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Comparison of arrhythmia detection by conventional Holter and a novel ambulatory ECG system using patch and Android App, over 24 h period

Chakkalakkal Prabhakaran Karunadas, Cibu Mathew*

Department of Cardiology, Government Medical College, Thrissur, Kerala, 680596, India

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ABSTRACT

Background: Ambulatory electrocardiogram (AECG) is done for evaluation of arrhythmia. Commonly used AECG system is 24 h Holter. Patch based second generation AECG monitoring devices, which can record for longer periods, are now available.

Objective: Android App based WebCardio using WiPatch is a new AECG system which records ECG in two leads for 72 h. Our study compared the arrhythmia detection by WebCardio and conventional Holter by simultaneously connecting both for 24 h in patients having indication for AECG.

Methods: The AECG of patients who had simultaneous recording with WebCardio and conventional Holter, in the department of Cardiology, Medical College, Thrissur were evaluated. Ability to detect any of the 6 arrhythmias: 1) atrial fibrillation (AF), 2) atrioventricular (AV) block, 3) sinus pause of ≥ 3 s (SP), 4) supraventricular tachycardia (SVT), 5) premature ventricular complex (PVC) and 6) ventricular tachycardia (VT)/ventricular fibrillation (VF) was compared. Detection of each arrhythmia was also compared. **Results:** 141 patients had simultaneous recordings by both systems of AECG. The WebCardio picked up at least one of the 6 arrhythmias; AF, AV block, SP, SVT, PVC or VT/VF in 98 cases compared to 88 in the Holter (McNemars test, two tail $P = 0.006$). In eleven cases WebCardio detected an arrhythmia where Holter could not. In one case Holter identified an arrhythmia and WebCardio could not. Individual arrhythmias; AF, SP, SVT and VT/VF were detected equally by both systems. AV block (23 Vs 18, $p = 0.0625$) and PVCs (83 Vs 74, $p = 0.0636$) were detected in more number of cases in WebCardio. In the five cases where WebCardio alone identified AV block, four had poor quality of P wave in the Holter.

Conclusion: Arrhythmia was picked up in more number of patients by the WebCardio compared to Holter. This was due to higher pickup of AV block and PVCs by WebCardio. Difference in AV block identification was due to better quality of P in WebCardio. WebCardio is a good alternative to Holter for AECG.

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1. Background

Ambulatory ECG monitoring (AECG) is used to evaluate the type and burden of arrhythmia. There are different types of AECG devices which can record ambulatory ECG for variable period of time ranging from event recorders to implantable loop recorders [1,2]. Conventional Holter records for 24 h though longer periods of recording can be helpful in many clinical situations. The

conventional Holter is bulky and some patients find it uncomfortable to wear. With advances in technology, miniaturization of devices is happening rapidly. Patches having embedded electrodes with capability to transmit ECG data wirelessly can record AECG for longer periods compared to conventional Holter [1].

Experience with patch based AECG recording is limited as it is a relatively new concept. Some of the devices available for patch based AECG are Zio patch (iRhythm Technologies, Inc), Carnation Ambulatory Monitor (CAM™, Bardy diagnostics) and Vpatch (Vpatch CardioPty Ltd.). In a study conducted by Barrett PM et al., the Zio patch with ability to record for 14 days, detected more arrhythmia events compared with the Holter monitor when the total wear time was considered, though Holter picked up more

* Corresponding author.

E-mail addresses: karunadascp@gmail.com (C.P. Karunadas), lizcibu@rediffmail.com (C. Mathew).

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arrhythmias in the first 24 h [3]. Patients found the patch comfortable to wear with lesser interference in activities of daily living [3].

'WebCardio systems' is a new patch based AECG device marketed by Gadgeon. It consists of LifeSignals Inc's WiPatch, a mobile phone with WebCardio App and WebCardio cloud server where the data is stored and analysed. The WiPatch is a small light weight (less than 18 g), disposable, coin cell operated patch which is to be placed at left upper part of the chest (Fig. 1). After applying to the patient's body, the patch is paired with the mobile phone using WebCardio Patient App (available for download in 'Google play store') installed in the phone. The patch records ECG in two leads and transmits data to the mobile device for upto 72 hours (h). The mobile device is to be kept near the patient within the wireless range of the patch. Since the patch has on-board memory for storing ECG for 4 h, occasional movement by patient out of range of the mobile is not a problem. The received ECG data is stored in the mobile temporarily and transmitted to remote server through internet using cellular network, and is stored there permanently. The data in the patch gets overwritten if the phone is not near the patch for more than 4 h continuously (newer version of the patch, the Life Signal Patch, has on-board memory of 32 h). The periods where the data is overwritten will be identified as 'lead off' and no recording, for the period of overwriting. The AECG is analysed using a proprietary algorithm in the remote centre by a qualified technician and report is generated. The report is sent to the physician or hospital by email. The entire AECG and report can be accessed by the physician online using WebCardio site and data can be analysed, events viewed and report edited (Fig. 2).

Since WebCardio is a new device with limited clinical data there is a need to evaluate the ability to identify arrhythmia. Considering the obvious ease of using a small patch with ability to record AECG for 72 h, if the pickup of arrhythmia and the quality of ECG are good, WebCardio will be a useful clinical tool.

2. Objective

The objective of the study was to compare the arrhythmia detection by two different AECG devices, the novel patch based WebCardio systems and the conventional Holter, by simultaneously connecting both systems in patients having clinical indication for AECG evaluation.

3. Methodology

The study was conducted in the department of cardiology of



Fig. 1. The patch used in WebCardio system.

Government Medical College Hospital, Thrissur, Kerala after approval from institutional ethics committee. Patients who needed AECG monitoring as part of their clinical workup and who consented for simultaneous evaluation with the two AECG systems were included. Critically ill patients, those with implanted devices like permanent pacemaker or implantable cardioverter defibrillator were excluded. The AECG of patients who had simultaneous recording with conventional 24 h Holter and WebCardio system were compared.

For the conventional Holter, we used either a 3 channel or a 12 channel recorder (Hanix- DL- 820/Hanix 820-DL pro). Soft gel adhesive electrodes were placed on the chest using the Mason Likar system after preparation of chest and the leads of the Holter recorder were connected. The recorder was secured to the body using a belt and the wires fixed using adhesive tape to minimise the movement and artefacts. The AECG data for 24 h was analysed using specific software, ECG Lab Holter 12 plus. The connection, transfer of data and early analysis of the AECG was done by the Holter technician. Initial report was generated by the Holter technician and verified by the treating cardiologist for each case. The report, entire AECG and arrhythmic events were evaluated by the two investigating cardiologists for the purpose of comparison of arrhythmia.

All patients had WiPatch applied in the left upper part of chest after skin preparation. The patch was applied immediately after the connection of conventional Holter. The WiPatch was paired with the mobile device having the WebCardio App. Relevant patient details were entered using the WebCardio App in the mobile phone at the start of the procedure. After the initial setup, the quality of ECG signal was ascertained, using the WebCardio setup system. After pairing, WiPatch continuously and wirelessly transmitted ECG signals to the mobile and from there to the remote server till disconnection or up to 72 h. All patients were encouraged to keep the mobile device always with them. The AECG was analysed using proprietary software by a qualified Holter technician in the remote centre and a report was generated. The report was sent through email to the hospital. The investigating cardiologists evaluated the entire AECG, arrhythmic events and the report in all cases after logging in at the WebCardio site.

Both the conventional Holter and the patch were connected for simultaneous recording. After the conventional Holter was connected, immediately the patch was applied and paired with the mobile device. Patients were sent home and they returned to hospital by 24 h for removal of the recording systems. All conventional Holter were for 24 h. Some patients continued to wear the patch for 72 h after removal of Holter as decided clinically for extended recording. In these patients data from the first 24 h of recording was taken for comparison of arrhythmia. Specific instruction was given to patients regarding care of the recording systems. They were not allowed to remove the recording systems by themselves or take bath as both systems of recordings are not water resistant. The wear time was same for both conventional Holter and patch, with differences of minutes possible between two devices while connecting and disconnecting. Neither the patch nor the conventional Holter was removed before completion of the recording period.

The ability to detect at least one of the following six arrhythmias; 1) atrial fibrillation (AF), 2) atrioventricular (AV) block, 3) sinus pause of ≥ 3 s (SP), 4) supraventricular tachycardia (SVT), 5) premature ventricular complex (PVC) and 6) ventricular tachycardia (VT)/ventricular fibrillation (VF), was compared. For reviewing events standard definitions of arrhythmia were used [4]. Apart from the ability to detect any one of the six arrhythmia, detection of individual arrhythmias by the two AECG systems was compared. Data was coded and entered in excel sheet and analysed.

Comparison of the pickup of arrhythmia was done using McNemar's test to assess the significance of the difference between two correlated proportions.

4. Result

141 patients had simultaneous recording of AECG using both conventional Holter and WiPatch based WebCardio system from 13/11/2017 to 22/8/2018. In patients who had 72 h of recording with WebCardio, the first 24 h period having simultaneous recording with Holter was considered for comparison. Age of the patients ranged from 9 years to 77 years with maximum number of patients in the age group of 40–60 (mean age 44.41 years, SD 19.409). Majority were females ($n = 74$, 52.5%). The intended wear time for both recordings was 24 h. Average duration of actual recording was 23.65 h (SD 2.791) for the Holter and 23.71 h (SD 1.98) with WebCardio. There were two cases in WebCardio with loss of data in between, possibly due to the data being overwritten as the mobile device was out of range with the patch, for a period of 1 h 22 min and 3 h 38 min respectively.

Ability to pick up arrhythmia events by WebCardio and Holter was compared. As decided in the study protocol, ability to identify at least one of the 6 arrhythmias; AF, AV block, SP, SVT, PVC or VT/VF was evaluated. The WebCardio picked up arrhythmia in more number of cases than the Holter (98 Vs 88). Eleven cases had arrhythmia picked up by the WebCardio only (Holter could not pick any arrhythmia). In one case, Holter picked up arrhythmia whereas the WebCardio could not pick up any. The difference was statistically significant, McNemars test, two tail $p = 0.006$ (Table 1). A sample of the AECG tracing, PVC picked up by the WebCardio, is given in Fig. 3.

Ability to pickup individual arrhythmias by the two systems was compared. AF, sinus pause of ≥ 3 s or VT/VF were detected by both systems equally and they were identified in the same patients. AF

was seen in 3 patients, SP in 1 patient and VT/VF in 7 patients. SVT was detected in equal number of recordings by both systems (19 each) but only 17 were in the same patients. Holter detected SVT in 2 cases where WebCardio could not and WebCardio identified SVT in 2 cases where Holter could not. AV block and PVCs were picked up by WebCardio in more number of cases than the Holter, but this difference was not statistically significant. AV block was seen in 23 recordings of WebCardio compared to 18 recordings of Holter. There were 5 cases where WebCardio detected AV block and Holter could not. There was no case where Holter could identify AV block without WebCardio identifying. PVCs were seen in 83 WebCardio recordings compared to 74 Holter recordings. In 14 cases, WebCardio could identify PVCs where Holter could not and in 5 cases, Holter identified PVCs where WebCardio could not. The pickup of individual arrhythmia was not statistically different between the two types of the AECG (Table 2).

5. Discussion

The study was conducted to compare the ability to pickup arrhythmias by WebCardio systems and conventional Holter during 24 h of simultaneous recording. Detection of six arrhythmias namely AF, AV block, sinus pause of ≥ 3 s, SVT, PVC or VT/VF was looked into. The WebCardio picked up at least one of the six arrhythmias in more number of cases compared to Holter (98 Vs 88, $p = 0.006$). In a previous study using Zio patch, conducted in 146 patients, conventional Holter picked up more arrhythmias in the 24 h simultaneous recording (61 cases in Holter compared to the 42 cases with Zio patch recordings, $P = 0.013$) [3]. The arrhythmias looked at in present study and Zio patch study are different. In the Zio patch study the arrhythmias evaluated were SVT, AF/Atrial Flutter, pause >3 s, AV block (Mobitz type II or third-degree), VT and polymorphic VT/VF. Our study had higher numbers of patients having arrhythmia, compared to the study using Zio patch. This is to

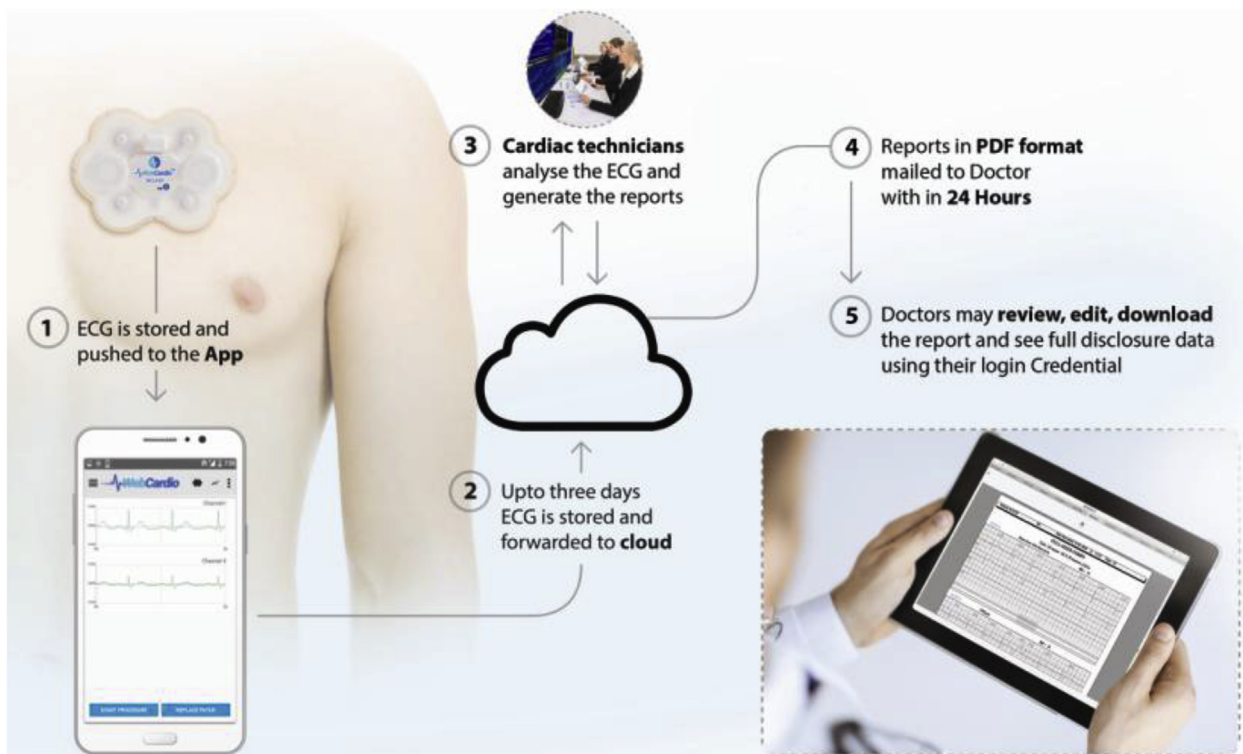


Fig. 2. Chart showing data acquisition, transfer, analysis and reporting in WebCardio.

Table 1
Ability to pick up one of the six- AF, AV block, sinus pause of ≥ 3 s, SVT, PVC or VT/VF.

Holter	Detection of at least one of the six - AF, AV block, SP, SVT, PVC or VT/VF		WebCardio		Total
	Yes	No	Yes	No	
	87	11	87	11	88
	42	53	42	53	53
Total	98	98	98	43	141

McNemars test, two tail, $p = 0.006$.

due to inclusion of PVC in our study.

Since pickup of infrequent PVC and first degree AV block may not be of high clinical significance, we evaluated detection of ≥ 100 PVC for the 24 h recording ($PVC \geq 100/day$) and 2nd or 3rd degree AV block. The detection of any of the six arrhythmia; AF, 2nd or 3rd degree AV block, Sinus pause ≥ 3 s, SVT, $PVC \geq 100/day$ or VT/VF were compared. When infrequent PVC and first degree AV block were excluded the difference in the pickup of arrhythmia was not significantly different between the two groups, $p = 0.0625$ (Table 3). WebCardio detected at least one arrhythmia in 52 cases compared to 48 in Holter. WebCardio identified arrhythmia in 4 cases where Holter could not identify any. There was no case where Holter detected arrhythmia and WebCardio could not. In the analysis of individual arrhythmias, the pickup of 2nd or 3rd degree AV block and $PVC \geq 100/day$ were better in the WebCardio, though statistically not significant. 15 WebCardio recordings identified 2nd or 3rd degree AV block compared to 11 by Holter. PVCs $\geq 100/day$ were seen in 24 WebCardio and 22 Holter recordings (Table 2).

To identify why the WebCardio picked up more arrhythmias,

further analysis was done. The pickup of AF, SVT, SP and VT/VF, was same in both types of recording. It can be seen from Table 2 that the difference in pickup of the PVC and AV block influenced the difference in overall ability to identify arrhythmias.

PVC identification reflects the ability of the system algorithm and is also dependent on the initial classification of the representative ECG events by the technician. Infrequent PVC may be missed if the event classification is not done properly. In the five cases where WebCardio identified AV block and Holter did not, analysis of the entire AECG of these cases were done. In 4 cases, P wave quality was poor in Holter and not clearly identifiable making diagnosis of AV block difficult. All the four cases had 2nd or 3rd degree AV block. The 5th case had first degree AV block. All the 5 cases had good quality P wave in WebCardio.

We have evaluated the quality of the P wave separately and found that the pickup of P was better in WebCardio compared to conventional Holter. We consider the following reasons for better pickup of P wave in WebCardio. The conventional Holter has wires which can produce noise during the recording due to patient

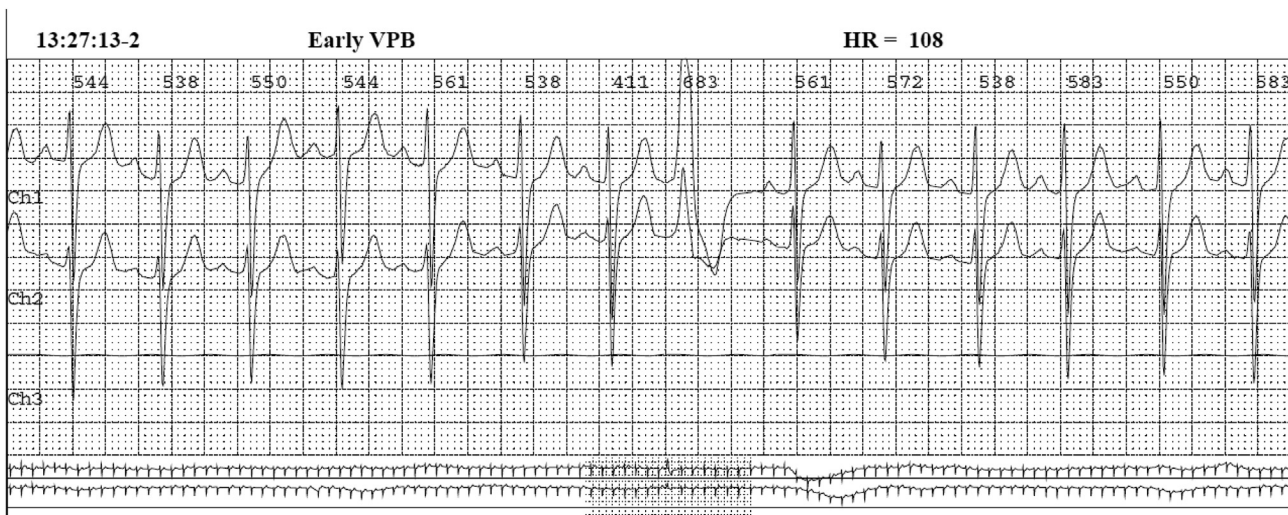


Fig. 3. An ECG strip showing PVC, WebCardio tracing.

Table 2
Detection of individual arrhythmia.

Arrhythmia	Detected by both Holter and WebCardio	Not detected by both Holter and WebCardio	In Holter only	In WebCardio only	Comment
AF	3	138	0	0	No difference between the two systems
Sinus pause ≥ 3 s	1	140	0	0	
SVT	17	120	2	2	
VT/VF	7	134	0	0	
AV block	18	118	0	5	McNemars test, two tail $P = 0.0635$
PVC	69	53	5	14	McNemars test, two tail $P = 0.0636$
AV block 2nd or 3rd degree	11	126	0	4	McNemars test, two tail $P = 0.125$
$PVC \geq 100/day$	22	117	0	2	McNemars test, two tail $P = 0.5$

Table 3Ability to detect of one of 6 - AF, AV block 2nd or 3rd degree, sinus pause of ≥ 3 s, SVT, PVC ≥ 100 /day or VT/VF.

Detection of at least one of the six- AF, 2nd or 3rd degree AV block, sinus pause of ≥ 3 s, SVT, PVC ≥ 100 /day or VT/VF.	WebCardio		Total
	Yes	No	
Holter			
Yes	48	0	48
No	4	89	93
Total	52	89	141

McNemars test, two tail, $p = 0.0625$.

movement, where as the WiPatch has no wires. Whatever noise is produced is likely to be amplified in Holter as the leads are placed more apart. The conventional Holter is reused several times and there can be small breaks in the wires connecting the leads, with possible risk of higher noise in recording, as the system becomes older. Previous studies have addressed clarity of P wave. A study using Carnation Ambulatory Monitor (CAM), a single channel ambulatory patch ECG monitor, designed specifically to ensure that the P wave component of the ECG be visible, showed a significantly improved rhythm diagnosis and avoided inaccurate diagnoses made by the standard 3 channel Holter monitor [5].

In the previous study using Zio patch the difference in arrhythmia pickup in the first the 24 h between Holter and patch was mainly because of the difference in the pickup of SVT. Once SVT was excluded the pickup of arrhythmia was comparable in both Holter and Zio Patch (27 vs 23) [3]. The main reason in the difference in pickup of SVT was identified as algorithm misclassification or a processing error in the classification of the potential events [3]. Apart from the quality of the ECG, the ability of the software and the training of the staff in classifying the events are important in identifying the arrhythmias. In our study the number of infrequent PVCs (less than 100/day) was the main contributor for the difference in the arrhythmia detection.

In the study by Barrett PM et al., with Zio patch capable of recording for 14 days, the patch monitoring detected more arrhythmia events compared with the Holter monitor (96 Vs 61, $P < 0.001$), during the total wear time (average recording time 11.1 days) [3]. Longer duration of recording is expected to pick up more arrhythmias. WebCardio is capable of recording for 72 h. The ability to pick up arrhythmias beyond first 24 h using WebCardio is to be studied separately.

There are certain differences between the Zio patch and Web-Cardio system. The Zio patch is to be mailed to the analyzing center after the recording. WebCardio does internet based data transfer and the ECG is available for analysis as soon as the recording ends. In WebCardio the report of the AECG can be generated within hours of ending the study. Zio patch records only one lead where as WebCardio is a two lead system, giving a potential advantage in ECG quality. Zio patch is water resistant where as WebCardio patch is not. Zio patch can record for 14 days and WebCardio records only for 3 days.

The national institute for health and care excellence of United Kingdom (NICE) gave a medtech innovation briefing (MIB) in 2017 on the Zio service for detecting cardiac arrhythmia [6]. This briefing is based on small comparative trials and large retrospective non comparative data using Zio patch. As per MIB by NICE, the innovative technology of patch based recording has a role in the arrhythmia analysis in the place of conventional Holter. Patch based recording is recommended as an alternative to the conventional Holter by several bodies. The 2017 Heart Rhythm Society Atrial Fibrillation Consensus Statement includes patch monitors as one

method of ambulatory electrocardiography monitoring [7]. The 2017 American College of Cardiology/American Heart Association/Heart Rhythm Society Guideline for the Evaluation and Management of Patients with Syncope listed patch monitoring as one of the recommended devices [8].

6. Conclusion

WebCardio detected arrhythmia in more number of cases compared to conventional Holter. The higher detection of arrhythmia in WebCardio was due to better pickup of the AV block and PVC. Once infrequent PVCs and first degree AV block were excluded there was no significant difference in the identification of arrhythmias. The difference in the quality of P wave, affecting the diagnosis of AV block, was a contributing factor in the difference in pickup of arrhythmias between the two types of recording. Pickup of AF, sinus pause, SVT and VT/VF were similar in both Holter and WebCardio. Considering the convenience of the small, disposable wireless patch and the ability to record for 72 h, WebCardio systems can be considered a good tool for AECG monitoring.

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