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Review

Diagnostic accuracy of urinary latex agglutination test (KAtex) for the diagnosis of visceral leishmaniasis: A meta-analysis

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Abstract

Latex agglutination test (KAtex) has been used in the last two decades for the diagnosis of visceral leishmaniasis (VL) in different VL-endemic areas. Here, we present a meta-analysis of studies which evaluated the KAtex for the diagnosis of VL to find out its overall diagnostic performance. A database search was performed on PubMed, Scopus, ISI Web of Science, Iranmedex and Google Scholar. The search of databases found 57 papers, of which 17 articles fulfilled our eligibility criteria. Meta-analysis of diagnostic accuracy (MADA) and Hierarchical Summary Receiver Operating Curve (HSROC) packages were used to do the meta-analysis and to obtain pooled estimates of sensitivity and specificity. Fixed effect bivariate analysis was conducted, using Mantel-Haenszel estimator, to measure the performance and diagnosis odds ratio (DOR) of the test. Heterogeneity of the test results was assessed by Chi-squared test.

The sensitivity of individual studies ranged from 39.8 to 100%, and the specificity ranged from 64 to100%. The combined sensitivity and specificity estimates of KAtex were 77% (95% CI, 70-83%), and 97% (95% CI, 93-97%), respectively. Comparing the performance of the test by region suggests a significant difference where the lowest and highest sensitivities are reported from Nepal/Tunisia and Europe/Middle East respectively ($p < 0.05$). On the other hand, the lowest and highest rates of specificity were reported from Sudan and America/Middle East respectively.

The overall specificity of KAtex is satisfactory. However, KAtex suffers from low sensitivity and this shortcoming should be improved. The test provides a rapid and simple diagnosis of VL and improvement of its sensitivity deserve further studies.

Keywords: KAtex; diagnosis; visceral leishmaniasis; meta-analysis.

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Introduction

Visceral leishmaniasis (VL) as a protozoan parasitic infection is a significant health problem in several countries of the world [1-4]. The disease is fatal in more than 95% of cases, if left untreated. Accurate diagnosis of VL is crucial for proper management of the disease. Several immunodiagnostic tests, with different sensitivity and specificity, have been developed for the diagnosis of VL [5-9]. Among them, tests which are based on detection of antigen in sera or urine received special attention. The most studied and the only antigen-based latex agglutination test for the diagnosis of VL is the Latex Agglutination Test (KAtex) which detects a 5-15 kDa low molecular weight carbohydrate antigen in the urine of VL patients [10,11]. The test was originally developed by Attar at Liverpool School of Tropical Medicine, UK, in 2001 [10] and soon after that was commercialized by Kalon Biological Ltd (Guildford, UK), known as KAtex. KAtex is a test of cure which detects only patients with active disease, and rapidly turns negative after successful treatment. The target antigen for KAtex disappears in the urine, soon after the treatment of the disease and this is one of the advantages of this test. KAtex is an easy-performing method which takes only a few minutes to perform the test. For KAtex, cross-reacting antigens are present in the urine of VL patients and also healthy individuals. Urine samples must be boiled (in boiling water) to eliminate the cross-reacting antigens. Attempt has been made to eliminate this step, by treating the samples with different chemicals, but the outcome has not been so satisfactory [12].

The diagnostic accuracy of KAtex has been evaluated in different VL-endemic areas with a

relatively diverse range of specificity and sensitivity [9,12-19]. In an appropriately comprehensive study, KAtex along with freeze-dried direct agglutination test (FD-DAT) and the rK39 dipstick were evaluated in the Indian subcontinent and East Africa for the diagnosis of VL [9]. Results showed a sensitivity and specificity of 84 and 87.8 in Kenya, 71 and 64% in Ethiopia, 66.1 and 87.6 in India, 35.8 and 97.8 in Nepal, and 72.9 and 98.3 in Sudan [9]. However, the study has not included all the relevant literatures about the KAtex and a few exciting studies about KAtex are available afterward.

KAtex showed a reasonable diagnostic performance for the diagnosis of VL in HIV/VL co-infected cases [18]. A monoclonal antibody raised against the KAtex target antigen showed a sensitivity of 94.1% and specificity of 100% when the monoclonal antibody was used in a capture ELISA for the diagnosis of VL [20].

While KAtex has been considered as a promising test for the diagnosis of VL and has been evaluated in different VL-endemic areas, a global assessment of this test is needed. The current meta-analysis was performed to evaluate the diagnostic accuracy of KAtex for the diagnosis of VL.

Methodology

All articles published after the introduction of latex agglutination test for the diagnosis of VL (2000), and when KAtex become available until March 2017 were searched.

Selection criteria

The inclusion criteria were visceral leishmaniasis (not CL, MCL or PKDL), human subjects, and availability of the absolute numbers of true positive, true negative, false positive and false negative in the presented data. Studies which evaluated the HIV/VL co-infection were also included. Those articles which reported other diagnostic tools (i. e., latex agglutination test for detection of anti-leishmanial antibodies) were excluded. Unavailability of control group or proper reference test was also considered as the exclusion criteria. Besides, studies which evaluated fewer than 10 VL patients' samples were excluded.

Literature review

All the related published literature cited within PubMed, ISI web of science, Google Scholar, Scopus, and Iranmedex were searched. The search terms, both as MeSH terms and text words, were "visceral leishmaniasis", "Leishmaniasis", 'Kala-azar' combined with "KAtex", "latex agglutination test", or "urinary antigen". The reference lists of the retrieved studies were also sought for additional studies. This initial search generated 57 articles. No duplicates were found. Following reading the title and/or abstract, of 57 articles, 30 studies were excluded and following reading the full text, 10 more articles were excluded because they did not meet the inclusion criteria. Thus, 17 studies met the eligibility criteria which constituted the basis of this meta-analysis.

Assessment of study quality

Quada-2 (quality assessment of diagnostic accuracy studies) tools were used for quality assessment of the included studies. Quality assessment was done by BS and MF and discrepancies, was resolved by consensus after discussion.

Data extraction

From each study, the following items were extracted from the full-length articles. (I) number of VL patients, (II) number of controls, (III) number of non-VL patients (patients with other diseases), (IV) sensitivity and specificity of the test, (V), positive predictive value (PPV) and negative predictive value (NPV), if presented, (VI) country where the sample originated (VII) reference test, (VIII) number of true positive, true negative, false positive and false negative. PPV and NPV were calculated in cases which were not present, based on the presented data. Moreover, the confidence interval for sensitivity and specificity were estimated from the available data when the studies did not provide them. Data were extracted from selected papers into structured tables containing all the descriptive and relevant variables.

Statistical analysis

R 3.2.2 was used to do the analysis. Meta-analysis of diagnostic accuracy (MADA) and Hierarchical Summary Receiver Operating Curve (HSROC) packages were used in order to do the meta-analysis and to obtain pooled estimates of sensitivity and specificity. Sensitivity, specificity, PPV, NPV, and OR are expressed by forest plots. Summary receiver operating characteristics (SROC) plot is also provided. Fixed effect bivariate analysis was conducted, using Mantel-Haenszel estimator, to measure the performance and diagnosis odds ratio (DOR), of the test. Heterogeneity of the test results was assessed by Chi-squared test and is presented by forest plot.

Results

Flowchart of the included studies is presented in Figure 1. Seventeen studies evaluating the latex agglutination test (KAtex) met the inclusion criteria and data from these studies were included in the meta-analysis. In some studies, (e.g. Attar *et al.*, 2001), samples had been collected from different geographical areas with related controls. Therefore, diagnostic performances were calculated based on the presented data [10]. The 17 articles, included 23 studies (i.e., more than one group of VL patients evaluated per article). The studies included a total of 2623 VL patients and 2350 controls. The main reference test in most of the studies was a positive parasitological detection of *Leishmania* amastigotes in spleen, lymph nodes or bone marrow samples. Table 1 summarizes the characteristics of the included studies.

Sensitivity ranged from 39.8 to 100% and specificity ranged from 64 to 100%. PPV and NPV ranged from 73.6 to 100% and 39.8 to 100%, respectively.

Figure 1. Flowchart of the included studies.

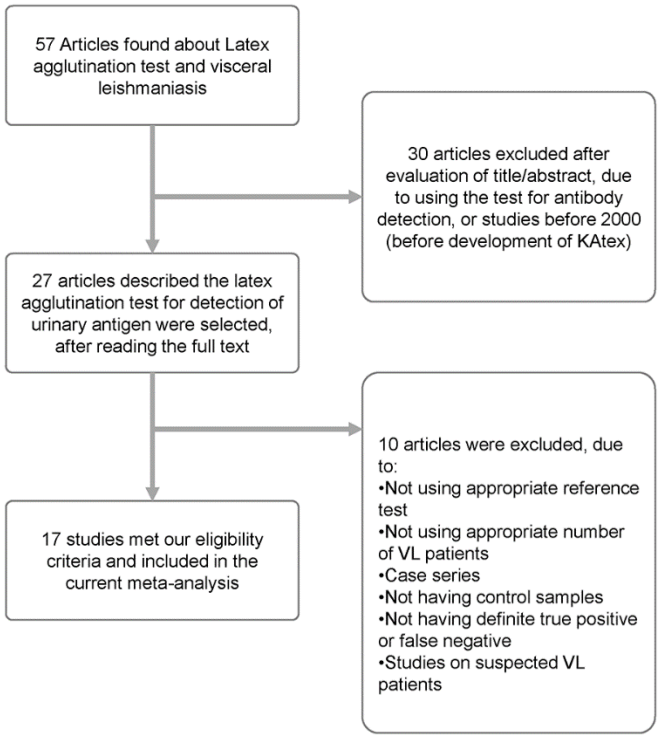


Table 1. Characteristics of the included studies.

No. of subjects		Sensitivity (%) (CI) *	Specificity (%) (CI)	PPV (%)(CI)	NPV (%)(CI)	Year	Author (Ref No.)	Country
VL patients	Controls							
230	170	73.5 (67.1-78.9)	99 (93.7-99.9)	99.4 (96.2-99.9)	61.8 (53.8-69.3)	2007	Sundar [25]	India
382	185	87 (83.3- 90.3)	99 (95.7-100)	99.4 (97.6-100)	78.8 (72.9-83.8)	2005	Sundar [26]	India
29	90	82.7 (67.4-95.4)	98.9 (93-99.9)	86.8 (78.4-99.7)	99.7 (88.7-98.6)	2002	Molai [28]	Iran
36	40	75 (57-87)	100 (89-100)	100 (84.4-100)	81.6 (67.4-90.7)	2007-2008	Salam [29]	Bangladesh
155	77	47.7 (39.7-55.9)	98.7 (93-100)	98.7 (92.8–100)	48.4 (40.4-56.4)	2001-2002	Rijal [21]	Nepal
HIV co infection (n:49)	59	85.7 (72-93.5)	100 (92.3-100)	100 (89.5-100)	89.4 (78.7-95.2)	1994-2003	Riera [30]	Spain
31	61	83.9 (65.5-93.9)	100 (92.6-100)	100 (83.9-100)	92.4 (82.4-97.1)	2005-2007	Ghatei [16]	Iran
18	71	77.7 (51.9-92.6)	98.3 (91.4-99.9)	93.3 (66-99.6)	93.3 (86.2-98.3)	2008	Gavgani [15]	Iran
62	194	95.2 (85.6-98.7)	100 (97-100)	100 (92.3-100)	98.1 (94.2-99.5)	2001-2002	El-safi [31]	Eastern Sudan
85	57	57 (46–67)	98 (88–100)	98 (89–100)	56 (45–67)	2005	Chappuis [27]	Nepal
294	183	72.9 (63.4—81.7)	98.3 (95.3—99.8)	96.9 (88.8-99)	86.1 (80.5-90.3)	2003	Boelaert [9]	Sudan
38	15	71.0 (52.0—87.1)	64.0 (40.0—84.6)	73.6 (48.5-89.8)	62.5 (38.5-83.7)	2004	Boelaert [9]	Ethiopia
308	120	84.5 (78.6—89.8)	87.8 (80.8—93.5)	91.3 (85.8-94.8)	78.3 (70.2-84.8)	2004-2005	Boelaert [9]	Kenya
352	72	66.1 (60.4—71.6)	87.6 (79.1—94.1)	95.3 (91.1-97.7)	39.8 (32.2-47.9)	2005	Boelaert [9]	India
158	72	35.8 (27.5—44.7)	97.8 (92.1—100)	95.3 (91.1-97.7)	39.8 (32.2-47.9)	2005	Boelaert [9]	Nepal
25	369	64 (42.6-81.2)	100 (98.7-100)	100 (75.9-100)	79 (63.5-89.4)	2001	Attar [10]	Brazil
29	369	86.2 (67.4-95.4)	100 (98.7-100)	100 (83.4-100)	98.8 (96.7-99.6)	2001	Attar [10]	Yemen
15	47	100 (98.7-100)	88.6 (76.2-95.3)	71.4 (47.6-87.8)	100 (89.3-100)	2001	Attar [10]	Sudan
12	73	100 (98.7-100)	96 (88-98.9)	84.2 (59.5-95.8)	100 (93.7-100)	2004	Vilaplana [32]	_
100	50	87 (78.4-92.6)	100 (91.1-100)		79.3 (66-88.1)	2007-8	Habib [17]	Bangladesh
50	50	94 (82.4-98.4)	98 (87.9-99.8)	97.91 (87.5-99.8)	94.23 (83.1-98.5	2008	Ahsan [13]	Bangladesh
35	62	51.4 (34.3-68.3)	98.3 (90.2-99.9)	94.7 (71.8-99.7)	78.2 (67.1-86.4)	2016	Ben-Abid [22]	Tunisia
150	305	87 (80.6-92)	98 (97-99.8)	98.4 (94.1-99.7)	94 (90.7-96.3)35	2010	Singh [33]	India

* VL: Visceral Leishmaniasis; PPV: Positive Predictive Value; NPV: Negative Predictive Value; CI: 95% Confidence Interval.

Figure 2. Individual and pooled sensitivity estimates of KAtex for the diagnosis of VL.

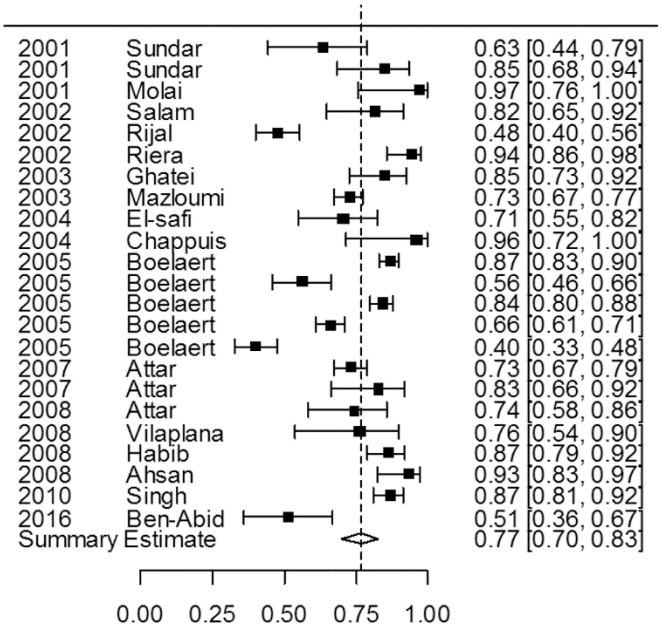


Figure 3. Individual and pooled specificity estimates of KAtex for the diagnosis of VL.

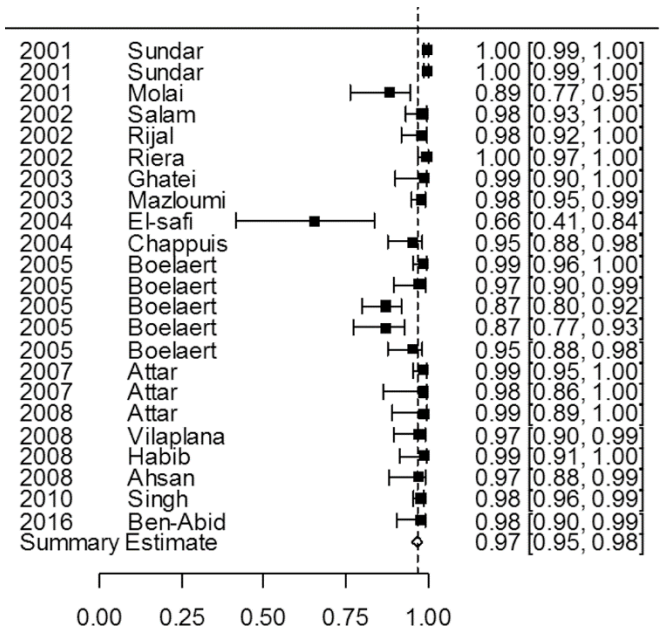


Figure 4. Individual and pooled PPV estimates of KAtex for the diagnosis of VL.

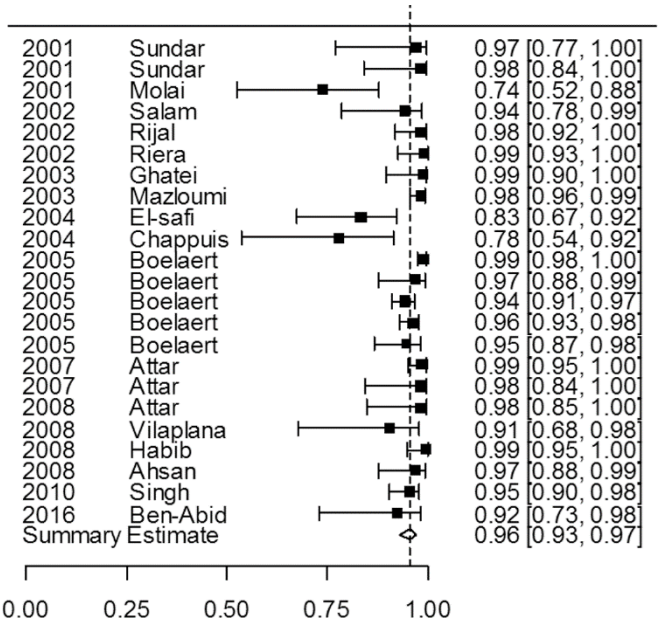
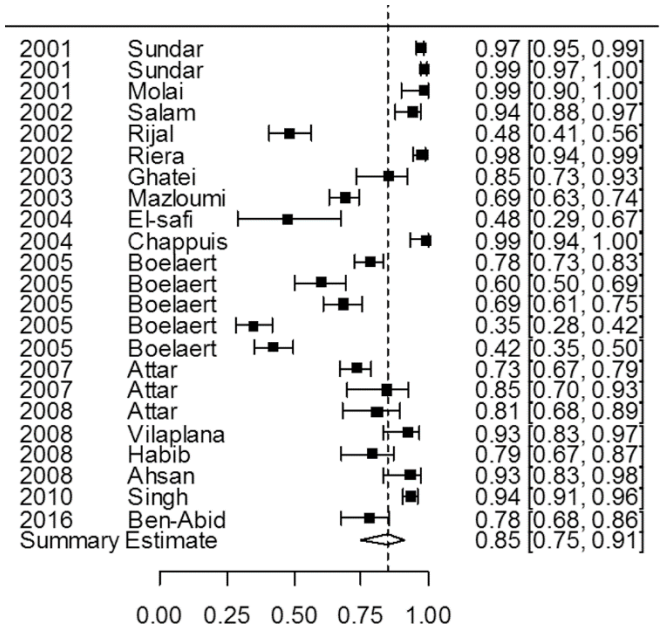
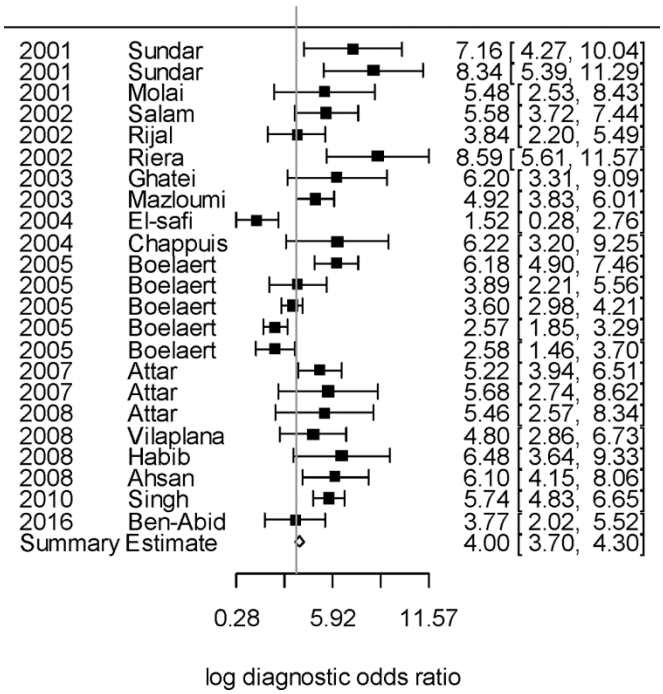


Figure 5. Individual and pooled NPV estimates of KAtex for the diagnosis of VL.



The pooled estimated sensitivity and specificity of KAtex were 77% (95: CI: 70-83%) and 97% (95% CI: 95-98%) respectively. Moreover the summary estimate of PPV and NPV for KAtex were 96% (95% CI: 93-97%) and 85% (95% CI: 75-91%) respectively. Figure 2 and 3 show the results of individual and pooled sensitivity and specificity estimates and Figure 4 and 5 shows the PPV and NPV for KAtex. Diagnostic odds ratio (DOR) of KAtex is depicted in Figure 6 and SROC curve for KAtex is illustrated in Figure 7. Comparing the performance of the test by region suggests a significant difference. Accordingly, the lowest and highest sensitivities are reported from Nepal/Tunisia and Europe/Middle East respectively ($p < 0.05$). On the other hand, the lowest and highest rates of specificity were reported from Sudan and America/Middle East respectively. With regard to positive and negative predictive values, again studies from the Middle East reported the highest rates ($p < 0.05$). Figure 8 shows the individual and summary estimates of sensitivity, specificity, NPV, and PPV of KAtex, based on region.

Figure 6. The diagnostic Odd ratio of KAtex.



Discussion

There are quite numbers of papers which evaluated the diagnostic performance of KAtex for the diagnosis of VL. Findings of the current meta-analysis revealed that KAtex has a reasonable and appropriate specificity (97%) in the diagnosis of VL. However, the summary estimate of the sensitivity of KAtex in this meta-analysis was 77%, which is somewhat far from appropriateness. On the other hand, KAtex has got a reasonable sensitivity in some of the VL-endemic areas of the world, including the Middle East and Europe. Very low sensitivity has been recorded for KAtex in Nepal and Tunisia [21-22]. Discrepancies in the sensitivity and specificity of the test may be linked to the participated patients (severity of the disease and parasite and also antigen load), geographical region of the study, and lack of homogeneity of the studied population.

KAtex is the most studied antigen detection assay for the diagnosis of VL. KAtex's target antigen has

Figure 7. The SROC curve for KAtex in the diagnosis of VL (AUC = 0.94).

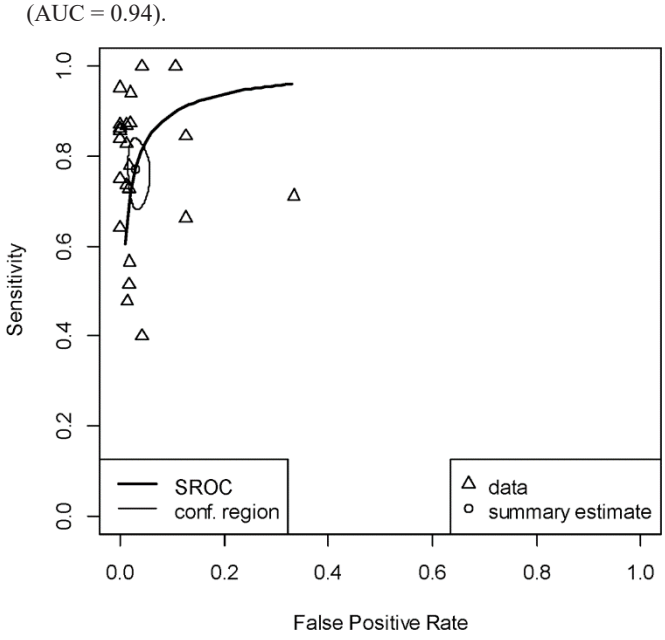
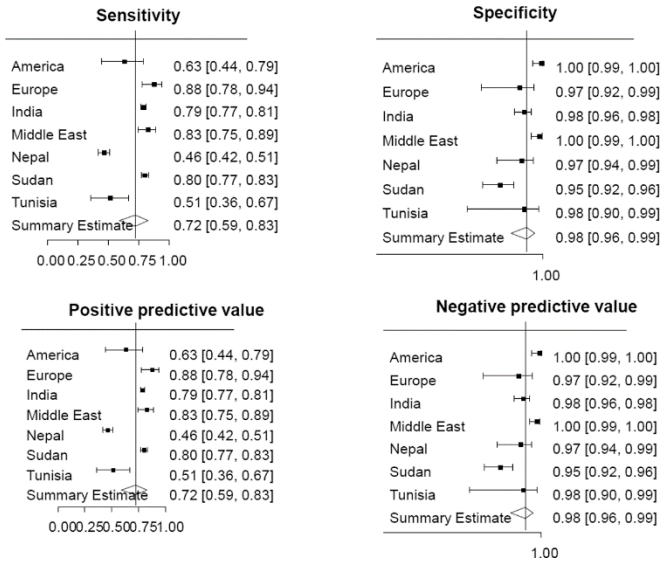


Figure 8. Individual and summary estimates of sensitivity, specificity, NPV, and PPV of KAtex, based on region.



found to be a carbohydrate compound which seems to be linked to the LPG of *Leishmania* [11]. KAtex has a very good prognostic value as the urinary antigen disappears within a few weeks of successful treatment.

Recently a few polypeptides antigens have been detected in the urine of VL patients with promising diagnostic performance [23]. Three distinct *L. infantum* parasite antigens including *L. infantum* iron superoxidase 1 and *L. infantum* nuclear transport factor 2 have been reported by Abeijon *et al.* [23]. Antibodies which have been produced against these antigens were applied in a standard ELISA system and a sensitivity of 89% and specificity of 100% were reported for the assay [24]. Utilizing the combination of the three protein antigens in an ELISA system showed 100 sensitivity and specificity when urine samples of 20 VL patients were tested by the assay [24]. However, the assay evaluated only small samples of VL patients and much more trials in the field are necessary to find out the actual accuracy of this assay for the diagnosis of VL. Furthermore, the assay is based on the detection of only *L. infantum* antigen and may not accurately detect the antigen of *L. donovani*, which is the main causative agent of VL in the Old World [24]. This is actually not the case for KAtex, as KAtex can detect antigen in the urine of VL patients caused by either *L. infantum* (*L. chagasi*) or *L. donovani*. Therefore, it can be said that KAtex is not species specific. Simultaneous detection of a panel of urinary antigen, both polypeptide and carbohydrate antigen, might be a reasonable approach for improving the sensitivity of urinary antigen-based detection assays. This requires the coating of latex particles with a cocktail of antibodies raised against currently recognized polypeptides and carbohydrate antigens.

In this metanalysis, due to the low number of studies in some regions, including Spain and Tunisia, only one study per region was included in the analysis. By no means, this is one of the limitations of the current study. The imperfection of the reference standard test is another limitation of this study which may be present in other similar studies about the performances of the diagnostic tests in the diagnosis of VL [19].

Taken together, findings of the current meta-analysis demonstrated that KAtex has a relatively high specificity for the diagnosis of VL in different VL-endemic areas, but its sensitivity is far from satisfactory. As KAtex is a simple, field applicable, easy performing and cost-effective test, improvement of its sensitivity deserve further studies.

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Author Contributions

BS performed the literature search and assessed the included studies, wrote the first draft of the manuscript, edited and approved the final version. SAK, ZR, and SNG performed the literature and approved the final version of the manuscript. MF helped with the assessment of included studies, performed the data statistical analysis and approved the final version of the manuscript.

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