Role of extended external loop recorders for the diagnosis of unexplained syncope, pre-syncope, and sustained palpitations

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Aims	To assess the diagnostic yield of new external loop recorders (ELRs) in patients with history of syncope, pre-syncope, and sustained palpitations.
Methods and results	Since 2005, we have established a registry including patients who consecutively received ELR monitoring for unexplained syncope or pre-syncope/palpitations. The registry included 307 patients (61% females, age 58 ± 19 years, range 8–94 years) monitored by high-capacity memory ELR of two subsequent generations: SpiderFlash-A® (SFA®, Sorin CRM), storing two-lead electrocardiogram (ECG) patient-activated recordings by loop-recording technique (191 patients, 54 patients with syncope, years 2005–09), and SpiderFlash-T® (SFT®), adding auto-trigger detection for pauses, bradycardia, and supraventricular/ventricular arrhythmias (116 patients, 38 patients with syncope, years 2009–12). All the patients previously underwent routine workup for syncope or palpitation, including one or more 24 h Holter, not conclusive for diagnosis. Mean monitoring duration was 24.1 ± 8.9 days. Among 215 patients with palpitations, a conclusive diagnosis was obtained in 184 patients (86% diagnostic yield for palpitation). Among 92 patients with syncope, a conclusive diagnosis was obtained in 16 patients (17% clinical diagnostic yield for syncope), with recording during syncope of significant arrhythmias in 9 patients, and sinus rhythm in 7 patients. Furthermore, asymptomatic arrhythmias were de novo detected in 12 patients (13%), mainly by auto-trigger detection, suggesting an arrhythmic origin of the syncope.
Conclusions	The diagnostic yield of ELR in patients with syncope, pre-syncope, or palpitation of unknown origin after routine workup was similar to implantable loop recorder (ILR) within the same timeframe, therefore, ELR could be considered for patients candidate for long-term ECG monitoring, stepwise before ILR.
Keywords	Syncope • Palpitations • Ambulatory ECG monitoring • Cardiac arrhythmias • External loop recorder • Implantable loop recorder

Introduction

The diagnosis of syncope and sustained palpitations of suspected arrhythmic origin remains a difficult task in clinical cardiology, often leading to multiple admittances to the emergency room and repetition of different diagnostic tests. The clinical presentation is often not univocal, as the history of pre-syncope, syncope, and sustained palpitations coexist in the same patient.

All the recent guidelines for the management of patients with syncope, palpitations, ventricular arrhythmias and sudden death, supraventricular arrhythmias, and atrial fibrillation recommend the use of prolonged electrocardiogram (ECG) monitoring techniques to allow a better correlation between the symptoms and the arrhythmias, and to detect asymptomatic significant rhythm disturbances.[1–6]

In the diagnostic work-up of the syncope, external or implantable ECG recorders are specifically recommended in patients with a high

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pre-test probability of arrhythmic syncope.[1,2] The choice of monitoring technique mainly depends on the predicted recurrence rate. Routine standard 24 h Holter recorders have a low diagnostic yield as they are unlikely to capture the reoccurrence of syncope, unless in extremely frequent episodes, while it may contribute to identifying ECG markers suggestive of arrhythmic origin. Implantable loop recorders (ILR) have a higher diagnostic yield for infrequent syncope; therefore, a more extensive early usage in the initial phase of the diagnostic work-up may be recommended.[1,7−9] However, ILR are expensive and mildly invasive, therefore unfit as first level diagnostic tools in general clinical practice.[10−12]

The role of external loop recorders (ELRs) in the diagnostic workup of the syncope is more debated, as the available studies showed conflicting results, with diagnostic yield spanning from 10 to 50%, mainly due to the duration limited to about 1 month.[2,4,13−15] Thus, current indications for ELR are limited to patients with a high probability of recurrent events.[2,4] However, technological advances such as auto-trigger capability and mobile cardiac outpatient telemetry are now showing promising results.[15−17]

In sustained palpitations, the indication for ELR is more clearly established, since several studies showed that ∼50−75% of sustained palpitations recurred within 1 month.[5,18] However, most available ELR have technical limitations, due to relatively low-memory capacity and lack of auto-trigger function.

The main goal of this study was to evaluate the diagnostic yield of a new generation of ELR with high-memory capacity, extended backward and forward memory, and auto-trigger functions in consecutive patients with syncopal and/or pre-syncope or palpitations.

Methods

Study population

Since January 2005, we have established a registry that prospectively included all consecutive patients with a history of syncope (fainting with total loss of consciousness, TLOC), pre-syncope (fainting without TLOC), or sustained palpitations referred to the Non-Invasive Electrophysiological Unit of our Department, who underwent ELR monitoring by SpiderFlash recorders. The registry included a total of 307 consecutive patients receiving ELR between January 2005 and September 2012. All the patients had previously completed a routine workup for syncope or palpitation, as recommended by the ongoing guidelines at the time of monitoring (including tilt test, sinus carotid massage, and electrophysiological test whenever appropriate), in all cases not conclusive for diagnosis. All the patients had received one or more 24 h Holter monitoring (median 3 recordings each, range 1−18 recordings), while only one patient with a history of syncope had previously had ILR before ELR.

As most patients had a history of multiple and heterogeneous symptoms (syncope and/or pre-syncope and/or palpitations), we identified two study groups. The first group consisted of patients with a history of at least one confirmed unexplained syncope (92 patients, 30%). The second group consisted of patients with a history of palpitations and/or pre-syncope (215 patients) (*Figure 1*).

Recording techniques

We utilized SpiderFlash-A® (SFA®, Sorin CRM) and SpiderFlash-T® (SFT®, Sorin CRM) digital ELRs, storing one- or two-lead ECG tracings on a high-capacity removable secure digital card (which can memorize
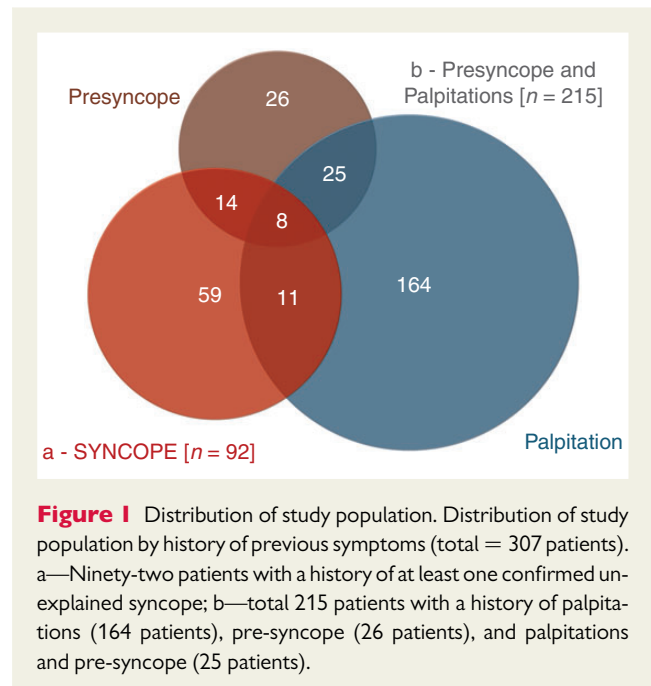

Figure 1 Distribution of study population. Distribution of study population by history of previous symptoms (total = 307 patients). a—Ninety-two patients with a history of at least one confirmed unexplained syncope; b—total 215 patients with a history of palpitations (164 patients), pre-syncope (26 patients), and palpitations and pre-syncope (25 patients).

a virtually unlimited number of events), with looping memory capabilities, intended for long-term ECG monitoring up to 30 days.

SpiderFlash recorders are programmed by Hook-up2® (v2.00) software, allowing the choice of several recording and pre-analysis parameters (such as pre- and post-event recording duration, time-table for pre-defined recordings, and type and characteristics of arrhythmias for auto-trigger functions, if available).

The first generation SFA® recorders (utilized in the period 2005−09) had two recording modalities: (i) patient-activated and (ii) programmable time-table. In patient-activated modality, continuous one- or two-lead ECG tracings were recorded by utilizing loop-recording technique, with backward and forward memory, which can be extended up to 30 min (15 min before and after the trigger). In programmable time-table modality, it is possible to memorize a maximum of 20 ECG tracings per day of maximum 900 s duration.

The second generation SFT® recorders, available since 2009, besides (i) patient-activated and (ii) programmable time-table recordings, also have (iii) auto-trigger capability which automatically detects and records pre-defined and programmable rhythm disturbances such as pauses, bradycardia, or supraventricular and ventricular tachyarrhythmias. SFT® recorders were programmed to identify rhythm disturbances according to the parameters listed in *Table 1*.

SFA® and SFT® recorders (sized 75 × 50 × 19 mm) were carried by the patient in a disposable bag hung around the neck. The recorders were connected to the thorax by lead wires and disposable adhesive electrodes, which the patients were trained to change daily for personal cleaning. The patients had to press a button on the recorder to store ECG tracings in case of symptoms ('patient-activated' events); otherwise no other manipulation was required. The patients were asked to annotate on a special diary all the symptoms (palpitations, syncope, or pre-syncope) occurring during the monitoring period. The patients were instructed to return the recorder when the recording ended (shown by a status light-emitting diode on the device) or when a significant symptom occurred. If the recorder stopped before the expected minimum of 21 days, and no symptoms had occurred, the recorder was restarted and the monitoring

Table 1 Rhythm disturbances programmed for auto-trigger detection (SpiderFlash-T® only)

Rhythm disturbances	Recorder parameters	Programmed thresholds
Supraventricular tachycardia	Prematurity	<75%
	Rate	>150 b.p.m.
	Minimum duration	>5 s
Ventricular tachycardia	Prematurity	<80%
	Rate	>120 b.p.m.
	Minimum duration	>1 s
Atrial fibrillation	Irregular RR[a] duration	>30 s
Bradycardia	Rate	<40 b.p.m.
	Minimum duration	>10 s
Pauses	Duration	>3000 ms
Missed beat	Duration	>1500 ms

[a]Irregular RR is a Sorin algorithm for the detection of atrial fibrillation.
b.p.m., beats per minute.

continued until the recorder stopped (maximum monitoring duration 50 days).

SFA® recorders were used in 191 patients (January 2005 to October 2009, 54 patients with syncope, 28%), while SFT® recorders in 116 patients (November 2009 to September 2012, 38 patients with syncope, 33%).

Analysis technique and quality control of the recordings

Analyses were performed by EventScope2® (v2.00), software dedicated for analysis of SFA® and SFT® recorders. The auto-trigger detection algorithm was validated in a dedicated study.[19] As the first step, the recordings were screened for quality of the tracing and real use by the patient by means of the analysis of the lead impedance. No monitoring had to be excluded due to insufficient quality, since in most tracings at least one of the two leads was adequate for arrhythmia analysis, even if in each monitoring some tracings had to be excluded due to motion artefacts. As the second step, all patient-activated tracings were checked and matched to the symptoms reported in the diary to verify the correspondence between the symptoms and the tracings and between the symptoms and the arrhythmias. As the third step, in SFT® only, all auto-triggered tracings were examined and whenever possible matched against the symptoms annotated in the diary. The number of available tracings for each recording was rather variable according to the patient characteristics and the presence or the absence of symptoms, with a median of about 1000 tracings memorized for each recording (about 50 tracings per day).

Statistical analysis

All the data with normal distribution were expressed as mean ± SD, and were compared by standard t-test wherever applicable. Data without normal distribution were tested by using non-parametric tests.

The reference standard for calculating the ELR diagnostic yield was 24 h Holter monitoring, which was negative or non-conclusive in all study patients. Wherever appropriate, the diagnostic yield of SFT® (with auto-trigger capability) was compared with SFA® (without auto-trigger capability). In all comparisons, P value <0.05 was considered significant.

Results

The baseline patient characteristics are illustrated in *Table 2*. The mean age was 58 years (range 8–94 years) and female gender was prevalent (61%). The mean duration of the recordings was 24.1 ± 8.9 days (SFA® 25.2 ± 10.2 days—SFT® 22.2 ± 5.8 days, NS, *Table 2*). In 85% of the cases, the monitoring lasted 3–5 weeks, while in 47 cases (15%) the monitoring lasted 2 weeks or less (*Figure 2*). Among those cases, ELR monitoring was interrupted prematurely due to the occurrence of significant symptoms (38 of 47 patients, 81%), while in the remaining 9 cases the recording was stopped due to skin reaction to the electrodes or due to patient lack of compliance. Events occurred almost evenly in each monitoring week, both for syncope and pre-syncope or palpitations.

As most patients had a history of multiple and heterogeneous symptoms (syncope and/or pre-syncope and/or palpitations), we separately analysed patients with a clear-cut history of at least one confirmed unexplained syncope from patients with more heterogeneous symptoms of palpitations and/or pre-syncope.

Patients with a history of syncope

Among the 92 patients with syncope (54 studied by SFA® and 38 studied by SFT®), about 30% had a history of ischaemic or non-ischaemic heart diseases (valvular or congenital heart disease), about 16% had a history of supraventricular arrhythmias, about 16% had conduction disturbances [first and second degree atrioventricular block (AVB), Mobitz 1 type, or left bundle branch block (LBBB) or right bundle branch block]. No statistically significant differences in the clinical baseline characteristics were found between patients studied by SFA® and SFT®.

Among them, a typical syncope reoccurred during monitoring in 17 patients. Electrocardiogram recording during syncope was available in 16 patients, while just 1 patient (male gender, 78 years) with SFA® did not activate the manual recording after recovering from syncope (*Table 3*).

Electrocardiogram findings observed during syncope are listed in *Table 4*. In seven patients (7 of 16, 44%) significant arrhythmias were recorded during syncope: bradycardia and pauses requiring pacemaker implant in three patients (*Figure 3*), and fast supraventricular tachyarrhythmia [paroxysmal atrial fibrillation (PAF)/paroxysmal supraventricular tachycardia (PSVT)] in four patients. In nine patients (9 of 16, 56%), only normal sinus rhythm or sinus tachycardia were recorded during syncope.

Among 38 patients studied by SFT® with auto-trigger capability, asymptomatic suggestive arrhythmias [pauses, bradycardia, AVB, and sustained PAF/PSVT/non-sustained ventricular tachycardia (NSVT)] were de novo detected in 11 patients (28.9%), indicating a possible arrhythmic cause for syncope (*Table 5*), leading to a major medical treatment [pacemaker implantation in 3 cases and radiofrequency (RF) ablation in 1 case] while in 2 cases ILR was later implanted for further ECG monitoring.

No differences in history of cardiac disease or arrhythmias, or cardiac therapy at the time of recording were observed in patients with or without recurrence of syncope during the monitoring period.

Table 2 Baseline clinical patient characteristics

Patients studied for syncope[a]	SpiderFlash-A® 2005–09 N = 54	SpiderFlash-T® 2009–12 N = 38	Total N = 92
Female gender	44.4%	50.0%	46.7%
Age, years (STD)	57.8 (20.4)	63.5 (19.0)	60.1 (19.9)
Mean recording duration, days (STD)	27.1 (9.6)	22.1 (7.6)	25.1 (9.1)
Clinical history[b]			
Arterial hypertension	29.6%	34.2%	31.5%
Ischaemic heart disease	20.3%	15.7%	18.4%
Non-ischaemic heart disease	7.4%	13.2%	9.8%
CAF/PAF/PSTV	13.0%	21.1%	16.3%
First or second degree AVB (Mobitz 1) or pauses <2 s	11.1%	10.5%	10.9%
LBBB or RBBB	7.4%	5.3%	6.5%
Any cardiac therapy during recording	33.3%	44.7%	38.0%
Patients studied for pre-syncope/palpitations[a]	**SpiderFlash-A® 2005–09 N = 137**	**SpiderFlash-T® 2009–12 N = 78**	**Total N = 215**
Female gender, %	70.8%	59.0%	66.5%
Age, years (STD)	57.7 (19.4)	55.6 (17.8)	56.9 (18.8)
Mean recording duration, days (STD)	24.4 (10.4)	22.2 (4.7)	23.6 (8.8)
Clinical history[b]			
Arterial hypertension	31.4%	41.3%	35.0%
Coronary heart disease	10.9%	10.9%	10.9%
Non-coronary heart disease	5.1%	10.9%	7.2%
CAF/PAF/PSTV	21.2%	39.1%	27.7%
First or second degree AVB (Mobitz 1) or pauses <2 s	4.4%	10.9%	6.7%
LBBB or RBBB	2.2%	2.2%	2.2%
Any cardiac therapy during recording	35.0%	54.3%	39.3%

CAF, persistent or permanent atrial fibrillation; PAF, paroxysmal atrial fibrillation; AVB, atrioventricular block; LBBB, left bundle branch block; RBBB, right bundle branch block; PSVT, paroxysmal supraventricular tachycardia.
[a]No statistically significant differences were found between patients studied by SFA® and SFT®.
[b]These categories are not mutually exclusive and some patients may have more than one condition.

Patients with a history of pre-syncope and/or palpitations

Among 215 patients with a history of pre-syncope and/or palpitation, about 18% had ischaemic or non-ischaemic heart diseases, about 28% had a history of supraventricular arrhythmias, and about 9% had conduction disturbances. No statistically significant differences were found between patients studied by SFA® and SFT®, although patients with PAF were slightly more frequent than in most recent patients.

Among them, typical palpitation or pre-syncope reoccurred during ELR monitoring in 184 patients (85.6%) (*Table 3*). Many patients had multiple episodes of pre-syncope or palpitations during recording (median 3 episodes per patient). Rhythm disturbances observed during the symptoms are listed in *Table 6* (*Figure 4*). As many patients had multiple episodes with multiple rhythm disturbances, the patients were classified according to the most severe arrhythmia observed during monitoring [e.g. if a patient had one palpitation with recording of sinus tachycardia and one with PAF, the final classification was PAF].

In SFA® recordings, sinus rhythm or sinus tachycardia was recorded in about one-third of the cases, and about one-third had sustained supraventricular tachycardia or PAF at the time of the symptoms. In the SFT® recordings, supraventricular tachycardia or PAF was recorded in about 46% of the cases, while bradycardia or pauses was recorded in about 13% of the cases.

Those differences in ECG findings during the symptoms observed by SFA® and SFT® (*Table 6*) can be partly explained by the slight prevalence of pre-syncope among patients studied by SFT® (28 vs. 21%, NS), accounting for a slightly higher incidence of bradycardia and pauses. However, when patients with a history of pre-syncope or with palpitation (51 vs. 164 patients) were analysed separately, no significant differences in the recurrence of symptoms or in the arrhythmia recorded were observed.

Among patients with palpitation studied by SFT®, asymptomatic arrhythmias were de novo detected by the auto-trigger function in seven cases (pauses in one case, PSVT in five cases, and NSVT > 5 beats in one case) (*Table 3*), suggestive of possible arrhythmic origin of palpitations/pre-syncope, although the clinical relevance of such asymptomatic arrhythmias remains to be determined.
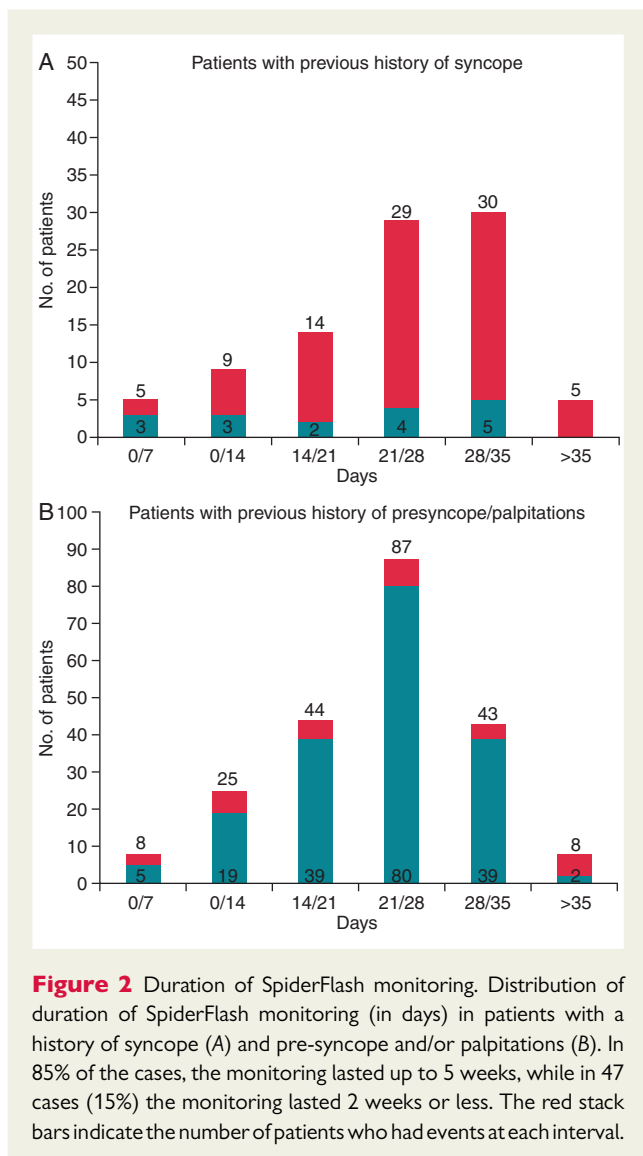
Figure 2 Duration of SpiderFlash monitoring. Distribution of duration of SpiderFlash monitoring (in days) in patients with a history of syncope (*A*) and pre-syncope and/or palpitations (*B*). In 85% of the cases, the monitoring lasted up to 5 weeks, while in 47 cases (15%) the monitoring lasted 2 weeks or less. The red stack bars indicate the number of patients who had events at each interval.

Discussion

In this prospective, single-centre, observational study of patients with a history of syncope and pre-syncope or palpitations remaining of unknown origin despite the recommended routine follow-up, the diagnostic yield of new ELRs with extended backward memory and auto-trigger function was 86% in patients with a history of palpitations or pre-syncope and ~30% in patients with a history of syncope, when considering both symptomatic and asymptomatic significant arrhythmias. The diagnostic yield of the ELR was higher than standard 24 h Holter monitoring, and similar to diagnostic yield of the ILR considering the same timeframe.[7–9]

Patients with syncope

The diagnostic yield for the syncope of ELR monitoring was 17.4%, when compared with standard Holter monitoring, mainly due to a longer monitoring period (median 25 days vs. median 24 h). The diagnostic yield of both SFA® and SFT® was consistently higher than the ELR of the previous generations,[4,13–15] thanks to the extended backward memory period (up to 15 min), which allowed the activation of recording after recovering from syncope, even without auto-trigger activation.

The diagnostic yield for syncope was slightly higher with SFT® than in SFA® (21.1 vs. 14.8%, NS, *Table 3*). It is possible that such difference reflects some changes in the characteristics of patients referred to the registry, thanks to the establishment in 2009 of a Syncope Unit in our Hospital, leading to a stricter implementation of the ECG criteria for possible arrhythmic origin of syncope, following the Guidelines for Management of Syncope.[1]

The recurrence rate for syncope was similar to that recently reported in the PICTURE registry including patients with unexplained syncope studied by ILR (19% at 3 months).[9] Thus, extended ELR and ILR (both with auto-trigger capability) had similar diagnostic yields, when considering the same time interval.

An arrhythmic origin for the syncope was found in 7 of 16 patients (44%), leading to symptomatic treatment with pacemaker in 3 cases with significant pauses, and ablation or change in medication in 4 patients with fast supraventricular arrhythmias (*Table 4*). In the remaining cases, an arrhythmic origin of syncope could be excluded,

Table 3 Diagnostic yield of SpiderFlash-A® and SpiderFlash-T® for syncope and palpitations/pre-syncope

	SpiderFlash-A®	SpiderFlash-T®		Total
Diagnostic yield—syncope	*n* = 54	*n* = 38	*P* value	*n* = 92
Conclusive	8 (14.8%)	8 (21.1%)	NS	16 (17.4%)
Suggestive	1[a] (1.9%)	11 (28.9%)	0.0001	12 (13.0%)
Not conclusive	45[b] (83.3%)	19 (50.0%)	–	64 (69.6%)
Diagnostic yield—palpitations/pre-syncope	*n* = 137	*n* = 78		*n* = 215
Conclusive	120 (87.6%)	64 (82.0%)	NS	184 (85.6%)
Suggestive	0	7 (9.0%)	0.0004	7 (3.2%)
Not conclusive	17 (12.4%)	7 (9.0%)	–	24 (11.2%)

[a]Recording activated by the patient due to palpitations.
[b]Including one patient, who did not activate the recording at the time of syncope.

Table 4 Conclusive diagnosis of syncope—ECG findings during syncope (16 patients)

	Age	Gender	Recorder	Clinical history	ECG findings	Outcome	Recording duration
1	76	Male	SFA®	HTN LBBB	Pauses (max 90 s)	Pacemaker	7
2	69	Female	SFT®	CAF	Pauses (max 60 s)	Pacemaker	5
3	84	Female	SFT®	HTN	Pauses (max 7.6 s) PAF	Pacemaker	23
4	76	Male	SFT®	HTN	PAF Bradycardia (28 b.p.m.) NSVT	Modified pharmacological therapy	25
5	28	Male	SFA®	PAF RF-TCA	Fast PAF	Modified pharmacological therapy	30
6	43	Female	SFA®	NCHD	Fast PSVT	RF-TCA	30
7	62	Female	SFA®	HTN RBBB	Fast PSVT	Modified pharmacological therapy	11
8	26	Female	SFT®	None	ST (160 b.p.m.)	Psychiatric	13
9	35	Male	SFT®	None	ST (130 b.p.m.)	Neurological epilepsy	20
10	83	Female	SFA®	HTN	NSR	Non-arrhythmic	6
11	82	Male	SFA®	HTN LBBB	NSR	Non-arrhythmic	33
12	29	Female	SFA®	None	NSR	Non-arrhythmic	25
13	71	Female	SFA®	HTN	NSR	Non-arrhythmic	35
14	76	Male	SFT®	HTN NCHD	NSR	Non-arrhythmic	12
15	80	Female	SFT®	HTN	NSR	Non-arrhythmic	31
16	81	Female	SFT®	HTN NCHD	NSR	Non-arrhythmic	21

b.p.m., beats per minute; CHD, coronary heart disease; HTN, arterial hypertension; ILR, implantable loop recorder; LBBB, left bundle branch block; NCHD, non-coronary heart disease; NSR, normal sinus rhythm; NSVT, non-sustained ventricular tachycardia; PAF, paroxysmal atrial fibrillation; PSVT, paroxysmal supraventricular tachycardia; RBBB, right bundle branch block; RF-TCA, radiofrequency trans-catheter ablation; ST, sinus tachycardia.
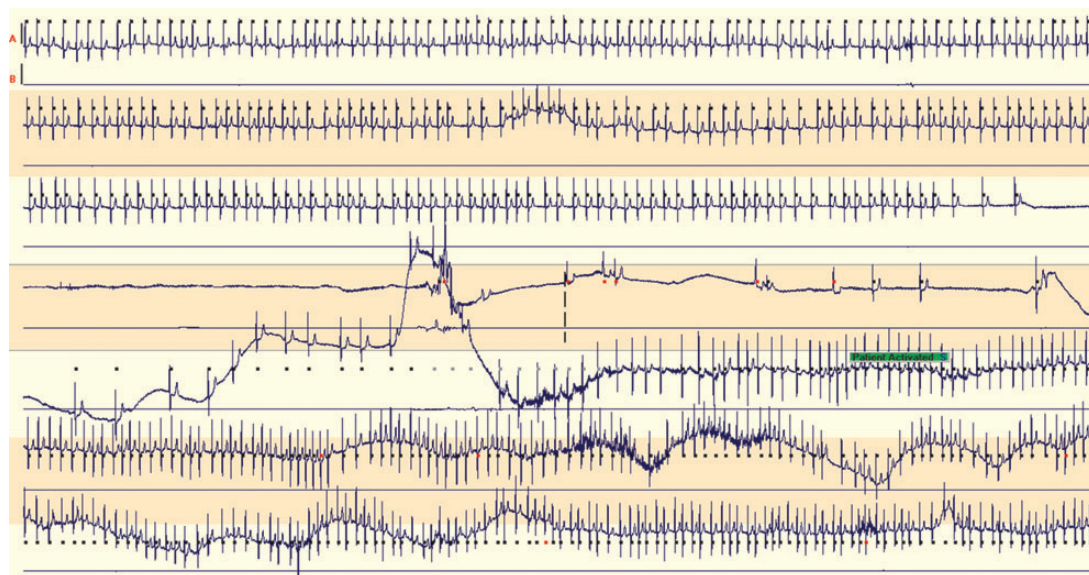

Figure 3 Auto-trigger activation due to pauses during syncope. Auto-trigger activation due to pauses by SFT® during traumatic syncope (occurring at Day 5 of monitoring), with recording of 60 s asystole during atrial fibrillation in a female patient, age 70 years, with a history of hypertension and chronic atrial fibrillation LBBB and previous traumatic syncope. Full disclosure of the event (30 s by line). The patient had a pacemaker implant (January 2011) and had been asymptomatic so far.

Table 5 Suggestive diagnosis of syncope—asymptomatic ECG findings (12 patients)

	Age	Gender	Recorder	Clinical history	ECG findings	Outcome	Recording duration
1	86	Female	SFT®	HTN CAF	Pauses (max 3.4 s) Bradycardia (22 b.p.m.)	Pacemaker	21
2	48	Male	SFT®	None	Pauses (max 3.2 s)	Clinical follow-up, ILR	18
3	13	Male	SFT®	None	Pauses (max 2.8 s) Bradycardia (27 b.p.m.) AVB grade II Mobitz 1	Clinical follow-up, ILR	22
4	83	Male	SFT®	HTN CHD	Pauses (max 2.8 s) NSVT	Pacemaker	25
5	77	Male	SFT®	HTN	Pauses (max 2.5 s) AVB grade II 2 : 1	Pacemaker	15
6	65	Male	SFA®a	CHD PAF LBBB	Pauses (max 2 s) AVB grade II Mobitz 2 PAF	Pacemaker	9
7	78	Male	SFT®	HTN CHD	Pauses (max 2.5 s) AVB grade II Mobitz 2 PAF	Modified pharmacological therapy	22
8	73	Male	SFT®	HTN	PAF (4 h) NSVT (12 beats)	Modified pharmacological therapy	18
9	71	Female	SFT®	HTN	PAF (4 h)	RF-TCA	21
10	54	Female	SFT®	None	PAF (4 h)	Modified pharmacological therapy	22
11	79	Female	SFT®	HTN PAF	PAF (12 h)	Modified pharmacological therapy	26
12	73	Male	SFT®	HTN	Fast PSVT	Modified pharmacological therapy	23

AVB, atrioventricular block; b.p.m., beats per minute; CHD, coronary heart disease; HTN, arterial hypertension; ILR, implantable loop recorder; LBBB, left bundle branch block; NCHD, non-coronary heart disease; NSR, normal sinus rhythm; NSVT, non-sustained ventricular tachycardia; PAF, paroxysmal atrial fibrillation; PSVT, paroxysmal supraventricular tachycardia; RBBB, right bundle branch block; RF-TCA, radiofrequency trans-catheter ablation; ST, sinus tachycardia.
aManual recording activated during palpitations.

and the patients were addressed to further non-cardiological investigations.

As shown in Table 5, asymptomatic suggestive arrhythmias (pauses, bradycardia, AVB, and sustained PAF/PSVT/NSVT) were de novo detected by SFT® in 11 out of 38 of the patients (28.9%). Asymptomatic arrhythmias were not taken as equivalent of syncope recurrence, even if they were an important finding in diagnostic workflow, leading to major medical treatment (pacemaker implant or RF ablation) or to ILR implant for further ECG monitoring.

When considering altogether the conclusive and the suggestive cases, the diagnostic yield for the syncope of ELR with extended backward memory and auto-trigger capability was comparable with ILRs, even if considering the shorter monitoring period.

Patients with palpitations or pre-syncope

In most patients, palpitations or pre-syncope recurred during monthly monitoring time. The recurrence rate of palpitations or pre-syncope was much higher than the recurrence rate of syncope (86 vs. 17%, $P < 0.0001$). When considering both symptomatic and asymptomatic arrhythmias, the diagnostic yield was ~90% when compared with standard Holter monitoring. Such a result was higher than the 66–75% diagnostic yield for palpitations reported in previous generation of ELRs, with shorter recording periods, lower memory capacities, and without auto-trigger capability.[4,13–15]

Most ECG recordings during symptoms were of good quality and generally onset and offset of arrhythmias were recorded. SpiderFlash-T® (SFT®) recorders were more likely than SpiderFlash-A® (SFA®) to detect bradycardia and pauses, brief PSVT, and NSVT, suggesting that ELR with auto-trigger capability had a superior capability of capturing transient rhythm disturbances (Table 6).

Following such findings, the extended ELR with auto-trigger capabilities should become the first-choice tool in the diagnostic flowchart of palpitations and pre-syncope. Only those patients whose palpitations were still unexplained after 1 month monitoring should undergo further investigation with more invasive and more expensive ILRs.

Recording of asymptomatic arrhythmias

The main clinical objective of ELR monitoring was to correlate the symptoms and the arrhythmias. However, both significant asymptomatic arrhythmias were de novo detected by the auto-trigger function in patients with syncope and palpitations and pre-syncope. De novo detection of asymptomatic arrhythmias should never be taken as equivalent of the symptoms.[1,5,6] The possibility to detect asymptomatic arrhythmias open new clinical applications in the non-invasive long-term evaluation of arrhythmic burden both of tachyarrhythmias and bradyarrhythmias.[20–22]

Table 6 ECG findings recorded in patients with a history of pre-syncope or palpitations

ECG findings	SFA® (N = 120)	SFT®ᵃ (N = 71)	Total (N = 191)
Sinus rhythm or sinus tachycardia (>100 b.p.m.)	31.7%	4.2%	21.5%
Frequent supraventricular or ventricular premature beats	27.5%	18.3%	24.1%
Brief paroxysmal supraventricular tachycardia (<60 s)	16.7%	38.0%	24.6%
Sustained paroxysmal supraventricular tachycardia (>60 s)	9.2%	4.2%	7.3%
Paroxysmal atrial fibrillation (>60 s)	8.3%	4.2%	6.8%
Unsustained ventricular tachycardia (>5 beats)	3.3%	16.9%	8.4%
Pauses <3 s, bradycardia (<40 b.p.m.), or second/third AVB	0.8%	12.7%	5.2%
Pauses >3 s	2.5%	1.5%	2.1%

b.p.m., beats per minute.
ᵃIn seven cases, the arrhythmic events were asymptomatic.

Early use of external loop recorder after an event

Several studies have reported that syncope and palpitations tend to occur in clusters, with higher recurrence in the early phase after the first event, and the early initiation of the diagnostic work-up may increase the likelihood of recording recurrent episodes.[1,8,12] However, the early use of ILR is difficult to implement in real clinical practice, due to the high cost and minimally invasive implanting procedures.[11,12] Non-invasive and easy-to-use ELRs can be more simply provided to patients even in the early phase of the diagnostic workup.[4,5,13,23,24] To test this hypothesis, since 2011, an international prospective study (SYNARR, Monitoring of SYNcopes and/or sustained palpitations of suspected ARRhythmic origin with External Loop-Recorder SpiderFLASH) was initiated with the aim to evaluate the diagnostic yield of SpiderFlash-T enroling 372 patients from 10 centres from 5 European countries.

Future technological advances

New generation ELRs, with extended recording memory, auto-trigger capability, and high-quality ECG tracings represent a major step towards the gold standard possibility to record and analyse full-disclosure very long-term continuous ECG tracings, allowing not only a precise correlation between the symptoms and the arrhythmias, but also a quantitative evaluation of the arrhythmic burden, both for symptomatic and asymptomatic arrhythmias. This will be possible thanks to high-power long-lasting batteries and due to larger and low-consuming storage circuits and to remote or cloud storage systems.
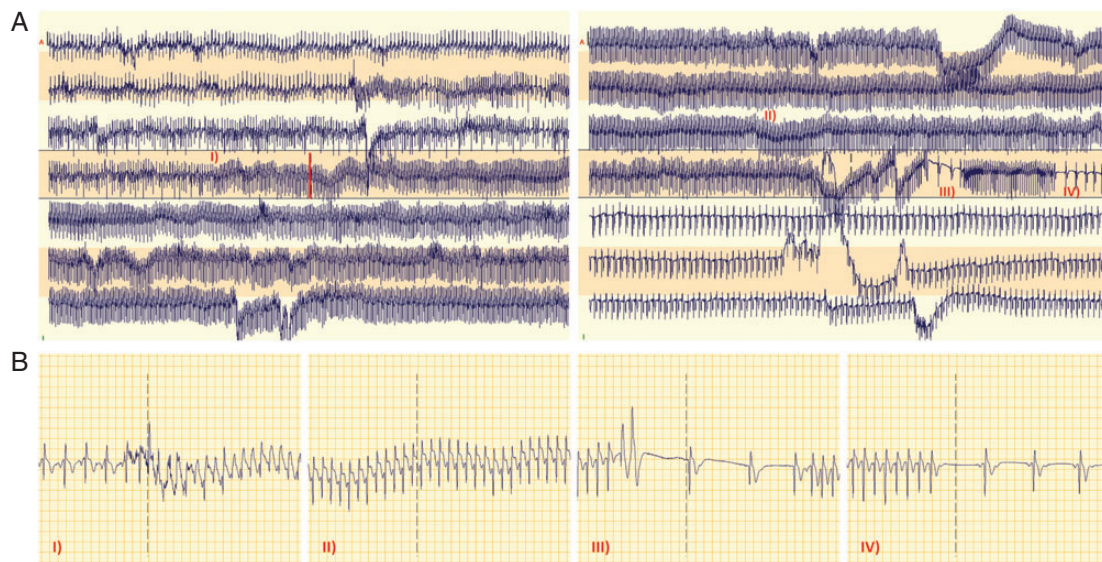

Figure 4 Manual activation during palpitations with recording of PSVT. Manual activation by SFA® during palpitations, with recording of PSVT in a female patient, age 16 years, with a history of palpitations and chest pain (no structural heart disease). Paroxysmal supraventricular tachycardia occurred at Day 16 of monitoring, total duration of the episode 20 min, maximum HR 240 b.p.m., ST elevation during episode (associated with chest pain). (A) Full disclosure of the event (30 s by line), the red bar marks the manual activation of recording. (B) Close-up tracings (paper speed 25 mm/s): (I) onset of PSVT, (II) PSVT with ST elevation at HR 240 b.p.m., (III) first termination of PSVT by a ventricular couplet, followed by two sinus beats and 5 s relapse to PSVT, (IV) definitive recovery of sinus rhythm. After recording of PSVT, the patient underwent a successful RF ablation (June 2006) and has been asymptomatic so far.

Future technological advances need to overcome the main limitation of the current ELR, still relying on lead wires and adhesive electrodes, which assure a standard ECG quality but are poorly tolerated and self-limit the recording duration to 3 or 4 weeks. Possible solutions, which have already been suggested, are belt or patch electrodes or vest or wireless non-contact ECG electrodes.[25]

Conclusions

In patients with a history of syncope and pre-syncope or palpitations remaining of unknown origin despite recommended routine follow-up, the diagnostic yield of new ELRs with extended backward memory and auto-trigger function was 86% in patients with a history of palpitations or pre-syncope and ∼30% in patients with a history of syncope, when considering both symptomatic and asymptomatic significant arrhythmias. In those patients candidate to long-term ECG monitoring, these results suggest that ELR rather than standard Holter monitoring or ILR should be used in the early diagnostic workflow.[26–28] The use of ELR, sharing the favourable characteristics of standard Holter monitoring (non-invasive, inexpensive, easy-to-use in all age groups, reusable, and providing high-quality ECG tracings), could be viewed as a first-choice tool to filter patients with early recurrence of syncope or palpitations. In a step-wise approach, the more expensive and minimally invasive ILR could be reserved for those cases where a clinical diagnosis could not be obtained after 1-month ELR monitoring.

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