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

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Abstract

AIM: To meta-analyze published data about the diagnostic accuracy of fluorine-18-fluorodeoxyglucose (18F-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 18F-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 18F-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 18F-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: ¹⁸F-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-postion 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.

Annunziata S, Pizzuto DA, Caldarella C, Galiandro F, Sadeghi R, Treglia G. Diagnostic accuracy of fluorine-18-fluorodeoxyglucose positron emission tomography in gallbladder cancer: A meta-analysis. World J Gastroenterol 2015; 21(40): 11481-11488 Available from: URL: http://www.wjgnet.com/1007-9327/full/v21/i40/11481.htm DOI: http://dx.doi.org/10.3748/wjg.v21.i40.11481

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[1,2].

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 (¹⁸F-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 ¹⁸F-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 ¹⁸F-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 ¹⁸F-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 ¹⁸F-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 ¹⁸F-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 18F-FDG-PET or PET/CT, mean age, gender) and technical aspects (injected activity of 18F-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 18F-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 18F-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 18F-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 FN lesion. We considered as negative a lesion with no uptake of 18F-FDG: when the lesion was histologically confirmed as malignant, this was considered a TN lesion, whereas a histologically confirmed benign lesion was considered as a FP lesion.

Sensitivity was determined according to the following formula: TP/(TP+FN); specificity was determined according to this formula: TN/(TN+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 I² 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 18F-FDG PET and PET/CT.

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

Statistical analyses were performed using MetaDiSc 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 [4-6,12-14,20], 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 18F-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 [1,4-6,12,13,18] provided information about TN and FP lesions, thus allowing to assess pooled specificity. The diagnostic accuracy values of 18F-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 18F-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 (I²: 42%) in their estimate of sensitivity only.

Subgroup analyses considering the different device used (PET or PET/CT) were performed. In studies in which 18F-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 18F-FDG-PET or PET/CT with GB lesions | Mean age (yr) | Gender (%male) |
|--------|------|----------|--------------|-------------------------------------------------------------|---------------|----------------|
| Koh et al[6] | 2003 | Japan     | NR           | 16                                                         | 68            | 44%            |
| Anderson et al[10] | 2004 | United States | NR           | 14                                                        | 65            | 57%            |
| Rodríguez-Fernández et al[11] | 2004 | Spain     | NR           | 16                                                        | 68            | 31%            |
| Nakabayashi et al[12] | 2005 | Japan     | Prospective  | 30                                                       | 71            | 50%            |
| Nishiyama et al[13] | 2006 | Japan     | Retrospective | 32                                                      | 70            | 37%            |
| Oe et al[14] | 2006 | Japan     | Retrospective | 12                                                      | 68            | 66%            |
| Petrovsky et al[15] | 2006 | Switzerland | Prospective | 14                                                      | NR            | NR             |
| Shukla et al[16] | 2008 | India     | NR           | 24                                                        | 45            | 33%            |
| Corvera et al[17] | 2008 | United States | Retrospective | 41                                                      | 62            | 52%            |
| Furukawa et al[18] | 2008 | Japan     | Retrospective | 18                                                      | NR            | NR             |
| Furukawa et al[19] | 2009 | Japan     | Retrospective | 18                                                      | NR            | NR             |
| Butte et al[20] | 2009 | Chile     | Prospective  | 53                                                        | 57            | 20%            |
| Lee et al[21] | 2010 | South Korea | Retrospective | 16                                                      | NR            | NR             |
| Zhu et al[22] | 2010 | United States | NR           | 10                                                        | NR            | NR             |
| Lee et al[23] | 2012 | South Korea | Retrospective | 20                                                      | 65            | 45%            |
| Kumar et al[24] | 2012 | India     | Retrospective | 49                                                      | 52            | 31%            |
| Yamada et al[25] | 2012 | Japan     | Retrospective | 14                                                      | NR            | NR             |
| Albaraz et al[26] | 2013 | United Kingdom | Retrospective | 30                                                      | NR            | NR             |
| Lee et al[27] | 2013 | South Korea | Retrospective | 9                                                       | NR            | NR             |
| Onal et al[28] | 2013 | Turkey    | Retrospective | 10                                                      | 63            | 70%            |
| Ramos-Fort et al[29] | 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 | 18F-FDG mean injected dose (MBq) | Time between 18F-FDG injection and image acquisition (min) | Image analysis | Other imaging methods performed |
|--------|------|--------|---------------------------------|----------------------------------------------------------|---------------|---------------------------------|
| Koh et al[6] | 2003 | PET    | 185                             | 60                                                       | Visual        | CT                              |
| Anderson et al[10] | 2004 | PET    | 370                             | 60                                                       | Visual        | CT                              |
| Rodríguez-Fernández et al[11] | 2004 | PET    | 370                             | 45-60                                                   | Visual and semiquantitative | US, CT |
| Nakabayashi et al[12] | 2005 | PET    | 185                             | 60                                                       | Visual        | CT                              |
| Nishiyama et al[13] | 2006 | PET    | 370                             | 45-60                                                   | Visual and semiquantitative | US, CT |
| Oe et al[14] | 2006 | PET    | 3/5kg                          | 45-60                                                   | Visual and semiquantitative | US, CT, MRI |
| Petrovsky et al[15] | 2006 | PET/CT | 370                             | 45                                                       | Visual and semiquantitative | CT, MRI |
| Shukla et al[16] | 2008 | PET    | 370                             | 60                                                       | Visual        | CT                              |
| Corvera et al[17] | 2008 | PET    | 370                             | 60                                                       | Visual and semiquantitative | CT, MRI |
| Furukawa et al[18] | 2008 | PET    | 200-250                        | 60                                                       | Visual and Semiquantitative | CT, MRI, PTC |
| Butte et al[20] | 2009 | PET/CT | 370                             | 60                                                       | Visual and semiquantitative | NR |
| Lee et al[21] | 2010 | PET/CT | 370                             | 60                                                       | Visual and semiquantitative | CT |
| Zhu et al[22] | 2010 | PET or PET/TC | 370-555                         | 45                                                       | Visual and Semiquantitative | CT |
| Lee et al[23] | 2012 | PET    | 370                             | 45-60                                                   | Visual        | NR                              |
| Kumar et al[24] | 2012 | PET    | 5.5kg                          | 60                                                       | Visual and semiquantitative | NR |
| Yamada et al[25] | 2012 | PET    | 4.5kg                          | 60                                                       | Visual and semiquantitative | NR |
| Albaraz et al[26] | 2013 | PET/CT | 400                             | 60                                                       | Visual and semiquantitative | CT, MRI |
| Lee et al[27] | 2013 | PET/CT | 370-555                        | 60                                                       | Visual and Semiquantitative | CT, MRCP, ERCP, EUS |
| Onal et al[28] | 2013 | PET/CT | 370-555                        | 60                                                       | Visual and Semiquantitative | MRI, CT |
| Ramos-Fort et al[29] | 2014 | PET    | 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 ($I^2 = 59%$).
DISCUSSION

To the best of our knowledge, this meta-analysis is the first to evaluate the diagnostic accuracy of \( ^{18} \text{F}-\text{FDG} \) PET and PET/CT in the evaluation of primary tumor in patients with GBCa. Several studies have used \( ^{18} \text{F}-\text{FDG} \) 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 \( ^{18} \text{F}-\text{FDG} \) 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 \( ^{18} \text{F}-\text{FDG} \) 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 \( ^{18} \text{F}-\text{FDG} \) 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...
considering the higher diagnostic accuracy of PET/CT compared to PET imaging\(^3\).

Regarding the diagnostic work-up of patients with GBCa, \(^{18}\)F-FDG PET and PET/CT may have little diagnostic advantage over traditional imaging modalities in detecting primary GBCa\(^2\). \(^{18}\)F-FDG PET and PET/CT can be complementary to US, MR, CT, PTC and ERCP in staging GBCa patients. Since \(^{18}\)F-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\(^2\). Nevertheless, the diagnostic performance of \(^{18}\)F-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

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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.

| Study            | Specificity (95%CI) |
|------------------|--------------------|
| Koh 2003         | 0.88 (0.47-1.00)   |
| Anderson 2004    | 0.80 (0.28-0.99)   |
| Rodrigues-Fernandez 2004 | 0.82 (0.46-0.98) |
| Nishiyama 2006   | 0.44 (0.14-0.79)   |
| Oe 2006          | 0.67 (0.09-0.99)   |
| Convera 2008     | 0.67 (0.09-0.99)   |
| Furukawa 2008    | 1.00 (0.16-1.00)   |
| Lee 2012         | 0.80 (0.61-0.92)   |
| Ramos-Font 2014  | 0.88 (0.64-0.99)   |

Pooled specificity = 0.78 (0.68-0.86)
\(\chi^2 = 7.91; df = 8 (P = 0.4419)\)
Inconsistency (\(I^2\)) = 0.0%

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

SROC curve
Symmetric SROC
AUC = 0.8787
SE (AUC) = 0.0278
Q* = 0.8091
SE (Q*) = 0.0280
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-fluorodeoxoyglucose (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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P- Reviewer: Cariati A, Lee KG
S- Editor: Ma YJ
L- Editor: AE- Editor: Liu XM
