activated complement were removed via apheresis as well as cellular factors, such as leukocytes. This type of therapy created an immunologically suppressed state in the patient, which is exactly the opposite effect on the immune system that is needed to treat a cancer patient .

SUMMARY OF THE INVENTION

[004a] In one aspect, there is provided a kit for treating a disease in a patient comprising: (a) an apheresis system including a blood perfusion filter comprising at least one bioincompatible material, and (b) a general anesthetic for anesthetizing the patient during use of the apheresis system and for at least 5 hours following that use for treating a disease in a patient, wherein use of the apheresis system creates a lymphocyte dominant state in the patient's immune system.

[005] Also disclosed is~~The invention provides~~ a way to strongly activate a person's immune system by using an extracorporeal blood perfusion filter that is present in an apheresis column. The resulting immunoactivation leads to the destruction of malignant tumor cells via apoptosis. The method of the present disclosure~~invention~~, however, causes substantial physiological impacts on the person including transient low blood pressure and hypoxia. To manage these impacts, the extracorporeal apheresis is conducted with the person under general anesthesia. The general anesthesia, along with careful blood pressure and oxygen saturation monitoring, assures the safe activation of the person's immune system and eliminates any discomfort associated with this procedure. The general anesthesia is administered not only during the apheresis procedure but also during intracorporeal immunoactive modulation period of 6 hours.

[006] It is possible to introduce immunostimulation using a perfusion filter with bioincompatible materials. Perfusion of patients' blood through an apheresis column containing such a filter for one hour at the rate of approximately 100ml/min, can generate such condition. The method of the present disclosure~~invention~~ leads to immunoactivation during the initial 30 minutes of extracorporeal circulation. This molecular surgery procedure for treating a malignant tumor by immnoactivation leads to direct and controllable effects in the first 30 minutes with a return to normal in several hours. These effects include hypotension (approximately 50% reduction in blood pressure), leukocytopenia (approximately a 70% reduction in leukocytes), and respiratory difficulty resulting in hypoxia with the lowest blood oxygen levels occurring 30 minutes after the procedure begins.

[007] These effects are reversible by reducing blood flow through the apheresis column and by providing physiological support to the person. Such support includes general anesthesia with endothracheal tube, blood pressure control (continuous monitoring of the blood pressure), and oxygen supply control (continuous monitoring of blood oxygen saturation).

[008] Because of the transient shock syndrome induced by immunoactivation apheresis systems, no specific immunoactivation columns were provided or applied clinically in the past. The United States Food and Drug Administration has classified such apheresis systems as clinically unsafe because of the shock symptoms associated with their use. The method of the present disclosure~~invention~~ overcomes this problem, by providing a way to powerfully activate the immune system while simultaneously controlling the shock symptoms that accompany the use of a blood perfusion filter according to the invention.

[009] The controlled immunological shock, induced by the bioincompatible material present in the blood perfusion filter of the present disclosure~~invention~~, produces an immunoactive status on experimental animals. To provide a safe, painless, effective, and reproducible therapeutic result, general anesthesia with endotracheal intubation is provided not only during the one-hour apheresis procedure but also for an additional five hours. No animal treated with this procedure died during animal experiments, nor were there any procedurally related physical or sensual abnormalities demonstrated.

[010] Providing general anesthesia for about six hours includes not only the initial 30 minutes of the hypotension and hypoxic stages of shock, but also the recovery stages in which the animals become hemodynamically normalized. After six hours, accumulated leukocytes in the lung are released back to the systemic circulation. During the initial stages of apheresis, granulocytes decrease almost 100% while lymphocytes decrease only 40-50%, this creating a transient lymphocyte dominant state in the person's immune system. During the six hours of general anesthesia, immunostimulatory cytokines TNF-α and IL-6 can increase up to 1,000 fold. After the 6 hours, leukocyte counts in the blood return almost back to pre-procedure levels, and later increases further. After 4 days, leukocyte counts

more than double compared to pre-procedure levels. Cellular and humoral activation then normalize after two weeks.

[011] The induced immunostimulation provided by the method of the present disclosure~~invention~~ can have therapeutic effects for treating malignant tumors and for treating incurable infectious diseases including acquired immunodeficiency syndrome (AIDS).

BRIEF DESCRIPTION OF THE DRAWINGS

[012] Figure 1 provides a schematic of the immunoactivation effects that occur in the patient as a result of the apheresis method of the invention. Not only are humoral factors activated, but also cellular factors are activated.

[013] Figure 2 shows the results of a 3 hour extracorporeal circulation for hemodialysis with a handmade cellophane membrane (blood flows 200 ml/min). The cellophane membrane is considered to be more blood incompatible than synthetic membranes used for apheresis.

[014] Figure 3 provides a schematic of the physiological impacts introduced by apheresis using the immunoactivation filter of the invention including transient leukocyte trapping in lung capillaries.

[015] Figure 4 shows the effect of apheresis on white blood cell counts in the blood over time using the following bioincompatible materials: polyethylene (PE), polymethylmethacrylate (PMMA), polyvinyl alcohol (PVA), and cellulose acetate (CA).

[016] Figure 5A provides a schematic of one example of an apheresis column according to the invention. Figure 5B is a photograph of an embodiment of the column.

[017] Figure 6 shows the effect of apheresis on complement activation, as measured by factor C_{3a} in inlet blood and outlet blood, over time using the following bioincompatible materials: polyethylene (PE), polymethylmethacrylate (PMMA), polyvinyl alcohol (PVA), and cellulose acetate (CA).

[018] Figure 7 provides a schematic of a miniature blood filtering column including a syringe and a bioincompatible material.

WE CLAIM:

1. A method of treating a disease in a patient comprising:

(a) providing an apheresis system including a blood perfusion filter comprising at least one bioincompatible material;

(b) connecting the patient's blood circulation with the apheresis system such that the patient's blood passes through the blood perfusion filter before reentering the patient's body;

(c) placing the patient under general anesthesia and providing physiological support to the patient;

(d) circulating the patient's blood through the apheresis system for about one hour; and

(e) keeping the patient under general anesthesia for at least 5 hours after circulating the patient's blood through the apheresis system,

wherein circulating the patient's blood through the blood perfusion filter activates the patient's immune system thereby treating the disease.

2. The method of claim 1, wherein the disease is a malignant tumor.

3. The method of claim 1, wherein the disease is an infectious disease.

4. The method of claim 3, wherein the infectious disease is acquired immune deficiency syndrome (AIDS) or hepatitis.

5. The method of claim 1, wherein the apheresis system further comprises an air chamber and/or a warming bag.

6. The method of claim 1, wherein the bioincompatible material is a cotton or a silk.

7. The method of claim 6, wherein the cotton is selected from Egyptian cotton, Australian cotton, and Pakistani cotton.

8. The method of claim 6, wherein the silk is selected from Japanese silk and Kanton silk.

9. The method of claim 1, wherein the bioincompatible material is biolized.

10. The method of claim 9, wherein the bioincompatible material is biolized with formaldehyde or glutaraldehyde.

11. The method of claim 1, wherein the patient is a human patient.

12. The method of claim 1, wherein the patient is a non-human animal.

13. The method of claim 1, wherein the general anesthesia is ketamine.

14. The method of claim 1, wherein the physiological support is chosen from at least one of maintenance of blood pressure and maintenance of blood gas levels.

15. The method of claim 1, further comprising the step of administering an anticoagulant to the patient before circulating the patient's blood through the apheresis system.

16. The method of claim 15, wherein the anticoagulant is heparin.

17. The method of claim 1, wherein the patient's blood is circulated through the apheresis system at a rate of about 100 to 200 ml/minute.

18. Use of:

(a) an apheresis system including a blood perfusion filter comprising at least one bioincompatible material, wherein the apheresis system is connected to a patient's blood circulation such that the patient's blood can pass through the blood perfusion filter before reentering the patient's body; and

(b) a general anesthetic for anesthetizing the patient during use of the apheresis system and for at least 5 hours following that use

for treating a disease in a patient, wherein use of the apheresis system activates the patient's immune system thereby treating the disease.

CLAIMS

1. A kit for treating a disease in a patient comprising:
   (a) an apheresis system including a blood perfusion filter comprising at least one bioincompatible material, and
   (b) a general anesthetic for anesthetizing the patient during use of the apheresis system and for at least 5 hours following that use for treating a disease in a patient,
   wherein use of the apheresis system creates a lymphocyte dominant state in the patient's immune system.

2. The kit of claim 1, wherein the disease is a malignant tumor.

3. The kit of claim 1, wherein the disease is an infectious disease.

4. The kit of claim 3, wherein the infectious disease is acquired immune deficiency syndrome (AIDS) or hepatitis.

5. The kit of claim 1, wherein the apheresis system further comprises an air chamber and/or a warming bag.

6. The kit of claim 1, wherein the bioincompatible material is a cotton or a silk.

7. The kit of claim 6, wherein the cotton is selected from Egyptian cotton, Australian cotton, and Pakistani cotton.

8. The kit of claim 6, wherein the silk is selected from Japanese silk and Kanton silk.

9. The kit of claim 1, wherein the bioincompatible material is biolized.

10. The kit of claim 9, wherein the bioincompatible material is biolized with formaldehyde or glutaraldehyde.

11. The kit of claim 1, wherein the patient is a human patient.

12. The kit of claim 1, wherein the patient is a non-human animal.

13. The kit of claim 1, wherein the general anesthesia is ketamine.

14. The kit of claim 1, wherein the physiological support is chosen from at least one of maintenance of blood pressure and maintenance of blood gas levels.

15. The kit of claim 1, further comprising the step of administration of an anticoagulant to the patient before circulating the patient's blood through the apheresis system.

16. The kit of claim 15, wherein the anticoagulant is heparin.

17. The kit of claim 1, wherein the patient's blood is circulated through the apheresis system at a rate of about 100 to 200 ml/minute.