allergens. *Clin Transl Allergy* 9, 32 (2019). https://doi.org/10.1186/s13601-019-0271-x). There is a considerable need for additional diagnostic tools to minimize the need for food challenges.

Therefore, the problem underlying the present invention is to provide reagents and methods for the diagnosis or for aiding in the diagnosis of sesame allergy, a sesame LTP sensitization and/or an LTP syndrome.

Another problem underlying the present invention is to provide reagents and methods for the detection of sesame-specific antibodies, preferably IgG and IgE antibodies.

Another problem is to provide methods and reagents for the diagnosis of sesame allergy having an improved diagnostic reliability, in particular sensitivity and/or specificity, compared to state of the art methods and reagents.

Another problem underlying the present invention is to provide reagents and methods for the differential diagnosis or aiding in the differential diagnosis of sesame allergy, whereby a sesame allergy can be distinguished from other plant food allergies, in particular a peach allergy.

Another problem underlying the present invention is to identify or aid in identifying plant materials which should be avoided by a patient suffering from an allergy, preferably a plant food allergy, more preferably an LTP syndrome.

The problem underlying the present invention is solved by the subject-matter of the attached independent and dependent claims.

Summary

In a first example, the problem underlying the present disclosure is solved by a polypeptide comprising a sesame nsLTP characterized by SEQ ID NO11 or a variant thereof, wherein the polypeptide is isolated, purified and/or immobilized.

In a second example, the problem underlying the present disclosure is solved by a diagnostically useful carrier comprising a solid phase coated with a polypeptide according to the present disclosure.

In a preferred example, the carrier is selected from the group comprising a bead, a test strip, a microtiter plate, a plastic surface, preferably polystyrene surface, a branched cellulose-based polymer, a microarray, a blot, preferably from the group comprising western blot, line blot and dot blot, a glass surface, a slide, a biochip and a membrane, and is most preferably a microtiter plate or a line blot.

In a preferred example, the polypeptide is in complex with an antibody from the sample of a patient, preferably an IgG and/or IgE class antibody.

In a third example, the problem underlying the present disclosure is solved by a kit comprising

a) the carrier and a means for detecting an antibody bound to the carrier, which means is preferably a secondary antibody or a polypeptide comprising a sesame nsLTP characterized by SEQ ID NO11 or a variant thereof, or

b) a diagnostically useful carrier comprising a means for capturing an antibody in a liquid solution, preferably a non-labeled secondary antibody, and a means for detecting an antibody bound to the carrier, preferably a polypeptide comprising a sesame nsLTP characterized by SEQ ID NO11 or a variant thereof, more preferably with a detectable label,

wherein the kit preferably comprises, in addition to a) or b), one or more, preferably all reagents from the group comprising a calibrator, preferably a set of calibrators, a washing buffer, a positive control and a negative control.

In a preferred example, the carrier is a test strip comprising spatially separate reagents which include a sesame nsLTP characterized by SEQ ID NO11 or a variant thereof, and one or more from the group comprising one or more calibrators, an anti-CCD (cross reactive carbohydrate determinants)-IgE control, a band or reagent indicating the presence of a secondary antibody, preferably a secondary antibody recognizing IgG and/or IgE class antibodies

In a fourth example, the problem underlying the present disclosure is solved by a pharmaceutical composition comprising a polypeptide comprising a sesame nsLTP characterized by SEQ ID NO11 or a variant thereof, preferably further comprising an adjuvant.

In a fifth example, the problem underlying the present disclosure is solved by a method comprising the step detecting in a sample the presence or absence of an antibody binding specifically to a sesame nsLTP characterized by SEQ ID NO11.

In a preferred example, the sample is selected from the group comprising whole blood, serum and plasma, preferably from a mammal, more preferably human.

In a sixth example, the problem underlying the present disclosure is solved by a method comprising the step contacting a device comprising a solid phase coated with a polypeptide comprising a sesame nsLTP characterized by SEQ ID NO11 or a variant thereof with a buffered solution comprising an antibody binding specifically to a sesame nsLTP characterized by SEQ ID NO11, which solution is preferably not a sample from a patient in need of a diagnosis, wherein preferably

a) the concentration of the antibody in the solution is known, and/or
b) the antibody is a recombinant antibody and/or
c) the medical or diagnostic device is contacted with two or more solutions comprising the antibody, wherein the two or more solutions have a different concentration of the antibody, and/or
d) the antibody is recognized by secondary antibodies binding specifically to IgG and/or IgE class antibodies,

followed by detection of a signal which indicates whether or not the antibody has bound to the polypeptide, optionally a signal relating to the concentration of the antibody in the solution or solutions.

In a seventh example, the problem underlying the present disclosure is solved by a use of a polypeptide comprising a sesame nsLTP characterized by SEQ ID NO11 or a variant thereof, the polypeptide, carrier or kit according to the present disclosure for detecting an antibody binding specifically to a sesame nsLTP characterized by SEQ ID NO11 or for manufacturing a device for detecting said antibody.

In an eighth example, the problem underlying the present disclosure is solved by a use of a polypeptide comprising a sesame nsLTP characterized by SEQ ID NO11 or of an antibody binding specifically to a sesame nsLTP characterized by SEQ ID NO11 or the carrier according to the present disclosure for the manufacture of a diagnostic kit.

In a preferred example, the antibody is an IgG or IgE class antibody and/or wherein the secondary antibody recognizes IgG and/or IgE class antibodies.

In a preferred example, the antibody is detected using a method from the group comprising immunodiffusion, immunoelectrophoresis, light scattering, agglutination, labeled immunoassays, preferably from the group comprising radiolabeled immunoassays, enzyme immunoassays such as colorimetric assays, chemiluminescence immunoassays and immunofluorescence immunoassays.

In a ninth example, the problem underlying the present disclosure is solved by an enriched, isolated or purified antibody, preferably IgG or IgE class antibody, or a recombinant antibody binding specifically to a sesame nsLTP characterized by SEQ ID NO11.

In a tenth example, the problem underlying the present disclosure is solved by a method comprising the step enriching or isolating an antibody to a sesame nsLTP characterized by SEQ ID NO11.

In one aspect, the present disclosure relates to a diagnostically useful carrier comprising a solid phase coated with a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

In another aspect, the present disclosure relates to a kit comprising a) the carrier as disclosed herein and a means for detecting an antibody bound to the carrier, which means is preferably a secondary antibody or a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, or b) a diagnostically useful carrier comprising a means for capturing an antibody in a liquid solution, preferably a non-labeled secondary antibody, and a means for detecting an antibody bound to the carrier, wherein the means for detecting an antibody is a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, preferably with a detectable label, wherein the kit preferably comprises in addition to a) or b) one or more, preferably all reagents from the group comprising a calibrator, preferably a set of calibrators, a washing buffer, a positive control and a negative control,
wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

In another aspect, the present disclosure relates to a pharmaceutical composition comprising a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, preferably further comprising an adjuvant, wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

In yet another aspect, the present disclosure relates to a method comprising the step detecting in a sample the presence or absence of an antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5.

In another aspect, the present disclosure relates to a method comprising the step contacting a device comprising a solid phase coated with a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof with a buffered solution comprising an antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5, which solution is preferably not a sample from a patient in need of a diagnosis, wherein preferably a) the concentration of the antibody in the solution is known, and/or b) the antibody is a recombinant antibody and/or c) the medical or diagnostic device is contacted with two or more solutions comprising the antibody, wherein the two or more solutions have a different concentration of the antibody, and/or d) the antibody is recognized by secondary antibodies binding specifically to IgG and/or IgE class antibodies, followed by detection of a signal which indicates whether or not the antibody has bound to the polypeptide, optionally a signal relating to the concentration of the antibody in the solution or solutions, wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

In another aspect, the present disclosure relates to a use of a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, the polypeptide, carrier or kit according to any of claims 1 to 5 for detecting an antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or for manufacturing a device for detecting said antibody, wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

In another aspect, the present disclosure relates to a use of a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or of an antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or the carrier as disclosed herein for the manufacture of a diagnostic kit.

In another aspect, the present disclosure relates to an enriched, isolated or purified antibody, preferably IgG or IgE class antibody, or a recombinant antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5.

In another aspect, the present disclosure to a method comprising the step enriching or isolating an antibody to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5.

Detailed description

The present invention is based on the inventors' surprising finding that antibodies exist in samples from sesame allergic patients which bind to polypeptides associated with the class of sesame nsLTP. The inventors have found that such antibodies do not exist in healthy patients and can be used to aid in the diagnosis of sesame allergy or an LTP syndrome.

According to the present invention a polypeptide comprising a sesame nsLTP characterized by SEQ ID NO11 or a variant thereof is provided. In a preferred embodiment, a sesame nsLTP is any polypeptide which is expressed by a plant from the order *Lamiales*, preferably *Sesamum sp*., more preferably *Sesamum indicum* and has a sequence which comprises SEQ ID NO11, preferably SEQ ID NO12, more preferably SEQ ID NO13 or a variant thereof. In a preferred embodiment, the polypeptide is selected from the group comprising SEQ ID NO1 (LTP1), SEQ ID NO2 (LTP2), SEQ ID NO3 (LTP3), SEQ ID NO4 (LTP4), SEQ ID NO5 (LTP5), preferably the group comprising SEQ ID NO2, SEQ ID NO3, SEQ ID NO4, SEQ ID NO5, most preferably the group comprising SEQ ID NO3, SEQ ID NO4, SEQ ID NO5 or a variant thereof. In a preferred embodiment, the polypeptide comprises SEQ ID NO1 or a variant thereof. In a preferred embodiment, the polypeptide comprises SEQ ID NO2 or a variant thereof. In a preferred embodiment, the polypeptide comprises SEQ ID NO3 or a variant thereof. In a preferred embodiment, the polypeptide comprises SEQ ID NO4 or a

Claims

1. A diagnostically useful carrier comprising a solid phase coated with a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof,
wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

2. The carrier according to claim 1, wherein the carrier is selected from the group comprising a bead, a test strip, a microtiter plate, a plastic surface, preferably polystyrene surface, a branched hydrophilic, preferably cellulose-based polymer, a microarray, a blot, preferably from the group comprising western blot, line blot and dot blot, a glass surface, a slide, a biochip and a membrane, and is most preferably a microtiter plate or a line blot.

3. The carrier according to any of claims 1 to 2, wherein the polypeptide is in complex with an antibody from the sample of a patient, preferably an IgG and/or IgE class antibody.

4. A kit comprising
   a) the carrier according to any of claims 1 to 3 and a means for detecting an antibody bound to the carrier, which means is preferably a secondary antibody or a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, or
   b) a diagnostically useful carrier comprising a means for capturing an antibody in a liquid solution, preferably a non-labeled secondary antibody, and a means for detecting an antibody bound to the carrier, wherein the means for detecting an antibody is a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, preferably with a detectable label,

   wherein the kit preferably comprises in addition to a) or b) one or more, preferably all reagents from the group comprising a calibrator, preferably a set of calibrators, a washing buffer, a positive control and a negative control,
   wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

5. The carrier or kit according to any of claims 1 to 4, wherein the carrier is a test strip comprising spatially separate reagents which include a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, and one or more from the group comprising one or more calibrators, an anti-CCD-IgE control, a reagent indicating the presence of a secondary antibody, preferably a secondary antibody recognizing IgG and/or IgE class antibodies, wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

6. A pharmaceutical composition comprising a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, preferably further comprising an adjuvant, wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

7. A method comprising the step detecting in a sample the presence or absence of an antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5.

8. The method according to claim 7, wherein the sample is selected from the group comprising whole blood, serum and plasma, preferably from a mammal, more preferably human.

9. A method comprising the step contacting a device comprising a solid phase coated with a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof with a buffered solution comprising an antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5, which solution is preferably not a sample from a patient in need of a diagnosis, wherein preferably

   a) the concentration of the antibody in the solution is known, and/or
   b) the antibody is a recombinant antibody and/or
   c) the medical or diagnostic device is contacted with two or more solutions comprising the antibody, wherein the two or more solutions have a different concentration of the antibody, and/or

d) the antibody is recognized by secondary antibodies binding specifically to IgG and/or IgE class antibodies,

followed by detection of a signal which indicates whether or not the antibody has bound to the polypeptide, optionally a signal relating to the concentration of the antibody in the solution or solutions,

wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

10. A use of a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or a variant thereof, the polypeptide, carrier or kit according to any of claims 1 to 5 for detecting an antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or for manufacturing a device for detecting said antibody,
wherein the variant has the ability to bind to an antibody to SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 or SEQ ID NO5.

11. A use of a polypeptide comprising a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or of an antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5 or the carrier according to any of claims 2, 3 or 5 for the manufacture of a diagnostic kit.

12. The carrier according to claim 3, the kit according to any of claims 4 to 5 or the method according to any of claims 7 to 9 or the use according to any of claims 10 to 11, wherein the antibody is an IgG or IgE class antibody and/or wherein the secondary antibody recognizes IgG and/or IgE class antibodies.

13. The method or use according to any of claims 7 to 11, wherein the antibody is detected using a method from the group comprising immunodiffusion, immunoelectrophoresis, light scattering, agglutination, labeled immunoassays, preferably from the group comprising radiolabeled immunoassays, enzyme immunoassays such as colorimetric assays, chemiluminescence immunoassays and immunofluorescence immunoassays.

14. An enriched, isolated or purified antibody, preferably IgG or IgE class antibody, or a recombinant antibody binding specifically to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5.

15. A method comprising the step enriching or isolating an antibody to a sesame nsLTP selected from the group comprising SEQ ID NO1, SEQ ID NO2, SEQ ID NO3, SEQ ID NO4 and SEQ ID NO5.