Limited§	Limited§	Inadequate

Due RCT, due ampi studi di coorte con follow up fino a 11 round di screening e uno studio caso-controllo

Nei trial, il rischio relativo di morte significativamente inferiore tra le persone con un risultato positivo del test al guaiaco seguito da con colonscopia di approfondimento, rispetto ai controlli (senza screening)

Rischi relativi erano inferiori del 9-14% con test al guaiaco senza reidratazione
e del 16-32% più basso con test al guaiaco con sensibilità più alta.

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Tre RCT, uno studio di coorte con follow up fino a 11 round di screening

Un RCT con 18 anni di follow up

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No RCT su incidenza o mortalità

3 studi di coorte: riduzione del rischio di morire del 10-40% tra soggetti che hanno effettuato un FIT rispetto ai controlli

Uno studio ecologico

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La valutazione considera anche:

-l'evidenza da RCT sul test al guaiaco, da cui possiamo inferire che il FIT dovrebbe ridurre la mortalità almeno quanto test al guaiaco

-l'evidenza da RCT che dimostrano che il FIT identifica più adenomi avanzati e cancri rispetto al guaiaco

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Riduzioni piccole-moderate dell'incidenza cumulativa

2 studi di coorte dopo 3 round di FIT ogni 2 anni

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Danni potenziali:
-Psicologici per se, o legati al ricevere un risultato positivo al test. Lievi e transitori.
-Invii in approfondimento non necessari
-Danni legati a colonscopia di approfondimento e sorveglianza

Tutti gli studi di modellazione, hanno dimostrato un guadagno di anni di vita aggiustati per la qualità, rispetto a nessuno screening, in particolare per FIT e guaiaco ad alta sensibilità.

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Nel complesso, vi sono evidenze sufficienti che i benefici superano i danni con qualsiasi tipo di test per il sangue occulto nelle feci.

FIT: La bilancia dipende dal cut-off di positività

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Quattro RCT di grandi dimensioni (3 in Europa, 1 in USA)
Incidenza significativamente inferiore del 18-26% tra le persone che hanno effettuato una sigmoidoscopia di screening. Mortalità significativamente inferiore del 22-31% tra le persone che hanno effettuato una sigmoidoscopia di screening.
Estensione del follow up di un trial a 17 anni: persistente riduzione significativa del 26% dell'incidenza, del 30% della mortalità (ITT analysis)

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2 studi di coorte, 9 studi caso-controllo

Meta-analisi di studi osservazionali: riduzione del 50% incidenza-mortalità. Effetto più forte nel colon distale

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Quattro RCT in progress, ma dati sull'effetto sull'incidenza e sulla mortalità non sono ancora disponibili

5 studi di coorte, 5 studi caso controllo

Meta-analisi di studi osservazionali: riduzione del 70% incidenza-mortalità. Effetto più forte nel colon distale

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Questa valutazione prende anche in considerazione risultati da RCT sulla sigmoidoscopia, ‘poiché una colonscopia completa, per definizione, include una sigmoidoscopia, e se noi supponiamo che ci sarà un tasso di falsi negativi simile per entrambe le procedure, la colonscopia sarà efficace almeno quanto la sigmoidoscopia nell’identificazione di adenomi avanzati e cancro del colon-retto’

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Attualmente, non ci sono prove sufficienti per valutare il beneficio di successivi round di screening endoscopici

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Danni potenziali:

-Psicologici

-Invii in approfondimento non necessari dopo un risultato positivo in sigmoidoscopia

-Danni legati a colonscopia di approfondimento e sorveglianza

-sanguinamento e perforazione (non comuni, con ogni evento che si verifica in 0,01 a 0,05% delle colonscopie)

- proporzione di sovradiagnosi incerta

Tutti gli studi di modellazione, hanno dimostrato un guadagno di anni di vita aggiustati per la qualità, rispetto a nessuno screening

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Nel complesso, vi sono prove sufficienti che i benefici superano i danni con un singolo round di screening con sigmoidoscopia

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Il consenso è stato di evidenze sufficienti che i benefici superano i danni con singolo screening con colonscopia, quando lo screening può essere di alta qualità.
Una parte dei membri del gruppo di esperti ha ritenuto che le evidenze fossero limitate a causa della variabilità e dell'accuratezza limitata delle stime degli effetti, dei danni associati con la colonscopia, e delle limitazioni inerenti nell'estrapolare i risultati relativi alla sigmoidoscopia per valutare la colonscopia.

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No RCT pubblicati, sulla incidenza o mortalità

Sono stati considerati informativi per la valutazione: un RCT e 4 studi tandem con screening consecutivi o paralleli su persone asintomatiche, che hanno confrontato i tassi di identificazione di adenoma con CTC con quelli con colonscopia.

Studi tandem (uno studio comparativo in cui la stessa persona è stata screenata sequenzialmente con i due metodi: tassi di identificazione di neoplasie avanzate (adenoma avanzato o cancro) simili.

RCT: tassi di identificazione simili per il cancro, ma inferiori per gli adenomi avanzati (5,6% vs 8,2%) e per gli adenomi avanzati >= 10 mm (5,4% vs 6,3%). Differenza scomparsa dopo l'aggiustamento per la partecipazione.

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Evidenze limitate che un singolo screening con CTC riduce l'incidenza o la mortalità.
Una parte dei membri del gruppo di esperti hanno ritenuto che le evidenze sono inadeguate a causa

- della mancanza di studi randomizzati o osservazionali con incidenza o mortalità come end point,
- del fatto che erano solo disponibili dati su performance e tassi di identificazione di adenomi,
- e dell'ampia estrapolazione necessaria per stimare una riduzione attesa dell'incidenza o della mortalità sulla base dei tassi di identificazione noti.

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Potenziali danni:
- effetti indotti dalle radiazioni
- gli effetti indotti dal rilevamento di lesioni non colorettali
- potenziali danni da colonscopia di follow-up

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Evidenze inadeguate che i benefici di un singolo screening con la CCT superano i danni

Comparative Effectiveness of Screening Techniques

L’evidenza da studi di comparative effectiveness per valutare un test rispetto ad un altro è stata considerate inconcludente

Conclusioni: alcune criticità

Non vengono date indicazioni su aspetti critici dei protocolli di screening

Colorectal cancer screening:

- men and women starting at age 50–60 years,
- and from then on, every 2 years if the screening test is the guaiac-based faecal occult blood test (gFOBT) or the fecal immunochemical test (FIT),
- or every 10 years or more if the screening test is flexible sigmoidoscopy (FS) or colonoscopy (TC).

Most programs continue sending invitations to screening up to age 70–75 years.

European Code against Cancer, 4th Edition: Cancer screening
Armaroli et al, Cancer Epidemiology 39S (2015) S139–S152

In generale, gli studi controllati randomizzati sono considerati gold standard per la stima degli effetti, in quanto meno inclini a diversi bias rispetto agli studi osservazionali, come bias di selezione di partecipanti allo screening, recall bias

Aspetti di maggiore criticità per la pratica clinica:

Tassi di partecipazione
Disagio e complessità dell'esame:
•preparazione intestinale,
•esami inadeguati e incompleti
•tassi di complicanze

costi,
qualità e disponibilità di risorse

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Grazie per l'attenzione!