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Patient-reported feasibility of chest and thumb ECG after cryptogenic stroke in Sweden: an observational study

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ABSTRACT

Objectives The aim of this study was to assess the feasibility, based on a questionnaire, of the chest and thumb ECG system Coala Heart Monitor in patients who recently had a stroke.

Design Observational study.

Setting Two stroke units, Region Gävleborg, Sweden.

Participants and interventions This study, Transient ECG Assessment in Stroke Evaluation (TEASE), included patients who had a stroke between 2017 and 2019. Patients eligible for anticoagulation in the presence of atrial fibrillation were scheduled for 28 days monitoring.

Primary and secondary outcome measures The questionnaire regarding feasibility of monitoring included seven questions, using a 100 mm Visual Analogue Scale which covered overall satisfaction, technical feasibility, remember to monitor, physical application, feeling of security, help from others and recommendation to others. A lower score indicated better outcome.

Results The prespecified number of 100 patients underwent the monitoring and 83 out of the 97 alive patients returned the questionnaire (response rate 85.6%). The median age was 69.5 years, mean CHA_2DS_2-VASc score was 4.4±1.3 points and 59.0% were men (n=49). The median time from index stroke to start of monitoring was 7.0 days. Patients performed on average 90.1%±15.0% of scheduled ECG-transmissions. In all seven questions, the median score ranged from 4 to 8. The vast majority reported acceptable outcomes, that is, the 95th percentile ranged from 30 to 54. There was no significant difference between men and women with regard to any of the seven questions (p values ranging from 0.117 to 0.849). Two of the seven outcome scores correlated significantly to patient age (Spearman's r=−0.238 and r=−0.308, and p values 0.031 and 0.005 for 'overall satisfaction' and 'remember to monitor', respectively).

Conclusion In stroke survivors, chest and thumb ECG two times per day over a period of 4 weeks is feasible from a patient's perspective. The Coala Heart Monitor provides a valuable and convenient tool for monitoring after stroke.

Trial registration number NCT03301662.

Strengths and limitations of this study

- This study included solely patients who had an ischaemic stroke and not transient ischemic attack (TIA).
- This study assesses patients' own stated experience of using the chest and thumb ECG after stroke.
- The questionnaire covered different aspects of feasibility of the Coala Heart Monitor.
- The response rate of the questionnaire was 85.6%.
- These findings cannot be generalised to patients who had a severely disabling stroke.

INTRODUCTION

Atrial fibrillation (AF) is the most common arrhythmia, which will affect a quarter of the general population over the course of their lifetime.[1] The same proportion, a quarter, will suffer from a stroke of any cause.[2] In fact, the risk of ischaemic stroke quadruples in patients with AF and AF is implicated in about a quarter of all stroke cases which are typically more disabling types of stroke.[3–5] Fortunately, three quarters of all strokes can be prevented provided adequate anticoagulation.[6 7] A non-vitamin K antagonist oral anticoagulant (NOAC) is often indicated and offer improved efficacy, better safety and fewer interactions compared with warfarin.[7] Importantly, in a quarter of patients who had an ischaemic stroke, the cause of stroke is cryptogenic, meaning that no attributable cause can be discerned.[4 8 9] Episodes of AF are often silent, thus not recognised or reported by the patient, but are nevertheless associated with the same risk of embolisation.[10–12] Silent episodes, approximately one-third of all AF, are especially common among the elderly. As a consequence, this warrants increased attention and resources to better diagnose AF.

Stroke survivors should be a prioritised group for extended AF detection because of the risk of recurrence.[13] This approach is endorsed by guidelines, but the monitoring tool, timing and duration remains to be established.[14 15] Technological advancements, often connected with smartphones, have emerged as options beyond conventional 12-lead ECG and Holter monitoring.[16]

Insertable cardiac monitors in cryptogenic stroke provide long-term continuous

monitoring, but this invasive strategy is seldom used in routine care because it requires considerable resources and involves high upfront costs, although insertable monitors have been deemed cost effective.[17 18] Alternative strategies include monitoring using continuous ECG in the hospital ward, repeated ECGs, Holter monitoring, external event or loop recorders, long-term monitoring using patches and handheld devices.

In the Transient ECG Assessment in Stroke Evaluation (TEASE) study[19] it was decided to use the Coala Heart Monitor. This newly developed device with proven detection algorithms, similar to Zenicor, uses a smartphone application and seems to be a promising alternative, but feasibility remains to be studied.[20] In the prospective observational TEASE trial, we evaluated the patient-reported feasibility of the device system. The aim of this paper is to describe the feasibility, based on a questionnaire, of the Coala Heart Monitor in patients who recently had a stroke.

METHODS

Setting and selection

Patients with a clinically confirmed diagnosis of ischaemic stroke were recruited consecutively from the stroke units in Gävle and Hudiksvall in Sweden between October 2017 and October 2019. The predefined number of participants was 100 who underwent the monitoring per protocol.

Inclusion and exclusion

Adult patients with an uneqivocal diagnosis of ischaemic cryptogenic stroke were eligible for the study. Patients who had a transient ischemic attack (TIA) were not included, because this diagnosis is often uncertain due to being based solely on patient history.

Patients must be indicated for NOAC in the presence of newly detected AF. A history of atrial arrhythmia or the presence of an implantable cardiac device were exclusion criteria as were indications for permanent anticoagulation for reasons other than AF, that is, venous thrombosis and mechanical heart valve.

Stroke definition and evaluation

Cryptogenic stroke is defined as cerebral ischaemia of unknown aetiology, that is, not attributable to a source of cardiac embolism, large artery atherosclerosis or small artery disease despite a standard vascular, cardiac and serologic evaluation. Patients were evaluated with a carefully taken patient history, physical examination, routine laboratory tests and standard evaluation using 12-lead ECG, 24-hour Holter, carotid Doppler ultrasonography and/or computed tomography (CT) angiography, CT and, when applicable, magnetic resonance imaging, echocardiography or transesophageal echocardiography, as well as extended coagulation tests.

Chest and thumb ECG

Each patient was scheduled to use the Coala Life Monitor for 28 consecutive days.

Patients were requested to apply the chest and thumb ECG monitor device two times per day, around 08:00 with an interval of 2 hours before and after, that is, at 06:00–10:00 and again at 18:00–22:00. Patients were asked to use the chest and thumb ECG monitor device two times per day, at 06:00 and 22:00. Monitoring was planned to begin as soon as possible after the stroke diagnosis. Each recording was stored in a web-based application accessible to the investigators.

The Coala Heart Monitor

The Coala Heart Monitor is a handheld two-lead ECG recording device with a high sampling rate that in addition to thumb ECGs can also provide chest ECGs, which could allow for better discrimination of arrhythmias by more discernible atrial signals. The interpretation is based on pattern recognition algorithms, including AF detection based on RR dispersion and atrial signals. The device is connected wirelessly via Bluetooth connectivity to a smartphone. The user can view the interpretation on the smartphone and store PDFs of the tracings. The tracings are stored in the portal accessible to the healthcare provider. Messages to the patient can also be viewed directly on the app. There is also a feature that allows users to add a special heart report service to their smartphone to discuss their ECG recordings with trained nurses, but in our study, we did not use this option. These features allow a single centralised and highly specialised healthcare function to provide first-line primary cardiac healthcare coverage for a large and geographically spread-out population, which can be very advantageous in for a post-stroke population.

The questionnaire

The questionnaire regarding feasibility of monitoring consists of seven questions with the same structure, all

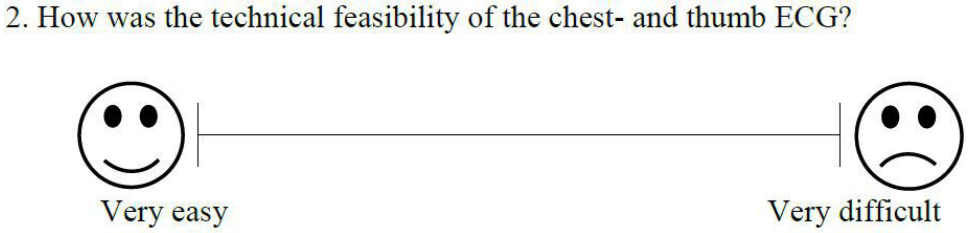

Figure 1 Example of question.

using a 100 mm Visual Analogue Scale (VAS) with words and pictures at each end (see figure 1 and online supplemental file). A lower score indicates better outcome. The questions are as follows:

1. Overall, what do you think about using the chest and thumb ECG? (Very satisfied, very dissatisfied)
2. How was the technical feasibility of the chest and thumb ECG? (Very easy, very difficult)
3. Did you remember to use the chest and thumb ECG as scheduled? (Always, never)
4. How was it physically to apply the chest and thumb ECG? (Very easy, very difficult)
5. Did the ECG monitoring affect your feeling of security? (Much more secure, much less secure)
6. Did you need help from others to perform the ECG monitoring? (Never needed help, always needed help)
7. Would you recommend other stroke patients use the chest and thumb ECG monitoring? (Strongly, not at all)

The following stroke symptoms were listed and the patient was asked to select a one-word descriptor (severe, moderate, mild, none) for each:

- Slurred speech.
- Impaired language comprehension.
- Arm weakness.
- Leg weakness.
- Impaired sensation.
- Memory problem.
- Fatigue.

Statistics

Numeric data are reported as frequencies, percentages, IQRs, percentiles and means, including SD. Differences in VAS results between subgroups were performed using the Mann-Whitney U test. Correlations between continuous variables were assessed using Spearman's coefficients. Categorical variables were examined using Fisher's exact test. A two-sided p value of <0.05 was was defined as statistical significance. The data were first recorded in Excel 2010 (Microsoft Corporation) and subsequently, imported into SPSS V.25 (IBM).

Patient and public involvement

No patient involved.

RESULTS

A total of 83 questionnaires were returned and analysed. The age of the participants ranged from 27.6 to 86.4 years, with a median age of 69.5 years (IQR: 62.9–75.0) and the mean age was 67.6±11.1 years. The majority was man (n=49; 59.0%). The mean age was similar between men and women (66.7±9.9 vs 68.8±12.7 years; p=0.396).

The median time from index stroke to start of monitoring was 7.0 days (IQR 3.0–13.0 days). Patients performed on average 90.1%±15.0% of scheduled transmissions.

Table 1 Patient characteristics at baseline

	All (%)
Patients	83 (100)
Mean age (years)	67.6±11.1
Median time from index stroke to inclusion (days)	7.0 (IQR 3.0–13.0)
Congestive heart failure	1 (1.2)
Hypertension	64 (77.1)
Age ≥75 years	20 (24.1)
Diabetes mellitus	13 (15.7)
Stroke	83 (100.0)
Vascular disease	14 (16.9)
Age 65–74 years	32 (38.6)
Sex category (female)	34 (41.0)
CHA_2DS_2-VASc score	
Mean total score	4.4±1.3
0 point	0 (0.0)
1 point	0 (0.0)
2 points	5 (6.0)
3 points	19 (22.9)
4 points	19 (22.9)
5 points	24 (28.9)
6 points	12 (14.5)
7 points	4 (4.8)
8 points	0 (0.0)
9 points	0 (0.0)

Data presented as frequencies (percentage in parenthesis)

At baseline, the mean CHA_2DS_2-VASc score was 4.4±1.3 points. Since stroke was an inclusion criterion, all patients had at least 2 points per se and no patient had 8 or 9 points. The characteristics of the cohort at baseline are summarised in table 1. As part of the questionnaire, patients scored remaining stroke symptoms, which is reported in table 2. The distribution of score is summarised in table 3.

Analysis of non-response

Among the 111 patients who consented to participate, 11 dropped out because of cognitive and/or physical impairment, which made them unable to handle the technology or they did not wish to participate. Among the 100 participants who completed the chest and thumb ECG monitoring, none died during the ECG monitoring period, but three patients died before the time of the survey. Among the eligible patients, the reasons for not taking the survey were cognitive/physical impairment in nine patients and unknown in five patients, who were unavailable despite two written reminders and follow-up by phone. Thus, the response rate was 85.6% (83 out of 97 alive patients).

Table 2 Self-reported stroke symptoms at the time of survey

Stroke symptoms	Severe	Moderate	Mild	None
Slurred speech	1 (1.3)	5 (6.5)	13 (16.9)	59 (76.6)
Impaired language comprehension	1 (1.3)	6 (7.8)	7 (9.1)	64 (83.1)
Arm weakness	9 (11.7)	9 (11.7)	13 (16.9)	47 (61.0)
Leg weakness	5 (6.5)	13 (16.9)	11 (14.3)	49 (63.6)
Impaired sensation	1 (1.3)	10 (13.0)	10 (13.0)	57 (74.0)
Memory problems	2 (2.6)	12 (15.6)	30 (39.0)	34 (44.2)
Fatigue	12 (15.6)	26 (33.8)	24 (31.2)	16 (20.8)

Data presented as frequencies (percentage in parenthesis). Out of 83 returned surveys, 5 had missing data with regard to stroke symptoms; thus 77 patients reported symptoms.

Outcome

Overall, patients reported very favourable experiences with Coala Heart Monitor. In all seven questions, the distribution was heavily skewed to the right (figure 2). The median score ranged from 4 to 8. The vast majority reported acceptable outcomes, that is, the 95th percentile ranged from 30 to 54.

There was no significant difference using Mann-Whitney U test between men and women with regard to any of the seven questions (p values ranging from 0.117 to 0.849).

Correlations

Two of the seven outcome scores correlated significantly to patient age (Spearman's r=−0.238 and r=−0.308, and p values 0.031 and 0.005 for 'Overall satisfaction' and 'Remember to monitor', respectively). The other five outcome score did not correlate significantly to patient age (Spearman's r ranging between −0.073 and −0.147, all p values ≥0.185).

DISCUSSION

Among patients who underwent chest and thumb ECG evaluation after stroke, the Coala Life Monitor demonstrated excellent feasibility over the 1 month period of two times per day monitoring.

All seven domains of patient experience that were evaluated by the questionnaire consistently showed a highly advantageous profile. These beneficial findings were seen despite advanced age and included both sexes. Obviously, patients who had a recent stroke are highly motivated to undergo extended evaluation. Nevertheless, the Coala Life Monitor is successful in providing a feasible tool for stroke survivors.

There is very limited self-reported feasibility information from other studies with handheld devices.

Handheld ECG after stroke

In another Swedish study of patients who had a stroke/TIA, using the Zenicor device 116 patients were enrolled but exclusion rates were high: 10 had cognitive impairment, 8

Table 3 Self-reported feasibility of the Coala Life Monitor after stroke

Question	Min	Max	5%	25%	50%	75%	95%	Mean (SD)
1.Overall, what do you think about using the chest and thumb ECG? (Very satisfied, very dissatisfied)	0	54	0	3	7	19	44	12.2 (13.2)
2.How was the technical feasibility of the chest and thumb ECG? (Very easy, very difficult)	0	80	0	3	8	10	54	14.1 (16.8)
3.Did you remember to use the chest and thumb ECG as scheduled? (Always, never)	0	65	0	3	7	22	53	14.3 (16.8)
4.How was it physically to apply the chest and thumb ECG? (Very easy, very difficult)	0	53	0	2	5	11	47	9.5 (12.3)
5.Did the ECG monitoring affect your feeling of security? (Much more secure, much less secure)	0	52	0	2	7	20	48	13.0 (15.0)
6.Did you need help from others to perform the ECG monitoring? (Never needed help, always needed help)	0	62	0	2	4	12	48	10.9 (14.9)
7.Would you recommend other stroke patients use the chest and thumb ECG monitoring? (Strongly, not at all)	0	55	0	2	4	7	30	6.9 (9.6)

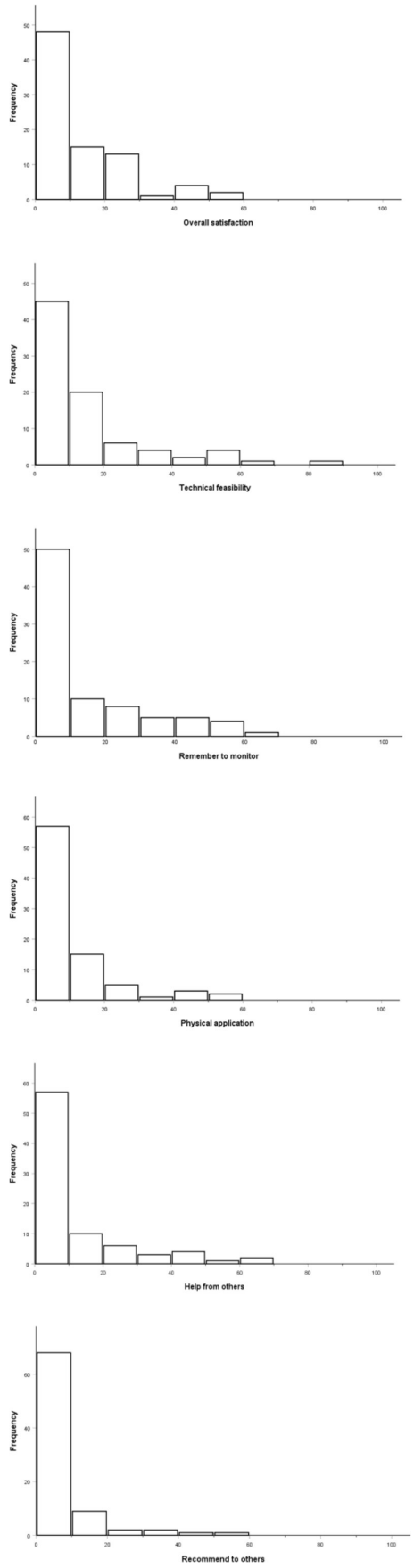

Figure 2 Histogram of frequency and outcome of patient reporting on a 100 mm scale. A higher score indicates worse outcome.

were unwilling to participate and 7 were unable to handle the device.[21]

In a Danish study using the Zenicor device, it was reported that 21.0% (314/1498) of patients were not eligible due to cognitive or physical impairment.[22]

In the largest study (n=284) of stroke patients using a dry-electrode belt around the chest (Cardiac Bio-Systems) and an event recorder (Er910AF Cardiac Event Monitor, Braemar), 82.0% completed the monitoring.[23]

In a retrospective analysis of handheld ECG devices with a smartphone app (Zenicor) in a Swedish setting of routine care, 116 patients were eligible for 3 weeks of screening after stroke/TIA. In this pragmatic trial, five patients were non-compliant due to misunderstanding, five were unable to complete the screening due to technical problems and three for other causes.[24]

A retrospective analysis of Zion-patch applications in patients who had a stroke/TIA showed high compliance (98.7%) during a median wearing time of 13.0 days.[25]

Handheld ECG in screening

The thumb ECG has been used in screening programmes in several settings.[16]

In the StrokeStop I study, a total of 80 149 tracings were recorded using the Zenicor thumb ECG system; tracings were obtained from 3209 patients aged 75 or 76 years.[26]

In the REHEARSE-AF study, an AliveCor Kardia monitor attached to a WiFi-enabled iPod was used in 500 elderly patients (72.6±5.4 years) with a mean CHA_2DS_2-VASc score 3.0; only 6.5% had a prior stroke/TIA.[27] The study duration was 52 weeks. As part of the study, a survey with a 5-point Likert scale was used. The vast majority were 'not at all' or only 'slightly' anxious about using the device: patients reported that they were 'not at all' restricted by the device; and the respondents said generally they were 'extremely satisfied' or 'very satisfied' with the use of the device.

A population-based study of 65 year olds with a CHA_2DS_2-VASc score ≥2 using the Zenicor device for 14 days screened 1601 subjects for participation, of whom 91 declined participation or failed to respond.[28]

Single-point studies

In another study using a point-of-care screening for 60 s (n=772; mean age 65.2±15.4; CHA_2DS_2-VASc≥2 in 75.7%) using the same device, the AliveCor Kardia monitor, the authors concluded that the screening provided collateral benefit in the form of patient and caregiver education. Participants were quite satisfied with the screening, and 90.6% agreed with the statement that they learnt more about AF.[29] Another single-point study shows feasibility in a national screening programme in Belgium.[30]

Miscellaneous monitoring systems

Activity monitors, for example, smartwatches, often record heart rate by photoplethysmography and are promising for AF detection when supplemented with sophisticated learning algorithms, but they still do

not produce diagnostic ECGs and if abnormalities are detected, further confirmation with an ECG is required. These consumer-oriented products need validation; nevertheless, it is hoped that they may promote and spur innovation in accurately detecting AF and handling large amounts of data with automatic interpretation or at least efficient sorting functions. In a large-scale study, a smartwatch-based (Apple Watch) irregular pulse notification algorithm identified possible AF; this was followed by a telemedicine visit and an ECG patch was mailed to the participant. This patch had to be worn for up to 7 days; 34% of rhythms were classified as AF and 84% were concordant with AF. Because the guidelines mandate ECG for the diagnosis of AF, handheld devices offer the advantage of providing a verifiable ECG tracing. Thus, it is a preferred screening tool. Smartwatches capable of producing ECGs have been developed, but need further validation before they can be used in healthcare settings. Handheld devices are more accurate than pulse palpation; the sensitivity is 94%–99% and the specificity 92%–97%.[31 32] The role of handheld devices as part of AF detection, both in primary and secondary prevention, is likely to increase in importance.[16]

Limitations

Even though this study demonstrates the feasibility of the Coala Life Monitor for use among patients who recently had a stroke, there are other options for monitoring AF that may be better suited to certain individual cases. Patients who participate in a study like this constitute a selection and are likely to represent patients with less disability. Indeed, the monitoring device requires some cognitive skills and physical abilities or support from others, which is why a personalised approach is warranted. In an ideal general setting of patients who had a stroke, several methods for AF monitoring should be available. A patch may be the preferred choice in some cases, and, in some cases of high suspicion of an embolic source, an insertable cardiac monitor may be the best choice. Moreover, different healthcare systems may have different prerequisites for adopting a specific method based on organisational and economical constraints. The implementation of digital applications may require educational efforts among healthcare personnel and restructure of working-flow. Nevertheless, the Coala Life Monitor has proven feasibility among stroke survivors and should be considered part of routine management.

Current position of poststroke monitoring

According to the 2013 and 2014 America Heart Association/American Stroke Association guidelines, ECG monitoring is recommended for 24 hours after cryptogenic stroke and prolonged rhythm monitoring for the next 30 days is considered reasonable.[14 15] According to 2016 ESC guidelines, prolonged monitoring for 72 hours for all patients who had a stroke is appropriate and long-term recordings in some patients should be considered.[6]

Future perspectives

Guidelines already allow for prolonged ECG monitoring: 'in patients who had a stroke, additional ECG monitoring by long-term noninvasive or implanted loop recorders should be considered to document silent AF' (class IIa recommendation, level of evidence B). The diagnostic yield based on randomised controlled trial and observational trials is high; the number needed to screen=8–14 and depends on the method and follow-up time.[4 33] Large-scale, pragmatic trials in different settings would be beneficial in order to study subgroups and finally standardise healthcare guidelines. In addition, the spur of technical advancement in ECG monitoring should be welcomed as an integral part of research and development projects.

Patient-led organisations may play an important role to engage policy-makers.[34] Furthermore, close collaborations between different stakeholder are necessary to enhance innovation and implementation to provide structured care in a personalised medical approach in the field of ECG monitoring.

CONCLUSION

In stroke survivors, chest and thumb ECG two times per day over a period of 4 weeks is feasible from a patient's perspective. The Coala Heart Monitor provides a valuable and convenient tool for monitoring after stroke.

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Competing interests The project received free product from Coala Life. Outside this project: PM has received speaker fees or grants from Abbott, Alnylam, Bayer, AstraZeneca, Boehringer-Ingelheim, Internetmedicin, Lilly, MSD, Novo Nordisk, Octopus Medical, Orion Pharma, Pfizer, Vifor Pharma and Zoll. AL has received speaker fees from Pfizer. GM has received speakers fee from Alnylam, MSD and Internetmedicin.

Patient consent for publication Not required.

Ethics approval The Regional Ethical Committee in Uppsala approved the study on 20 September 2017 (protocol number 2017/321). Patients consented to participation after oral and written information by any of the investigators.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. No additional data sharing available.

terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

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