[0016] Patients already ascertained by conventional means, such as a Holter monitor, as having episodes of long duration AFib and above threshold levels of AFib burden are preferably monitored as above before being placed on budiodarone to assess a baseline number and duration of the episodes of long duration AFib as well as AFib burden to determine whether subsequent pharmacotherapy is efficacious. In any event, all qualified patients placed on budiodarone therapy are maintained on monitoring after the start of therapy. Such continued monitoring allows the clinician to evaluate the efficacy of the drug for that patient. In essence, the methods disclosed herein provide for pharmacotherapy with budiodarone as a form of personalized medicine where the severity of the disease in a qualified patient is matched with an appropriate dose of budiodarone that is minimally efficacious for that patient – or if the patient is a non-responder, the patient is disqualified from budiodarone therapy. The methods disclosed herein avoid the use of excessive amounts of budiodarone in treating AFib while understanding that some patients require more budiodarone than others to achieve therapy. Still further, the ability to remove a non-responder from therapy represents a new paradigm in treatment by limiting therapy to those patients who are responders.

[0016a] According to a first aspect of the present invention, there is provided a method to assess whether a patient with either paroxysmal or persistent atrial fibrillation (AFib) qualifies for budiodarone therapy, the method comprising:

a) fitting said patient with a wearable, wherein said patient is afflicted with paroxysmal or persistent AFib, and wherein said wearable comprises:

i) at least one of an electrode or an optical sensor, wherein the at least one of the electrode or the optical sensor is configured to, when the wearable is fitted on the patient, continuously or semi-continuously monitor a heart rhythm of the patient;

ii) a first computing device configured to collect and store heart rhythm data based on the monitored heart rhythm; and

iii) a transmission component configured to transmit data based on the heart rhythm data in the first computing device to a second computing device accessible by a clinician;

b) causing transmission of the data to the second computing device, wherein the data indicates at least one of:

a presence of a long duration episode of AFib,

an absence of a long duration episode of AFib,

a number of long duration episodes of AFib, and

an extent of AFib burden;

c) determining, based on a portion of the data collected over a time period of at least two weeks over which said patient is not provided budiodarone therapy, at least one of a baseline number of long duration episodes of AFib experienced by said patient over the time period and/or a baseline AFib burden of the said patient over the time period;

d) qualifying said patient for budiodarone therapy based on a determination that the at least one of the baseline number of long duration episodes of AFib and/or the baseline AFib burden satisfies at least one of a threshold number of long duration episodes of AFib and/or a threshold AFib burden; and

e) continuously or semi-continuously monitoring said patient for long duration episodes of AFib or AFib burden after initiating budiodarone therapy. [0016b] According to a second aspect of the present invention, there is provided a method to assess whether a patient with either paroxysmal or persistent atrial fibrillation (AFib) qualifies for a budiodarone therapy coupled with heart rhythm monitoring, the method comprising:

a) fitting said patient with a wearable, wherein said patient is afflicted with paroxysmal or persistent AFib, and wherein said wearable comprises:

i) at least one of an electrode or an optical sensor, wherein the at least one of the electrode or the optical sensor is configured to, when the wearable is fitted on the patient, continuously or semi-continuously monitor a heart rhythm of the patient; and

ii) a first computing device configured to collect and store heart rhythm data based on the monitored heart rhythm;

b) causing transmission of data, based on the heart rhythm data, to a second computing device accessible to a clinician, wherein the data indicates at least one of:

a presence of a long duration episode of AFib,

an absence of a long duration episode of AFib,

a number of long duration episodes of AFib, or

an extent of AFib burden;

c) determining, based on the data collected over a time period of at least two weeks over which said patient is not provided budiodarone therapy, at least one of a baseline number of long duration episodes of AFib experienced by the patient over the time period and/or a baseline AFib burden of the patient over the time period;

d) qualifying said patient for subsequent budiodarone therapy coupled with non-invasive monitoring of heart rhythm during said subsequent budiodarone therapy, wherein said qualifying is based on a determination that the at least one of the baseline number of long duration episodes of AFib and/or the baseline AFib burden satisfies at least one of a threshold number of long duration episodes of AFib and/or a threshold AFib burden.

[0016c] According to a third aspect of the present invention, there is provided a method to assess whether a patient with either paroxysmal or persistent atrial fibrillation (AFib) qualifies for a budiodarone therapy coupled with heart rhythm monitoring, the method comprising:

a) fitting said patient with a wearable, wherein said patient is afflicted with paroxysmal or persistent AFib, and wherein said wearable comprises:

i) at least one of an electrode or an optical sensor, wherein the at least one of the electrode or the optical sensor is configured to, when the wearable is fitted on the patient, continuously or semi-continuously monitor a heart rhythm of the patient; and

ii) a first computing device configured to collect and store heart rhythm data based on the monitored heart rhythm;

b) causing transmission of data, based on the heart rhythm data, to a second computing device accessible to a clinician, wherein the data indicates at least one of:

a presence of a long duration episode of AFib,

an absence of a long duration episode of AFib,

a number of long duration episodes of AFib, or

an extent of AFib burden;

c) determining, based on the data collected over a time period of at least two weeks over which said patient is not provided budiodarone therapy, a baseline number of long duration episodes of AFib experienced by the patient over the time period;

d) qualifying said patient for subsequent budiodarone therapy coupled with non-invasive monitoring of heart rhythm during said subsequent budiodarone therapy, wherein said qualifying is based on a determination that the baseline number of long duration episodes of AFib satisfies a threshold number of long duration episodes of AFib.

[0016d] According to a fourth aspect of the present invention, there is provided a method to assess whether a patient with either paroxysmal or persistent atrial fibrillation (AFib) qualifies for a budiodarone therapy coupled with heart rhythm monitoring, the method comprising:

a) fitting said patient with a wearable, wherein said patient is afflicted with paroxysmal or persistent AFib, and wherein said wearable comprises:

i) at least one of an electrode or an optical sensor, wherein the at least one of the electrode or the optical sensor is configured to, when the wearable is fitted on the patient, continuously or semi-continuously monitor a heart rhythm of the patient; and

ii) a first computing device configured to collect and store heart rhythm data based on the monitored heart rhythm;

b) causing transmission of data, based on the heart rhythm data, to a second computing device accessible to a clinician, wherein the data indicates at least one of:

a presence of a long duration episode of AFib,

an absence of a long duration episode of AFib,

a number of long duration episodes of AFib, or

an extent of AFib burden;

c) determining, based on the data collected over a time period of at least two weeks over which said patient is not provided budiodarone therapy, a baseline AFib burden of the patient over the time period;

d) qualifying said patient for subsequent budiodarone therapy coupled with non-invasive monitoring of heart rhythm during said subsequent budiodarone therapy, wherein

said qualifying is based on a determination that the baseline AFib burden satisfies a threshold AFib burden.

[0017] In one embodiment, the overall efficacy of budiodarone in one or more patients can be improved by limiting the continued administration of the drug to those patients evidencing a therapeutic result. In one instance, qualified patients are those who have been previously identified or confirmed to meet minimum thresholds. Qualified patients who show efficacy with budiodarone, either initially and/or after dose adjustments, are continued on the therapy whereas those patients who lack such efficacy (non-responders) are removed from the therapy. Given the variability of the underlying AFib burden as well as the number of long duration AFib episodes in a cohort of patients, budiodarone is efficacious in a significant number of patients, but likely not all patients. Using the methods and devices described herein in combination with budiodarone therapy, the clinician is able to ascertain whether a given patient qualifies for budiodarone therapy and/or whether that therapy is providing efficacious results, thereby allowing the clinician the ability to maintain therapy for only those patients who benefit from budiodarone treatment and at a minimal dose that is needed to achieve efficacious results.

[0018] The above represents a significant advancement in the treatment of symptomatic and asymptomatic paroxysmal or persistent AFib in patients who may or may not have episodes of long duration AFib and/or who may or may not obtain efficacious results with

WHAT IS CLAIMED IS:

1. A method to assess whether a patient with either paroxysmal or persistent atrial fibrillation (AFib) qualifies for budiodarone therapy, the method comprising:

a) fitting said patient with a wearable, wherein said patient is afflicted with paroxysmal or persistent AFib, and wherein said wearable comprises:

i) at least one of an electrode or an optical sensor, wherein the at least one of the electrode or the optical sensor is configured to, when the wearable is fitted on the patient, continuously or semi-continuously monitor a heart rhythm of the patient;

ii) a first computing device configured to collect and store heart rhythm data based on the monitored heart rhythm; and

iii) a transmission component configured to transmit data based on the heart rhythm data in the first computing device to a second computing device accessible by a clinician;

b) causing transmission of the data to the second computing device, wherein the data indicates at least one of-:

a presence of a long duration episode of AFib,

an absence of a long duration episode of AFib,

a number of long duration episodes of AFib, and

an extent of AFib burden;

c) determining, based on a portion of the data collected over a time period of at least two weeks over which said patient is not provided budiodarone therapy, at least one of a baseline number of long duration episodes of AFib experienced by said patient over the time period and/or a baseline AFib burden of the said patient over the time period; d)qualifying said patient for budiodarone therapy based on a determination that the at least one of the baseline number of long duration episodes of AFib and/or the baseline AFib burden satisfies at least one of a threshold number of long duration episodes of AFib and/or a threshold AFib burden; and

e) continuously or semi-continuously monitoring said patient for long duration episodes of AFib or AFib burden after initiating budiodarone therapy.

2. The method of claim 1, wherein the first computing device is configured to determine the data based on the heart rhythm data by evaluating the stored heart rhythm data to determine the presence of a long duration episode of AFib and the number of long duration episodes of AFib.

3. The method of claim 2, wherein said evaluating is continuous over the time period.

4. The method of claim 2, wherein said evaluating is semi-continuous over the time period.

5. The method of claim 1, wherein the first computing device is programmed to, based on the data, alert at least one of the clinician or the patient of a detected long-duration episode of AFib that places the patient at risk of stroke.

6. The method of claim 1, wherein the time period is a time period of at least 30 days over which said patient is not provided budiodarone therapy, and wherein the qualifying said patient for budiodarone therapy comprises determining, based on the data collected over the time period, that the patient meets at least one of the following criteria:

a) at least one AFib episode of at least 5 hours duration in a 30-day period or at least two episodes at least 1 hour in duration in a 30-day period coupled with an AFib burden at least 2.5% during the 30-day period;

b) at least one AFib episode of at least 5 hours duration in a 30-day period or at least 2 episodes at least one hour in duration in a 30-day period coupled with an AFib burden at least 5% during the 30-day period;

c) at least one AFib episode of at least 5 hours duration in a 30-day period coupled with an AFib burden of at least 2.5% during the 30-day period;

d) at least one AFib episode of at least 5 hours duration in a 30-day period coupled with an AFib burden of at least 5% during the 30-day period;

e) at least two AFib episodes of at least 1 hour in duration in a 30-day period coupled with an AFib burden of at least 2.5% during the 30-day period; or

f) at least two AFib episodes of at least 1 hour duration in a 30-day period coupled with an AFib burden of at least 5% during the 30-day period.

7. The method of claim 1, wherein the wearable is one or more of a patch, a watch, a wristband, a strap, a ring, or a device that adheres to a body when fitted; and

wherein the wearable is configured to measure the heart rhythm and transmit the heart rhythm data directly or indirectly to the second computing device.

8. The method of claim 1, wherein the selecting the patient comprises determining that the patient is refractory to one or more other methods of treating AFib.

9. The method of claim 1, wherein a long-duration episode of AFib is defined as an episode of AFib that lasts at least 5 hours.

10. The method of claim 1, wherein the patient was selected from a plurality of potential patients based on being afflicted with paroxysmal or persistent AFib.

11. A method to assess whether a patient with either paroxysmal or persistent atrial fibrillation (AFib) qualifies for a budiodarone therapy coupled with heart rhythm monitoring, the method comprising:

a) fitting said patient with a wearable, wherein said patient is afflicted with paroxysmal or persistent AFib, and wherein said wearable comprises:

i) at least one of an electrode or an optical sensor, wherein the at least one of the electrode or the optical sensor is configured to, when the wearable is fitted on the patient, continuously or semi-continuously monitor a heart rhythm of the patient; and

ii) a first computing device configured to collect and store heart rhythm data based on the monitored heart rhythm;

b) causing transmission of data, based on the heart rhythm data, to a second computing device accessible to a clinician, wherein the data indicates at least one of:

a presence of a long duration episode of AFib,

an absence of a long duration episode of AFib,

a number of long duration episodes of AFib, or

an extent of AFib burden;

c) determining, based on the data collected over a time period of at least two weeks over which said patient is not provided budiodarone therapy, at least one of a baseline number of long duration episodes of AFib experienced by the patient over the time period and/or a baseline AFib burden of the patient over the time period;

d) qualifying said patient for subsequent budiodarone therapy coupled with non-invasive monitoring of heart rhythm during said subsequent budiodarone therapy, wherein said qualifying is based on a determination that the at least one of the baseline number of long duration episodes of AFib and/or the baseline AFib burden satisfies at least one of a threshold number of long duration episodes of AFib and/or a threshold AFib burden.

12. A method to assess whether a patient with either paroxysmal or persistent atrial fibrillation (AFib) qualifies for a budiodarone therapy coupled with heart rhythm monitoring, the method comprising:

a) fitting said patient with a wearable, wherein said patient is afflicted with paroxysmal or persistent AFib, and wherein said wearable comprises:

i) at least one of an electrode or an optical sensor, wherein the at least one of the electrode or the optical sensor is configured to, when the wearable is fitted on the patient, continuously or semi-continuously monitor a heart rhythm of the patient; and

ii) a first computing device configured to collect and store heart rhythm data based on the monitored heart rhythm;

b) causing transmission of data, based on the heart rhythm data, to a second computing device accessible to a clinician, wherein the data indicates at least one of:

a presence of a long duration episode of AFib,

an absence of a long duration episode of AFib,

a number of long duration episodes of AFib, or

an extent of AFib burden;

c) determining, based on the data collected over a time period of at least two weeks over which said patient is not provided budiodarone therapy, a baseline number of long duration episodes of AFib experienced by the patient over the time period;

d) qualifying said patient for subsequent budiodarone therapy coupled with non-invasive monitoring of heart rhythm during said subsequent budiodarone therapy, wherein said qualifying is based on a determination that the baseline number of long duration episodes of AFib satisfies a threshold number of long duration episodes of AFib.

13. A method to assess whether a patient with either paroxysmal or persistent atrial fibrillation (AFib) qualifies for a budiodarone therapy coupled with heart rhythm monitoring, the method comprising:

a) fitting said patient with a wearable, wherein said patient is afflicted with paroxysmal or persistent AFib, and wherein said wearable comprises:

i) at least one of an electrode or an optical sensor, wherein the at least one of the electrode or the optical sensor is configured to, when the wearable is fitted on the patient, continuously or semi-continuously monitor a heart rhythm of the patient; and

ii) a first computing device configured to collect and store heart rhythm data based on the monitored heart rhythm;

b) causing transmission of data, based on the heart rhythm data, to a second computing device accessible to a clinician, wherein the data indicates at least one of:

a presence of a long duration episode of AFib,

an absence of a long duration episode of AFib,

a number of long duration episodes of AFib, or

an extent of AFib burden;

c) determining, based on the data collected over a time period of at least two weeks over which said patient is not provided budiodarone therapy, a baseline AFib burden of the patient over the time period;

d) qualifying said patient for subsequent budiodarone therapy coupled with non-invasive monitoring of heart rhythm during said subsequent budiodarone therapy, wherein said qualifying is based on a determination that the baseline AFib burden satisfies a threshold AFib burden.