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New digital adherence devices could prevent millions of strokes from atrial fibrillation by the end of the next century

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ABSTRACT

The effectiveness and safety of a pharmacologic intervention is highly dependent on patient's capability to follow the recommended treatment regimen. Non-adherence to pharmacologic treatments is associated with worsening conditions including hospitalization and death. This is a significant burden to healthcare systems on a global scale with non-adherence rates being as high (or higher) as 50% in the first treatment year. The most common causes for non-adherence are forgetfulness, busy lifestyle or complexity and changes in therapeutic schedules. In conditions like atrial fibrillation (AFib) this leads to a drastic increase in event rates, e.g. strokes. Patients diagnosed with AFib are strongly recommended to receive anticoagulant treatments for stroke prevention. Treatments with Vitamin K antagonists or novel oral anticoagulants (NOACs) can dramatically lower the risk of ischemic strokes in the presence of AFib. Non-adherence can expose the patients to an increased stroke risk. This is especially true for NOACs, due to their short half-life. Patients have to take these medications once or twice daily for adequate stroke prevention, i.e., single non-use of the medication can already diminish or reset the anticoagulative effect. Adherence devices could help improve patient's compliance by reminder or feedback function. They have shown to be successful in a number of clinical trails. Especially, newer devices that make use of digital technologies show promising results but are not used broadly in clinical practice. Here we provide evidence for our hypothesis that newly available adherence devices might increase adherence rates and thereby reduce the number of strokes in patients with AFib.

Introduction

Anticoagulant-adherence in the context of "atrial fibrillation (AFib)"

Adherence to medication regimen is crucial for effective treatment of any illness. Non-adherence can lead to a worsening condition, comorbid diseases and in the worst case death [1]. Adherence becomes especially difficult, if the medication plan includes different drugs as well as different doses and timings [2]. According to the World Health Organization (WHO) adherence among patients with chronic illnesses averages at about 50% in developed countries and is even lower in developing ones [3]. There are also studies conducted specifically concerning the use of oral anticoagulant drugs which have shown that after the first treatment year less than 50% of the patients were adherent [4]. Non-adherence can be especially dangerous when the drug has a shorter half-life and patients are exposed to an increased risk if they miss a single dose. Therefore, non-adherence is responsible for approximately 125000 deaths per year in the United States [5]. The total cost of non-adherence is estimated to be between $100 billion to $300 billion in the US alone [6].

Relationship between AFib, ischemic stroke and treatment

An increased risk of ischemic stroke is one of the consequences of AFib. The risk can be lowered dramatically by treatment with Vitamin K antagonists (VKA) or Novel Oral Anticoagulants (NOACs) [7–9]. In the near future the number of patients with AFib is going to rise, and with it the incidence of ischemic stroke [10]. Though, NOACs and VKAs should cap the risk of an ischemic stroke in patients diagnosed with AFib [11,12].

The hypothesis

We hypothesize, that a main reason for the increase in incidence of ischemic strokes in patients diagnosed with AFib is

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Table 1
Non-digital adherence devices.

1st Author	Study Year	PMID	Device Name	Device details	Medical Condition	No. of patients	Trial length [months]	Details	Intervention Mean level of Adherence [%]	Control Mean Level of Adherence [%]	Increase of Adherence [%]
Schmitz	2005	15957569	Medication Event Monitoring System IV (Aardex)	adherence recorder	Smoking cessation	46	1.5	female patients, age 30 and 70, <10 cigarettes/d, intervention group received weekly feedback, control group unaware	73.0	48.0	25.0
Cramer	1999	9952254	Medication Event Monitoring System (Aprex)	Adherence recorder	Psychiatric disorders	45	6	Intervention group was aware and had sessions with feedback and reinforcing techniques vs usual care	76.0	57.0	19.0
Mooney	2007	16839698	Medication Event Monitoring System (Aardex)	adherence recorder	Smoking cessation	55	1.5	therapy with MEMS feedback (10 min) vs. therapy only	77.0	54.0	23.0
Rosen	2004	14998735	Medication Event Monitoring System SmartCap (Aardex)	adherence recorder, audio visual alarm, liquid crystal display	Diabetes / hyperglycemia	33	3.5	Caps with displays, cue-dose training and feedback vs displays only	80.0	65.0	15.0
Rigsby	2000	11119180	Medication Event Monitoring System (Aprex)	adherence recorder	HIV	55	1	cue-dose training and feedback vs cue-dose training with monetary reinforcement vs usual care	75.0	60.0	15.0
Mengden	2006	16942618	Medication Event Monitoring System (Aardex)	adherence recorder and liquid crystal display	Hypertension	62	3	hypertensive patients using MEMS with display and teaching program vs patients using MEMS without display with self BP tests vs well controlled patients using MEMS	99.0	98.0	1.0
Forni Ogna	2012		Medication Event Monitoring System (Aardex)	adherence recorder and liquid crystal display	Platelet inhibition	48	6	providing feedback to patients using MEMS data (2 months intervals) vs simply registering MEMS adherence data	99.0	97.0	2.0
Kruse	1994	7820327	Medication Event Monitoring System (Aprex)	adherence recorder	Hypertension	24	7	receiving adherence feedback vs not receiving feedback	92.0	82.5	9.5
Murray	2004	15555479	Medication Event Monitoring System V (Aardex)	adherence recorder	Heart failure	270	12	delivering education and monitoring data (send to a personal computer) vs standard of care	78.8	67.9	10.9
Russel	2010		Medication Event Monitoring System V TrackCap (Aprex)	adherence recorder	Renal transplant	13	9	individual data feedback and implementation of personal system changes vs brochures	88.0	77.0	11.0
de Bruin	2005	15989434	Medication Event Monitoring System 6 SmartCap (Aardex)	adherence recorder and liquid crystal display	HIV	19	3	adherence was monitored for 2 months, after that the data was used to give feedback to patients	93.0	82.0	11.0
Wagner	2002	11819185	Medication Event Monitoring System (Aardex)	adherence recorder	HIV	173	1	electronic monitoring caps vs medication diaries vs no surveillance	91.4 (e monitoring) vs 92,4 (diaries)	93.8	-2.4
Laster	1996	8979657	Prescript TimeCap (Wheaton Medical Technologies)	adherence recorder, audio visual alarm, liquid crystal display	Glaucoma	13	2	cap that displays the last time the vial was opened vs normal caps	95.8	83.1	12.7