Neutralizing Anti-Idioitypes to IgG Autoantibodies of Autoimmune Patients and Protects from Exaperimental Autoimmune Disease", Blood, 1997, Vol. 90, No. 10, 4004-4013; and Cesena, HY. "Immune-modulation by polyclonal IgM treatment reduces atherosclerosis in hypercholesterolemic apoE -/- mice", Atherosclerosis, 2012, Vol. 220, 59-65).

Septic conditions and other complications of microbial infections are often associated with an over-stimulation of the immune system, and are often impossible to control due to their exaggerated magnitude and quick evolution. Therefore, there remains a need for effective treatment regimens to reduce, inhibit or prevent over-stimulation of the immune system.

SUMMARY

In one aspect, the present disclosure refers to a use of a composition comprising IgM in the manufacture of a medicament for treating immune complications produced by infections in patients in need thereof.

In another aspect, the present disclosure refers to a use of IgM in the manufacture of a medicament for the immunomodulation of an infection in a patient in need thereof, characterized in that it comprises a composition comprising IgM to be administered.

In another aspect, the present disclosure refers to a use of a composition comprising IgM in the manufacture of a medicament for treating sepsis.

An example of the present disclosure provides a composition comprising, consisting essentially of, or consisting of plasma-derived IgM and optionally one or more excipients in a pharmaceutical carrier.

In a further example, the present disclosure provides a composition comprising IgM for use in the treatment of sepsis.

In a further example, the present disclosure provides a composition comprising IgM for use in the treatment of immune complications produced by infections.

In a further example, the present disclosure provides a method for the treatment of immune complications produced by infections in patients in need thereof, characterized

in that it comprises the administration of a composition comprising IgM.

In a further example, the present disclosure also provides a method for the immunomodulation of an infection in a patient in need thereof, characterized in that it comprises the administration of a composition comprising IgM.

BRIEF DESCRIPTION OF THE FIGURES

For a better understanding, the present invention is described in more detail below with reference to the accompanying figures, which are presented by way of example, and with reference to illustrative examples which are not a limitation of the present invention.

Figure 1 shows the results obtained for the assessment of the effect of IgM on *Escherichia coli* LPS-induced NF-κB activation in THP-1 cells harboring a stable NF-κB reporter plasmid. Both in figure 1A and 1B, the y-axis shows the fold increase in NF-κB activity, as measured by the NF-κB SEAP reporter, said increase is proportional to the induction of NF-κB activity. Also in both figures (1A and 1B), the various treatment groups are shown on the x-axis. Standard error is indicated on each bar.

Figure 2 shows the results obtained for the induction of NF-κB by Toxoid A or Toxoid B of *Clostridium difficile* in THP-1 cells harboring a stable NF-κB reporter plasmid. The fold increase in NF-κB activity, as measured by the NF-κB SEAP reporter, is indicated on the y-axis and is proportional to the induction of NF-κB activity. The

CLAIMS

1. Use of a composition comprising IgM in the manufacture of a medicament for treating immune complications produced by infections in patients in need thereof.

2. The use according to claim 1, characterized in that the infection is produced by *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Streptococcus pneumoniae*, *Clostridium difficile*, *Clostridium botulinum*, or combinations thereof.

3. The use according to claim 1, characterized in that treatment of immune complications is performed through immunomodulation.

4. The use according to claim 3, characterized in that immunomodulation is performed through inhibition NF-κB induction, through the inhibition of proliferation of peripheral blood mononuclear cells or combination thereof.

5. The use according to claim 1, characterized in that the composition used has at least 90% (w/v) of IgM purity.

6. The use according to claim 5, characterized in that the composition has a 95% (w/v) of IgM purity.

7. The use according to claim 1, characterized in that the dose to be administered of the composition is from 75 mg IgM/kg patient to 1 g IgM/kg patient.

8. The use according to claim 7, characterized in that the composition is to be administered at least once a week.

9. The use according to claim 1, characterized in that IgM is recombinant, plasma-derived, cell culture-derived, transgenic or chemically synthesized.

10. The use according to claim 9, characterized in that IgM is plasma-derived IgM, isolated from a suitable fraction of plasma.

11. The use according to claim 1, characterized in that the composition comprising IgM is to be administered alone.

12. The use according to claim 1, characterized in that the composition comprising IgM is to be administered together with one or more other compositions or molecules selected from anti-inflammatory molecules, small molecule antibiotics, molecules that are antimicrobial in nature, natural or synthetic peptide antimicrobials, proteins with antimicrobial properties, other immunomodulators or combinations thereof.

13. The use according to claim 12, characterized in that said other compositions or molecules are vancomycin, meropenem, lactoferrin or combinations thereof.

14. Use of IgM in the manufacture of a medicament for the immunomodulation of an infection in a patient in need thereof, characterized in that it comprises a composition comprising IgM to be administered.

15. The use according to claim 14, characterized in that immunomodulation is used for the treatment or the prevention of infections or infection-related symptoms or conditions.

16. The use according to claim 14, characterized in that the infection is produced by *Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Klebsiella pneumoniae, Streptococcus pneumoniae, Clostridium difficile, Clostridium botulinum*, or combinations thereof.

17. The use according to claim 14, characterized in that immunomodulation is performed through inhibition NF-κB induction, through the inhibition of proliferation of peripheral blood mononuclear cells or combination thereof.

18. The use according to claim 14, characterized in that the composition used has at least 90% (w/v) of IgM purity.

19. The use according to claim 18, characterized in that the composition has a 95% (w/v) of IgM purity.

20. The use according to claim 14, characterized in that the dose to be administered of the composition is from 75 mg IgM/kg patient to 1 g IgM/kg patient.

21. The use according to claim 20, characterized in that the composition is administered at least once a week.

22. The use according to claim 14, characterized in that IgM is recombinant, plasma-derived, cell culture-derived, transgenic or chemically synthesized.

23. The use according to claim 22, characterized in that IgM is plasma-derived IgM, isolated from a suitable fraction of plasma.

24. The use according to claim 14, characterized in that the composition comprising IgM is to be administered alone.

25. The use according to claim 14, characterized in that the composition comprising IgM is to be administered together with one or more other compositions or molecules selected from anti-inflammatory molecules, small molecule antibiotics, molecules that are antimicrobial in nature, natural or synthetic peptide antimicrobials, proteins with antimicrobial properties, other immunomodulators or combinations thereof.

26. The use according to claim 25, characterized in that said other compositions or molecules are vancomycin, meropenem, lactoferrin or combinations thereof.

27. Use of a composition comprising IgM in the manufacture of a medicament for treating sepsis.

28. The use according to claim 27, characterized in that sepsis is produced by *Escherichia coli, Pseudomonas aeruginosa, Staphyloccus aureus, Klebsiella pneumoniae, Streptococcus pneumoniae, Clostridium difficile, Clostridium botulinum*, or combinations thereof.

29. The use according to claim 27, characterized in that treatment of sepsis is performed through immunomodulation.

30. The use according to claim 29, characterized in that immunomodulation is performed through inhibition NF-κB induction, through the inhibition of proliferation of peripheral blood mononuclear cells or combination thereof.

31. The use according to claim 27, characterized in that the composition used has at least 90% (w/v) of IgM purity.

32. The use according to claim 31, characterized in that the composition has a 95% (w/v) of IgM purity.

33. The use according to claim 27, characterized in that the dose to be administered of the composition is from 75 mg IgM/kg patient to 1 g IgM/kg patient.

34. The use according to claim 33, characterized in that the composition is to be administered at least once a week.

35. The use according to claim 27, characterized in that IgM is recombinant, plasma-derived, cell culture-derived, transgenic or chemically synthesized.

36. The use according to claim 35, characterized in that IgM is plasma-derived IgM, isolated from a suitable fraction of plasma.

37. The use according to claim 27, characterized in that the composition comprising IgM is to be administered alone.

38. The use according to claim 27, characterized in that the composition comprising IgM is administered together with one or more other compositions or molecules selected from anti-inflammatory molecules, small molecule antibiotics, molecules that are antimicrobial in nature, natural or synthetic peptide antimicrobials, proteins with antimicrobial properties, other immunomodulators or combinations thereof.

39. The use according to claim 38, characterized in that said other compositions or molecules are vancomycin, meropenem, lactoferrin or combinations thereof.