

Diagnostic accuracy of fluorine-18-fluorodeoxyglucose positron emission tomography in gallbladder cancer: A meta-analysis

Salvatore Annunziata, Daniele Antonio Pizzuto, Carmelo Caldarella, Federica Galiandro, Ramin Sadeghi, Giorgio Treglia

Salvatore Annunziata, Daniele Antonio Pizzuto, Carmelo Caldarella, Institute of Nuclear Medicine, Department of Bioimaging and Radiological Sciences, Catholic University of the Sacred Heart, 00168 Rome, Italy

Federica Galiandro, Postgraduate School of General Surgery, Catholic University of the Sacred Heart, 00168 Rome, Italy

Ramin Sadeghi, Nuclear Medicine Research Center, Mashhad University of Medical Sciences, 91735315 Mashhad, Iran

Giorgio Treglia, Department of Nuclear Medicine and PET Center, Oncology Institute of Southern Switzerland, 6500 Bellinzona, Switzerland

Author contributions: Annunziata S, Galiandro F and Treglia G designed research; Annunziata S and Pizzuto DA performed research; Caldarella C and Sadeghi R analyzed data; Annunziata S, Pizzuto DA and Treglia G wrote the paper.

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Correspondence to: Salvatore Annunziata, MD, Institute of Nuclear Medicine, Department of Bioimaging and Radiological Sciences, Catholic University of the Sacred Heart, Largo Agostino Gemelli 8, 00168 Rome, Italy. salvatoreannunziata@live.it
Telephone: +39-6-30154978
Fax: +39-6-3058185

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Abstract

AIM: To meta-analyze published data about the diagnostic accuracy of fluorine-18-fluorodeoxyglucose (^{18}F -FDG) positron emission tomography (PET) and PET/computed tomography (PET/CT) in the evaluation of primary tumor in patients with gallbladder cancer (GBCa).

METHODS: A comprehensive literature search of studies published through 30th June 2014 regarding the role of ^{18}F -FDG PET and PET/CT in the evaluation of primary gallbladder cancer (GBCa) was performed. All retrieved studies were reviewed. Pooled sensitivity and specificity of ^{18}F -FDG PET or PET/CT in the evaluation of primary GBCa were calculated. The area under the summary receiving operator characteristics curve (AUC) was calculated to measure the accuracy of these methods. Sub-analyses considering the device used (PET vs PET/CT) were carried out.

RESULTS: Twenty-one studies comprising 495 patients who underwent ^{18}F -FDG PET or PET/CT for suspicious GBCa were selected for the systematic review. The meta-analysis of 13 selected studies provided the following results: sensitivity 87% (95%CI: 82%-92%), specificity 78% (95%CI: 68%-86%). The AUC was 0.88. Improvement of sensitivity and specificity was observed when PET/CT was used.

CONCLUSION: ^{18}F -FDG-PET and PET/CT demonstrated to be useful diagnostic imaging methods in the assessment of primary tumor in GBCa patients, nevertheless possible sources of false-negative and false-positive results should be kept in mind. PET/CT seems to have a better diagnostic accuracy than PET alone in this setting.

Key words: Positron emission tomography; Positron emission tomography/computed tomography; Fluorine-18-fluorodeoxyglucose; Gallbladder cancer

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Core tip: Fluorine-18-fluorodeoxyglucose-positron emission tomography (PET) and PET/computed tomography (CT) demonstrated to be useful diagnostic imaging methods in the assessment of primary tumor in gallbladder carcinoma patients, nevertheless possible sources of false-negative and false-positive results should be kept in mind. PET/CT seems to have a better diagnostic accuracy than PET alone in this setting.

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INTRODUCTION

Gallbladder carcinoma (GBCa) is the most common carcinoma derived from biliary cells. It is one of the most common carcinoma of gastro-enteric system^[1].

The only curative treatment is surgery, but the anatomical complexity of the porto-hepatic system, the morbidity and mortality of liver resection and the risk of tumoral spread induced by the manipulation of unknown GBCa, as well as the absence of effective chemotherapy, explain the high mortality resulting from these tumors^[1].

Consequently, accurate evaluation and staging are critical to provide indication to surgery and to avoid unnecessary surgical interventions^[2].

Several diagnostic tools have been used in this setting, including ultrasonography (US), computed tomography (CT), magnetic resonance (MR), endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous transhepatic cholangiography (PTC).

Fluorine-18-fluorodeoxyglucose (^{18}F -FDG) positron emission tomography (PET) and PET/CT have been proposed as non-invasive imaging methods to assess

the disease extent in cancer patients. Since ^{18}F -FDG is a glucose analogue, this radiopharmaceutical may be very useful in detecting malignant lesions which usually present high glucose metabolism^[3]. Hybrid PET/CT device allows enhanced detection and characterization of neoplastic lesions, by combining the functional data obtained by PET with morphological data obtained by CT^[3].

Several studies have evaluated the diagnostic accuracy of ^{18}F -FDG-PET or PET/CT in the evaluation of primary tumor in patients with GBCa, reporting different values of sensitivity and specificity^[1,2,4-22]. The purpose of our study is to systematically review and meta-analyze published data on this setting in order to provide more evidence-based data.

MATERIALS AND METHODS

Search strategy

A comprehensive computer literature search of PubMed/MEDLINE and EMBASE databases was carried out to find relevant published articles concerning the evaluation of primary tumor in patients with GBCa.

We used a search algorithm based on a combination of the terms: (1) "PET" OR "positron emission tomography"; and (2) "gallbladder" or "gall" or "gall-bladder". Only articles in English language were considered. The search was performed from inception to June 30th, 2014. To expand our search, references of the retrieved articles were also screened for additional studies.

Study selection

Studies or subsets in studies investigating the accuracy of ^{18}F -FDG PET or PET/CT in the evaluation of primary GBCa were eligible for inclusion. Case reports, small case series, review articles, letters, editorials, and conference proceedings were excluded. The following inclusion criteria were applied to select studies for this meta-analysis: (1) original studies in which ^{18}F -FDG PET or PET/CT were performed in patients with GBCa or suspicious GBCa; (2) a sample size of at least nine patients with GBCa or suspicious GBCa; (3) sufficient data to reassess sensitivity and specificity of ^{18}F -FDG PET or PET/CT in detecting the primary tumor in patients with GBCa; and (4) no data overlap.

Three researchers (SA, DAP and CC) independently reviewed titles and abstracts of the retrieved articles, applying the above-mentioned selection criteria. Articles were rejected if clearly ineligible. The same three researchers then independently evaluated the full-text version of the included articles to determine their eligibility for inclusion.

Data extraction

Information about basic study (authors, year of publication, country of origin), study design (prospective or retrospective), patients' characteristics

(number of patients with biliary ducts lesions performing ^{18}F -FDG-PET or PET/CT, mean age, gender) and technical aspects (injected activity of ^{18}F -FDG, time between injection and image acquisition) were collected.

Each study was analyzed to retrieve the number of true-positive (TP), true-negative (TN), false-positive (FP), and false-negative (FN) findings of ^{18}F -FDG PET or PET/CT in patients with GBCa or suspicious GBCa, according to the reference standard. Only studies providing such complete information were finally included in the meta-analysis.

Quality assessment

The 2011 Oxford Center for Evidence-Based Medicine checklist for diagnostic studies was used for quality assessment of the studies included in the meta-analysis. This checklist has 5 major parts as follows: representative spectrum of the patients, consecutive patient recruitment, ascertainment of the gold standard regardless of the index test results, independent blind comparison between the gold standard and index test results, enough explanation of the test to permit replication.

Statistical analysis

Sensitivity and specificity of ^{18}F -FDG PET and PET/CT in the evaluation primary GBCa were obtained from the individual studies, on a per patient-based analysis. We considered as positive a biliary ducts lesion with increased uptake of ^{18}F -FDG, according to the criteria reported by the different authors. When a positive lesion was histologically confirmed as malignant, this was considered a TP lesion, whereas an histologically confirmed benign lesion was considered as a FP lesion. We considered as negative a lesion with no uptake of ^{18}F -FDG: when the lesion was histologically confirmed as malignant, this was considered a FN lesion, whereas a histologically confirmed benign lesion was considered as a TN lesion.

Sensitivity was determined according to the following formula: $\text{TP}/(\text{TP}+\text{FN})$; specificity was determined according to this formula: $\text{TN}/(\text{TN}+\text{FP})$. Statistical pooling of the data was performed by means of a random effects model. Pooled data are presented with 95% confidence intervals (95%CI). Heterogeneity between studies was assessed by a I^2 index. A summary receiving operator characteristics (ROC) curve was obtained for selected studies and area under the curve (AUC) was calculated to assess the overall accuracy of ^{18}F -FDG PET and PET/CT.

Subsequently, subgroup analyses were also performed, calculating the pooled sensitivity and specificity of ^{18}F -FDG PET and PET/CT in two groups based on the different device used (PET or PET/CT).

Statistical analyses were performed using Meta-DiSc statistical software version 1.4.

RESULTS

Literature search

The comprehensive computer literature search from PubMed/MEDLINE and EMBASE databases revealed 250 articles. Reviewing titles and abstracts, 229 records were excluded as reviews, editorials or letters, case reports or case series or no direct link with the main subject. Finally, 21 articles including 495 patients were selected and were eligible for the systematic review^[1,2,4-22]; no additional studies were found screening the references of these articles. The characteristics of the included studies are presented in Table 1, Table 2 and Table 3.

Qualitative analysis (systematic review)

Using the database search, 21 original articles written over the past 11 years were selected^[1,2,4-22]. About the study design, 4 of these studies were prospective^[1,7,10,15], 12 retrospective^[2,8,9,12-14,16,18-22] and in 5 articles this information was not provided^[4-6,11,17]. Ten studies used hybrid PET/CT^[1,2,10,11,15,16,18,19,21,22], ten studies used PET only^[4-9,12-14,20], one study used both PET or PET/CT^[17]. Heterogeneous technical aspects between the included studies were found (Table 2). PET image analysis was performed by using qualitative criteria (visual analysis) in all the included studies^[1,2,4-22] and adjunctive semi-quantitative criteria [based on the calculation of the standardized uptake value (SUV)] in 15 articles^[1,2,6,8-10,12,14-17,19-22].

The reference standard used to validate the ^{18}F -FDG PET or PET/CT findings in the included studies were quite different.

Quantitative analysis (meta-analysis)

Only 13 over 21 studies included in the systematic review had sufficient data to calculate the pooled sensitivity^[1,2,4-6,8-10,12,13,16,18,20], whereas only 9 studies^[1,4-9,12,13,18] provided information about TN and FP lesions, thus allowing to assess pooled specificity. The diagnostic accuracy values of ^{18}F -FDG PET and PET/CT in the studies included in the meta-analysis are presented in Figures 1 and 2.

Sensitivity and specificity values of ^{18}F -FDG PET or PET/CT on a per patient-based analysis ranged from 69% to 100% and from 44% to 100%, with pooled estimates of 87% (95%CI: 82%-92%) and 78% (95%CI: 68%-86%), respectively. The area under the summary ROC curve was 0.88 (Figure 3). The included studies showed mild statistical heterogeneity (I^2 : 42%) in their estimate of sensitivity only.

Subgroup analyses considering the different device used (PET or PET/CT) were performed. In studies in which ^{18}F -FDG PET was used, values of sensitivity (8 eligible studies) and specificity (8 eligible studies) on a per patient-based analysis ranged from 69% to 100% and from 0% to 100%, respectively, with

Table 1 Basic characteristics of the studies included in the systematic review

Ref.	Year	Country	Study design	Patients performing		Mean age (yr)	Gender (%male)
				¹⁸ F-FDG-PET or PET/CT with GB lesions			
Koh <i>et al</i> ^[4]	2003	Japan	NR	16		68	44%
Anderson <i>et al</i> ^[5]	2004	United States	NR	14		65	57%
Rodríguez-Fernández <i>et al</i> ^[6]	2004	Spain	NR	16		68	31%
Wakabayashi <i>et al</i> ^[7]	2005	Japan	Prospective	30		71	50%
Nishiyama <i>et al</i> ^[8]	2006	Japan	Retrospective	32		70	37%
Oe <i>et al</i> ^[9]	2006	Japan	Retrospective	12		68	66%
Petrowsky <i>et al</i> ^[10]	2006	Switzerland	Prospective	14		NR	NR
Shukla <i>et al</i> ^[11]	2008	India	NR	24		45	33%
Corvera <i>et al</i> ^[12]	2008	United States	Retrospective	41		62	52%
Furukawa <i>et al</i> ^[13]	2008	Japan	Retrospective	18		NR	NR
Furukawa <i>et al</i> ^[14]	2009	Japan	Retrospective	18		NR	NR
Butte <i>et al</i> ^[15]	2009	Chile	Prospective	53		57	20%
Lee <i>et al</i> ^[16]	2010	South Korea	Retrospective	16		NR	NR
Zhu <i>et al</i> ^[17]	2010	United States	NR	10		NR	NR
Lee <i>et al</i> ^[18]	2012	South Korea	Retrospective	20		65	45%
Kumar <i>et al</i> ^[19]	2012	India	Retrospective	49		52	31%
Yamada <i>et al</i> ^[20]	2012	Japan	Retrospective	14		NR	NR
Albazaz <i>et al</i> ^[21]	2013	United Kingdom	Retrospective	30		NR	NR
Lee <i>et al</i> ^[21]	2013	South Korea	Retrospective	9		NR	NR
Onal <i>et al</i> ^[22]	2013	Turkey	Retrospective	10		63	70%
Ramos-Font <i>et al</i> ^[11]	2014	Spain	Prospective	49		68	43%

¹⁸F-FDG: Fluorine-18-fluorodeoxyglucose; PET: Positron emission tomography; CT: Computed tomography; NR: Not reported; GB: Gallbladder; GBCa: Gallbladder carcinoma.

Table 2 Technical characteristics of the studies included in the systematic review

Ref.	Year	Device	¹⁸ F-FDG		Image analysis	Other imaging methods performed
			mean injected dose (MBq)	Time between injection and image acquisition (min)		
Koh <i>et al</i> ^[4]	2003	PET	185	60	Visual	CT
Anderson <i>et al</i> ^[5]	2004	PET	370	60	Visual	CT, MRI
Rodríguez-Fernández <i>et al</i> ^[6]	2004	PET	370	45-60	Visual and semiquantitative	US, CT
Wakabayashi <i>et al</i> ^[7]	2005	PET	185	60	Visual	CT
Nishiyama <i>et al</i> ^[8]	2006	PET	185-370	40-55	Visual and semiquantitative	US, CT
Oe <i>et al</i> ^[9]	2006	PET	3/kg	62-146	Visual and semiquantitative	US, CT, MRI
Petrowsky <i>et al</i> ^[10]	2006	PET/CT	370	45	Visual and semiquantitative	CT
Shukla <i>et al</i> ^[11]	2008	PET/CT	370	60	Visual	CT
Corvera <i>et al</i> ^[12]	2008	PET	370-555	NR	Visual and semiquantitative	CT, MRI
Furukawa <i>et al</i> ^[13]	2008	PET	200-250	60	Visual	CT
Furukawa <i>et al</i> ^[14]	2009	PET	200-250	60	Visual and Semiquantitative	CT, MRI, PTC
Butte <i>et al</i> ^[15]	2009	PET/CT	370	60	Visual and semiquantitative	NR
Lee <i>et al</i> ^[16]	2010	PET/CT	370-555	60	Visual and semiquantitative	CT
Zhu <i>et al</i> ^[17]	2010	PET or PET/TC	370-555	45	Visual and Semiquantitative	CT
Lee <i>et al</i> ^[18]	2012	PET/CT	370	45-60	Visual	NR
Kumar <i>et al</i> ^[19]	2012	PET/CT	5.5/kg	60	Visual and semiquantitative	NR
Yamada <i>et al</i> ^[20]	2012	PET	4.5/kg	60	Visual and semiquantitative	NR
Albazaz <i>et al</i> ^[21]	2013	PET/CT	400	60	Visual and semiquantitative	CT, MRI
Lee <i>et al</i> ^[21]	2013	PET/CT	370-555	60	Visual and semiquantitative	CT, MRCP, ERCP, EUS
Onal <i>et al</i> ^[22]	2013	PET/CT	370-555	60	Visual and Semiquantitative	MRI, CT
Ramos-Font <i>et al</i> ^[11]	2014	PET/CT	370	60	Visual and semiquantitative	NR

¹⁸F-FDG: Fluorine-18-fluorodeoxyglucose; PET: Positron emission tomography; CT: Computed tomography; MR: Magnetic resonance; US: Ultrasonography; CR: Chest radiography; PTC: Percutaneous transhepatic cholangiography; NR: Not reported; CT: Computed tomography; ERCP: Endoscopic retrograde cholangiopancreatography.

pooled estimates of 83% (95%CI: 75%-90%) and 71% (95%CI: 55%-84%), respectively. No statistical heterogeneity was found in these sub-analyses.

In studies in which hybrid ¹⁸F-FDG PET/CT was used, values of sensitivity (5 eligible studies) and specificity (4 eligible studies) on a per patient-based

analysis ranged from 80% to 100% and from 0% to 88%, respectively, with pooled estimates of 93% (95%CI: 85%-97%) and 80% (95%CI: 66%-90%), respectively. Statistical heterogeneity was found both in their estimate of sensitivity ($I^2 = 65%$) and specificity ($I^2 = 59%$).

Table 3 Diagnostic accuracy data of fluorine-18-fluorodeoxyglucose-positron emission tomography and positron emission tomography/computed tomography on a per patient-based analysis

Ref.	Year	Overall				PET				PET/CT			
		TP	FP	FN	TN	TP	FP	FN	TN	TP	FP	FN	TN
Koh <i>et al</i> ^[4]	2003	6	1	2	7	6	1	2	7	NR	NR	NR	NR
Anderson <i>et al</i> ^[5]	2004	7	1	2	4	7	1	2	4	NR	NR	NR	NR
Rodríguez-Fernández <i>et al</i> ^[6]	2004	4	2	1	9	4	2	1	9	NR	NR	NR	NR
Nishiyama <i>et al</i> ^[8]	2006	19	5	4	4	19	5	4	4	NR	NR	NR	NR
Oe <i>et al</i> ^[9]	2006	3	1	0	2	3	1	0	2	NR	NR	NR	NR
Petrowsky <i>et al</i> ^[10]	2006	14	1	0	0	NR	NR	NR	NR	14	1	0	0
Corvera <i>et al</i> ^[12]	2008	24	1	4	2	24	1	4	2	NR	NR	NR	NR
Furukawa <i>et al</i> ^[13]	2008	17	0	1	2	17	0	1	0	NR	NR	NR	NR
Lee <i>et al</i> ^[16]	2010	14	0	2	0	NR	NR	NR	NR	14	0	2	0
Lee <i>et al</i> ^[18]	2012	16	6	4	24	NR	NR	NR	NR	16	6	4	24
Yamada <i>et al</i> ^[20]	2012	9	1	4	0	9	1	4	0	NR	NR	NR	NR
Albazaz <i>et al</i> ^[2]	2013	15	1	0	0	NR	NR	NR	NR	15	1	0	0
Ramos-Font <i>et al</i> ^[11]	2014	20	2	0	15	NR	NR	NR	NR	25	2	0	22

NR: Not reported; IH-CCA: Intrahepatic cholangiocarcinoma; H-CCA: Hilar cholangiocarcinoma; EH-CCA: Extrahepatic cholangiocarcinoma; TP: True positive; FP: False positive; FN: False negative; TN: True negative.

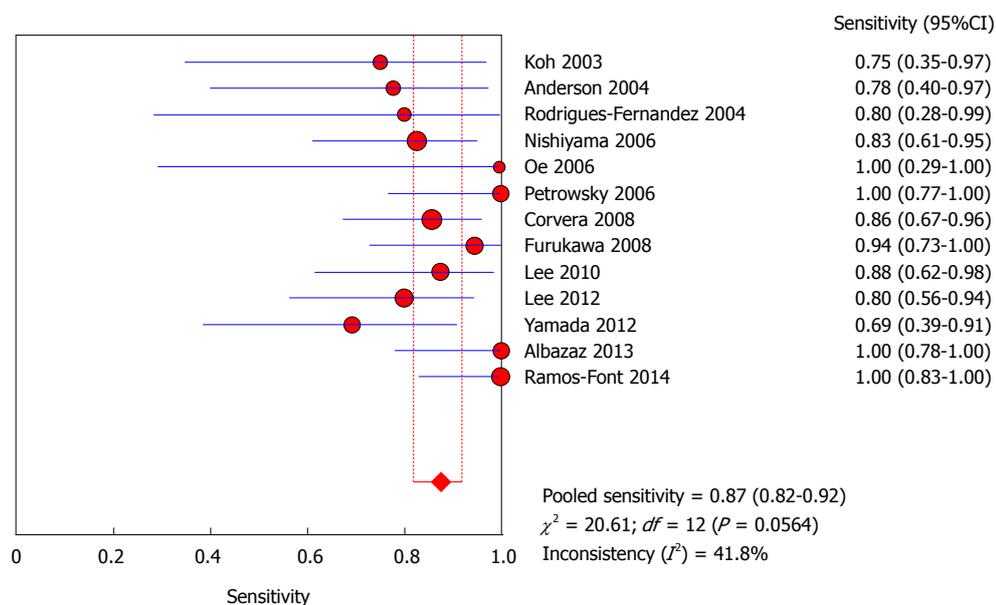


Figure 1 Sensitivity values of fluorine-18-fluorodeoxyglucose positron emission tomography and positron emission tomography/computed tomography in the studies ($n = 13$) included in the meta-analysis.

DISCUSSION

To the best of our knowledge, this meta-analysis is the first to evaluate the diagnostic accuracy of ^{18}F -FDG PET and PET/CT in the evaluation of primary tumor in patients with GBCa. Several studies have used ^{18}F -FDG PET or PET/CT in this setting reporting different values of sensitivity and specificity. However, many of these studies have limited power, analyzing only relatively small numbers of patients. In order to derive more robust estimates of the diagnostic accuracy of ^{18}F -FDG PET or PET/CT in this setting we pooled published studies. A systematic review process was adopted in ascertaining studies, thereby avoiding selection bias^[23].

Pooled results of our meta-analysis indicate that ^{18}F -FDG PET or PET/CT have a good sensitivity (87%) and specificity (78%) in the evaluation of primary tumor in patients with GBCa. Furthermore, the value of the AUC (0.88) demonstrates that ^{18}F -FDG PET or PET/CT are accurate diagnostic methods in this setting.

Possible sources of false-positive results (such as inflammatory diseases of the gallbladder) and false negative results (such as small size and/or low-grade tumors) should be considered.

A subgroup analysis considering different device used (PET vs PET/CT) was performed. We found higher pooled sensitivity and specificity when PET/CT was used compared to PET. This is not surprising

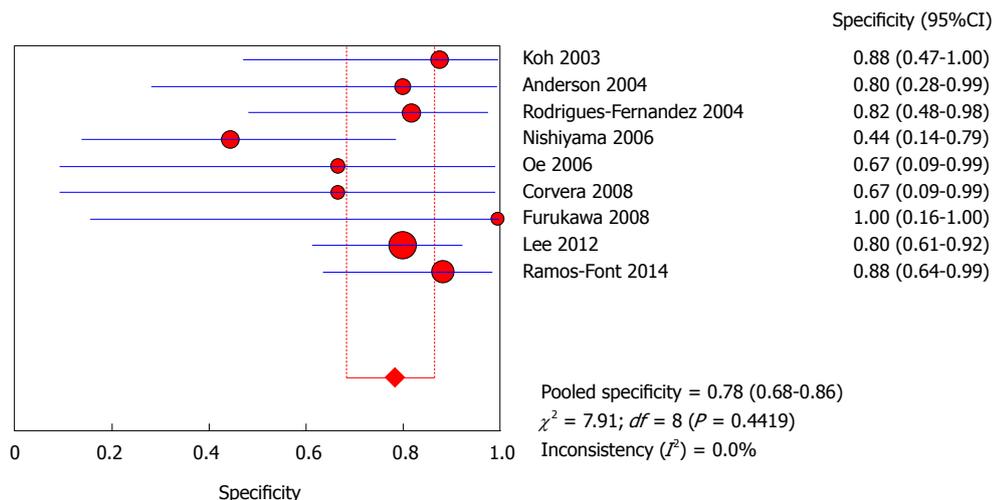


Figure 2 Specificity values of fluorine-18-fluorodeoxyglucose positron emission tomography and positron emission tomography/computed tomography in the studies (n = 9) included in the meta-analysis.

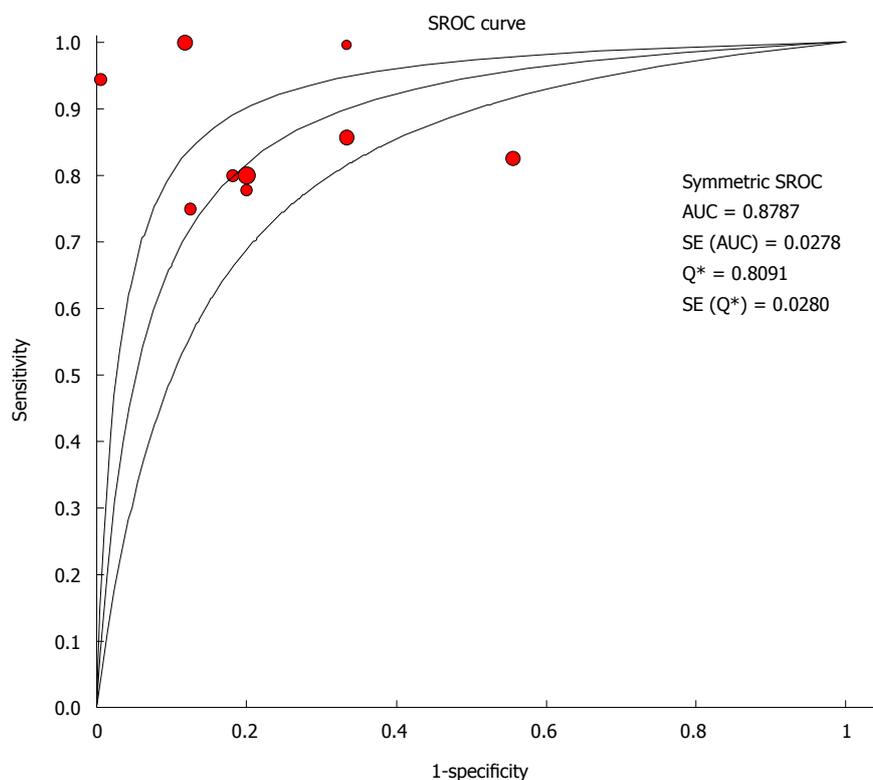


Figure 3 Receiving operator characteristics curve analysis of accuracy values of studies (n = 9) included in the meta-analysis.

considering the higher diagnostic accuracy of PET/CT compared to PET imaging^[3].

Regarding the diagnostic work-up of patients with GBCa, ¹⁸F-FDG PET and PET/CT may have little diagnostic advantage over traditional imaging modalities in detecting primary GBCa^[2]. ¹⁸F-FDG PET and PET/CT can be complementary to US, MR, CT, PTC and ERCP in staging GBCa patients. Since ¹⁸F-FDG PET is a whole-body scanning technique, it allows detection of unsuspected metastatic lymph nodes or distant spread that may lead to major changes in the surgical

management of patients with biliary tract cancer^[20]. Nevertheless, the diagnostic performance of ¹⁸F-FDG PET or PET/CT in detecting metastatic lymph nodes or distant spread was not object of our analysis.

This meta-analysis has some limitations such as the heterogeneity between the studies, the publication bias and the limited number of articles available for the subgroup analysis.

Heterogeneity between studies may represent a potential source of bias in a meta-analysis. This heterogeneity is likely to arise through diversity in

methodological aspects between different studies. The baseline differences among the patients in the included studies, the reference standard used, and the study quality may contribute to the heterogeneity of the results too. In our pooled analysis the included studies were statistically mild heterogeneous in their estimate of pooled sensitivity only.

Publication bias is a major concern in all meta-analyses as studies reporting significant findings are more likely to be published than those reporting non-significant results. Indeed, it is not unusual for small-sized early studies to report a positive relationship that subsequent larger studies fail to replicate. We cannot exclude a publication bias in our meta-analysis.

Only a limited number of articles were available for the subgroup analysis based on the different device used (PET vs PET/CT) and this could limit the statistical power of the subgroup analysis.

Overall, ¹⁸F-FDG PET and PET/CT demonstrated to be quite accurate non-invasive tools in the evaluation of primary tumors in patients with GBCa. Nevertheless, multicentric studies and cost-effectiveness analyses about the role of ¹⁸F-FDG PET/CT in this setting are needed.

¹⁸F-FDG-PET and PET/CT demonstrated to be quite accurate diagnostic imaging methods in the evaluation of primary tumors in patients with GBCa. PET/CT seems to have a better diagnostic accuracy than PET alone in this setting.

COMMENTS

Background

Several studies have evaluated the diagnostic accuracy of fluorine-18-fluorodeoxyglucose (¹⁸F-FDG) positron emission tomography (PET) or PET/computed tomography (CT) in the evaluation of primary tumor in patients with gallbladder cancer (GBCa), reporting different values of sensitivity and specificity.

Applications

¹⁸F-FDG-PET and PET/CT demonstrated to be quite accurate diagnostic imaging methods in the evaluation of primary tumors in patients with GBCa. PET/CT seems to have a better diagnostic accuracy than PET alone in this setting.

Peer-review

It is an interesting article. This article was well designed meta-analysis about gallbladder cancer diagnosis.

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