Definition of diagnostic accuracy
The two-by-two table
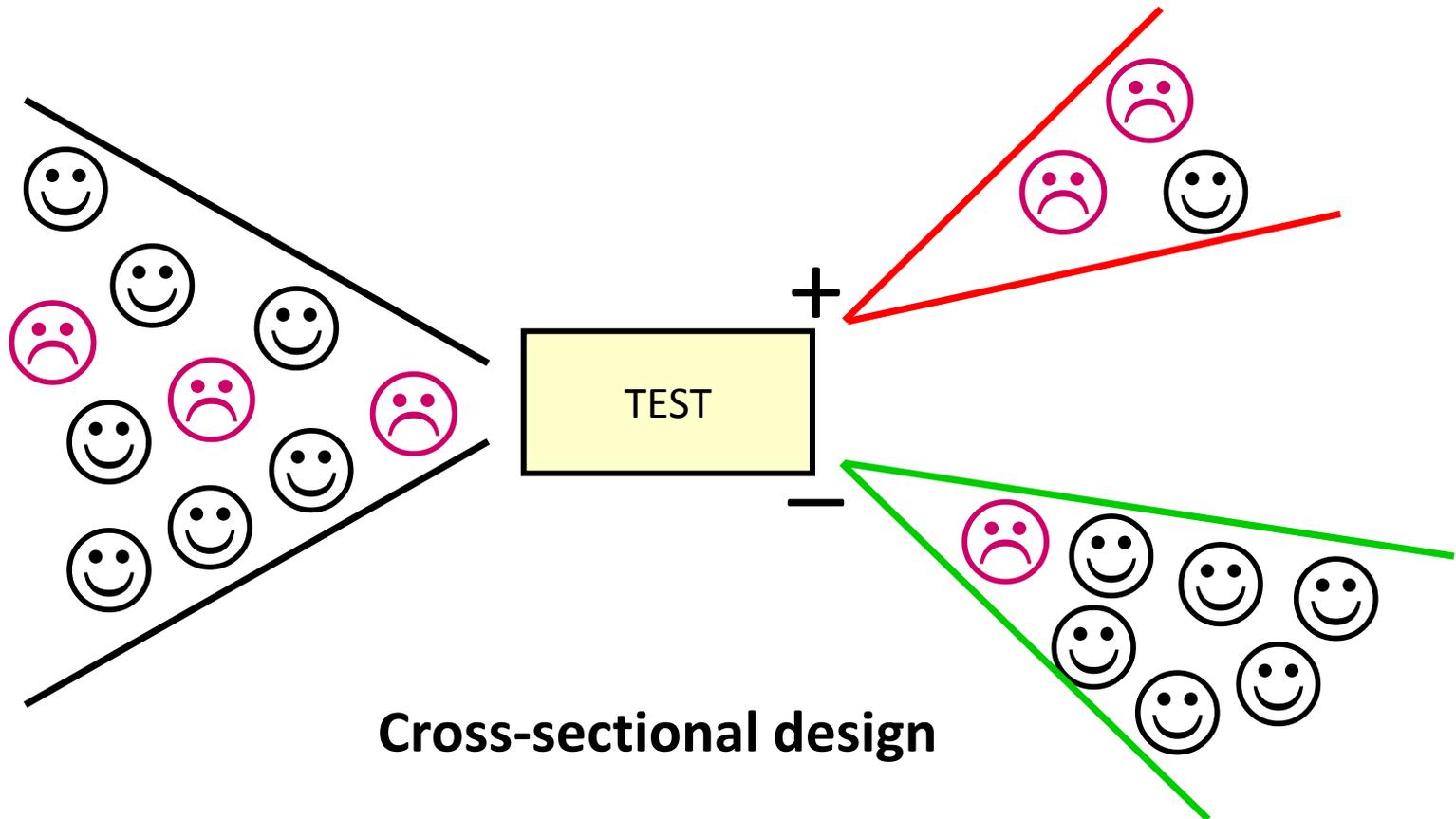# True and false results

Giovanni Casazza
Università degli Studi di Milano
The Cochrane Hepato-Biliary Group

DIAGNOSIS AND PROGNOSIS: CLINICAL AND RESEARCH PROBLEMS
October 8-11, 2014
Gargnano

Study design

The aim of a diagnostic accuracy study is to evaluate the association between the test result and the disease status of the study participants.

Cross-sectional design

Study design

Index test (test under evaluation)

Reference standard (previously "gold standard")

Target condition (disease of interest)

Key points of the diagnostic accuracy assessment procedure:

setting and patients selection modality (consecutive? inappropriate exclusions?)
technical characteristics of the two tests
blinding
same reference standard for all the participants
threshold (predefined?)
time interval between index and reference (appropriate?)
statistical analysis (appropriate? participants excluded from the analysis?)

Diagnostic tests

When using a diagnostic test in clinical practice we would avoid errors (misclassification of patients).

A perfect index test:

If a patient is **positive** he/she certainly has the target condition.

If a patient is **negative** he/she certainly has not the target condition.

Unfortunately this happens only in an ideal world. In the real world the result of an index test may sometimes be wrong.

We have to deal with false results

Results of the study

How to summarize the results of a diagnostic test accuracy study?

The 2x2 table

The 2x2 table

It is a cross tabulation.

Built by crossing index test and reference standard results.

It is a summary description of the study participants.

Table 2 Accuracy of CE for diagnosis of EVs

CE diagnosis of EVs	EGD diagnosis of EVs		Total
	(+)	(−)	
(+)			
(−)			
Total			119

Is small-bowel capsule endoscopy effective for diagnosis of esophagogastric lesions related to portal hypertension?

Taiki Aoyama,* Shiro Oka,† Hiroshi Aikata,* Makoto Nakano,* Ikue Watari,* Noriaki Naeshiro,*
Shigeto Yoshida,† Shinji Tanaka† and Kazuaki Chayama*

We conducted a retrospective study to evaluate the ability of CE to accurately detect esophagogastric lesions and to clarify the clinical usefulness of CE for diagnosis of esophagog... related to PHT in patients with cirrhosis.

Methods: One hundred nineteen consecutive patients with PHT comprised the study group. All had undergone esophagogastroduodenoscopy (EGD) prior to CE. The diagnos-...

EVs were found by EGD in 71 patients (Table 2).

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Table 2 Accuracy of CE for diagnosis of EVs

CE diagnosis of EVs	EGD diagnosis of EVs		Total
	(+)	(−)	
(+)			51
(−)			68
Total			119

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Methods: One hundred nineteen consecutive patients with PHT comprised the study group. All had undergone esophagogastroduodenoscopy (EGD) prior to CE. The diagnostic yield of CE for esophageal varices (EVs), gastric varices (GVs), and portal hypertensive gastropathy (PHG) was evaluated. In addition, diagnostic yield in relation to form, location of the varices, grade, and extent of PHG was evaluated.

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CE diagnosis of EVs	EGD diagnosis of EVs (+)	(−)	Total
(+)			51
(−)			68
Total	71	48	119

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It is a cross tabulation containing four (2x2=4) numbers.

These four numbers carry all the information needed.

Table 2 Accuracy of CE for diagnosis of EVs

CE diagnosis of EVs	EGD diagnosis of EVs (+)	(−)	Total
(+)	51	0	51
(−)	20	48	68
Total	71	48	119

Four cells

Two rows

Two columns

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CE diagnosis of EVs	EGD diagnosis of EVs		Total
	(+)	(−)	
(+)	**TP** 51	**FP** 0	51
(−)	**FN** 20	**TN** 48	68
Total	71	48	119

TP: True Positives
FN: False Negatives

FP: False Positives
TN: True Negatives

The 2x2 table contains all the information needed for the quantitative assessment of the diagnostic accuracy.

<u>Accuracy</u>: how many times the result of the index test was "right"?
51+48=99   **99/119=83%**

<u>Inaccuracy</u>: how many times the result of the index test was "wrong"?
20+0=20   **20/119=17%**

The 2x2 table
An example

Esophageal Capsule Endoscopy vs. EGD for the Evaluation of Portal Hypertension: A French Prospective Multicenter Comparative Study

M.G. Lapalus, MD[1,9], E. Ben Soussan, MD[2,9], M. Gaudric, MD[3,9], J.C. Saurin, MD, PhD[4,9], P.N. D'Halluin, MD[5,9], O. Favre, MD[6,9], B. Filoche, MD, PhD[7,9], F. Cholet, MD[8,9], A. de Leusse, MD[1,9], M. Antonietti, MD[2,9], J.L. Gaudin, MD[4,9], P. Sogni, MD[3,9], D. Heresbach, MD, PhD[5,9], T. Ponchon, MD, PhD[1,9] and J. Dumortier, MD, PhD[1,9]

OBJECTIVES: **Esophagogastroduodenoscopy (EGD) is the standard method for the diagnosis of esophago-gastric varices. The aim of this prospective multicenter study was to evaluate the PillCam esophageal capsule endoscopy (ECE) for this indication.**

METHODS: **Patients presenting with cirrhotic or noncirrhotic portal hypertension underwent ECE followed by EGD at the time of diagnosis. Capsule recordings were blindly read by two endoscopists.**

RESULTS: **A total of 120 patients (72 males, mean age: 58 years; mean Child–Pugh score: 7.2) were included. Esophageal varices were detected in 74 patients. No adverse event was observed after either EGD or ECE. Seven (6%) patients were unable to swallow the capsule. The mean recording time was 204 s (range 1–876). Sensitivity, specificity, negative predictive value, and positive predictive value of ECE for the detection of esophageal varices were 77%, 86%, 69%, and 90%, respectively. Sensitivity, specificity, negative and positive predictive values of ECE for the indication of primary prophylaxis (esophageal varices ≥grade 2 and/or red signs) were 77, 88, 90, and 75%, respectively, and 85% of the patients were adequately classified for the indication (or not) of prophylaxis. Interobserver concordance for ECE readings was 79.4% for the diagnosis of varices, 66.4% for the grading of varices, and 89.7% for the indication of prophylaxis.**

CONCLUSIONS: **This large multicenter study confirms the safety and acceptable accuracy of ECE for the evaluation of esophageal varices. ECE might be proposed as an alternative to EGD for the screening of portal hypertension, especially in patients unable or unwilling to undergo EGD.**

Table 1. Classification of esophageal varices from EGD and ECE

113 Patients	ECE grade 0	ECE grade I	ECE grade II	ECE grade III
EGD grade 0	36	4	2	0
EGD grade I	14	15	7	0
EGD grade II	2	6	17	7
EGD grade III	0	0	1	2

ECE, esophago-gastro-duodenoscopy; EGD, esophageal capsule endoscopy; pts, patients.

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		EGD		
		+	-	
PillCam	+	55 **TP**	6 **FP**	
	-	16 **FN**	36 **TN**	
		71	42	113

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		71	42	113

Misclassification of 22 patients

Accuracy: (55+36)/113=80.5%

Inaccuracy: (16+6)/113=19.5%

The 2x2 table
An example

		EGD		
		+	-	
PillCam	+	55 **TP**	22 **FP**	
	-	0 **FN**	36 **TN**	
		55	58	113

Misclassification of 22 patients

Inaccuracy: (22+0)/113=19.5%

Accuracy: (55+36)/113=80.5%

		EGD		
		+	-	
PillCam	+	55 **TP**	0 **FP**	
	-	22 **FN**	36 **TN**	
		77	36	113

Misclassification of 22 patients

Inaccuracy: (0+22)/113=19.5%

Accuracy: (55+36)/113=80.5%

The 2x2 table

Accuracy or inaccuracy?

80.5% accurate or 19.5% inaccurate?

These two numbers carry the same information.

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Why inaccuracy? Just to put the emphasis on the false results.

Take home message

The 2x2 table contains all the information needed to assess the diagnostic accuracy.

The overall accuracy is a "rough" estimate of the accuracy of an index test: false positives and false negatives are assumed to have the same importance.