Improving the assessment of pediatric chronic pain: Harnessing the potential of electronic diaries

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Current methods for evaluating chronic pain in children suffer from methodological problems. Real-time data capture approaches using electronic diaries have been proposed as a new standard for pain measurement. However, there is limited information available regarding the development, feasibility and validity of these approaches in children. The present paper reviews problems with current measures; rationale for developing real-time data capture approaches using electronic diaries; mechanics of developing electronic pain diaries; current evidence regarding their usability, feasibility and validity; and discusses future directions for research in this area.

Key Words: Child; Electronic diary; Pain; Real-time data capture

Chronic pain and pain-related disabilities are a significant health problem for children and adolescents (1). Chronic pain significantly impairs children's quality of life, causing physical disability and emotional distress (2). Although precise estimates of the prevalence of chronic pain are difficult to ascertain, approximately 15% to 25% of children are estimated to experience recurrent and chronic pain (1). The complexity of chronic pain requires reliable and valid assessment of the multiple dimensions of pain to comprehensively evaluate pain treatments (3). Existing measures rely on recall, do not allow for prospective longitudinal assessment in naturalistic environments (eg, home and school) and fail to incorporate the multidimensional nature of pain (4). Real-time data capture (RTDC) approaches, in which patients report how they feel at that time using pain diaries, minimize the issue of recall bias by enabling the collection of real-time momentary data from participants, and enhance ecological validity (reflecting everyday real life) (5).

Paper pain diaries are commonly used in clinical and research practice. However, paper pain diaries suffer from several important limitations, including noncompliance in participants and inaccuracies in data entry (5). In adults, electronic (ie, personal digital assistant [PDA]) pain diaries have been used as an effective way to maximize participants' compliance with completing chronic pain intensity ratings and validity of those ratings (6,7). For example, compliance is enhanced by the signalling features of electronic diaries, whereby participants are beeped or signalled by the device when it is time to complete a diary entry. For these reasons, electronic pain diaries that use methods for RTDC have been proposed as a new standard for measurement of chronic pain because they circumvent many of these problems (5).

Although electronic diaries are becoming more prevalent, there is very little known about their use in children (8). Electronic diaries need to be comprehensively studied with children, giving particular consideration to how developmental issues (eg, age and stage of development) influence the validity of results, and the usability (intuitiveness of user interface) and feasibility (ie, compliance and acceptability) of this method in pediatric populations. The purpose of the present paper is to review current problems with assessment of chronic pain in children; discuss the rationale for and mechanics of RTDC approaches to assessing chronic pain; review the literature on electronic pain diaries for children and youth; and discuss future research directions for improving assessment of chronic pain in children using electronic pain diaries.

CURRENT METHODS FOR ASSESSING CHRONIC PAIN IN CHILDREN

Although a plethora of validated, single-item, self-report pain intensity measures exist for children with acute and chronic pain (9), only three multidimensional measures have been validated for chronic pain in children: the Pediatric Pain Questionnaire (10), the Pediatric Pain Assessment Tool (11) and the Adolescent Pediatric Pain Tool (12). These measures vary greatly in terms of their established reliability and validity.
evidence of sensitivity (ie, ability to detect change) and responsiveness (ie, ability to detect clinically important change) and comprehensive inclusion of the dimensions of pain (9). The most notable shortcomings of these measures are that they elicit a static single index of perceived pain intensity, rely on recall (eg, averaging and summarizing ratings over the past week) and do not allow for prospective longitudinal assessment in children's everyday environments (eg, home and school).

Single measures of pain intensity are inappropriate for chronic pain measurement because the resulting index of perceived pain is limited to one point in time. This approach fails to capture the dynamic nature of pain and its impact on all aspects of functioning. For example, reports of pain in children with arthritis appear to change over time, including during the course of a day; children often report worst pain in the morning due to joint stiffness (4). Also, a variety of environmental factors (eg, setting and person eliciting self-report) may influence pain intensity ratings obtained from children at a single point in time. Furthermore, reliance of measures on global and retrospective reports of average pain over a specified time period is problematic because single measures of recalled average or usual pain have been found to be less valid indicators of average pain than measures that incorporate a number of daily pain ratings (4,13).

Children with chronic pain are most often asked to recall their pain over protracted periods of time (eg, one week, two weeks or one month) in both clinical and research contexts. This measurement approach may lead to recall bias. The cognitive demands of indicating how much one hurts 'now' are less complex than the process of recalling average pain over many hours, days or weeks. Each step of the recall process has the potential to introduce significant error and distortion into recalled data (14,15). Also, the recall process may be influenced by the cognitive development of the child, as well as other physical, psychosocial and behavioural factors (15).

Furthermore, while patients' self-reports of pain are the accepted standard in clinical and research practice, we do not fully understand what patients' ratings mean and how they are derived. For example, we often ask children and adolescents to provide an estimate of their average or usual pain intensity over the past week. However, it is unclear how patients interpret this question. Do patients interpret this as a request for information about their pain intensity, frequency of pain, pain at rest or with activities, their ability to cope with pain, the impact of pain on aspects of everyday life (such as school) and ability to socialize with peers, or a combination of these? Several studies in adults with chronic pain have shown that patients construct their responses to these types of questions in complex and idiosyncratic ways (16,17). This, thus, seemingly simple task of asking children to recall their average pain over the past week is a deceptive, complex phenomenon.

In summary, single measures of recalled pain fail to capture the dynamic nature of pain and its influence on aspects of everyday life. More importantly, they can introduce systematic and random error into measurement results due to the effects of recall bias (5,14). Measures that include multiple prospective assessments of pain may be more sensitive than periodic single measures for assessing the subtle, day-to-day changes that would be expected following treatment intervention. Furthermore, growing interest by clinicians and researchers in moment-to-moment correlations among pain intensity and other variables give impetus for developing repeated, simple and comprehensive measures for assessing chronic pain in children using prospective RTDC diary methods.

RTDC APPROACHES

RTDC is a family of techniques that are used to collect data about an experience as it naturally unfolds in a person's life. Individuals are asked to report how they feel at a particular moment in time. These methods differ from traditional methods of assessment in that they are based on sampling moments from peoples' lives to more precisely capture the variability of the pain experience and reduce memory and other biases associated with recall of such experiences (5). RTDC approaches assess particular events in subjects' lives or assess subjects at periodic intervals, often by random time sampling, using technologies ranging from written diaries and telephones, to electronic diaries and physiological sensors.

Rationale for using RTDC approaches

There are several qualities of RTDC approaches (ie, paper and electronic diaries) that make them ideally suited for the assessment of chronic pain in children. First, these approaches involve real-time data collection about momentary or near-immediate states. This feature prevents retrospective distortion of data (recall bias) and maximizes the validity of subjective reports. Researchers have shown that reports of recalled pain are influenced by a phenomenon referred to as the peak-end effect. This occurs when the most salient or intense experiences, and those that occur nearer to the time of reporting, have an especially strong influence on recalled pain. In addition, individuals tend to ignore periods of no pain, which has been referred to as duration neglect (5,18). Therefore, these and other memory processes tend to distort reports of recalled pain (18).

The second quality is that RTDC approaches allow for the investigation of within-person associations (19). RTDC typically involves sampling multiple momentary assessments per day and across days. Collecting multiple data points enables the researcher to examine changes in patient experience and the pain phenomena over time. For example, questions about pain at time 1 can be used to predict pain experiences at time 2 and so on, using time series or cross-lagged panel analyses (5). Burton et al (19) conducted a systematic review of electronic diaries as a tool for investigating associations between physical symptoms and psychological variables. They classified electronic diaries into five categories to investigate associations including experience (recording data when symptoms were present), interaction (testing relationships between variables at different levels), sequential (observing associations at different time lags), process (recording possible mediating constructs such as catastrophizing) and intervention (recording during treatment to identify trends) (19). When relations between variables are analyzed within subjects over time using RTDC approaches (paper or electronic diaries), researchers can make strong conclusions regarding study results.

The third quality is that RTDC approaches allow for higher resolution of treatment response because they enable the collection of many assessments over time. Clinical pain trials
typically use pre- and post-treatment measures of recalled pain to assess efficacy of treatments. Several researchers have shown that the aggregation of summary measures from RTDC approaches are more reliable and valid than single recalled assessments (4,13). There is also evidence that methods relying on recall (compared with RTDC approaches using electronic diaries) may produce a placebo response with patients improving in clinical trials when no intervention has occurred (19). Therefore, RTDC approaches may be better able to differentiate therapeutic responses from measurement artifacts associated with recalled average weekly pain measures.

The fourth reason is that certain RTDC approaches have been found to enhance compliance. Electronic diary measures have been found to have superior compliance to traditional approaches using paper diaries. Using a paper pain diary instrumented to track diary use, Stone et al (6) demonstrated that participants’ actual compliance with making scheduled diary entries was only 11%, while ‘faked’ compliance (ie, backfilling to appear compliant) exceeded 90%. Palermo et al (20) compared the compliance and acceptability of an end-of-day electronic diary with a written diary in a study of 60 children with recurrent or chronic headaches and arthritis pain over a seven-day period. Children completed a total of 312 (74%) electronic diary entries of 420 possible diary entries. Children in the electronic diary group completed significantly more daily diary entries (mean 6.6) than children using the paper format (mean 3.8; P<0.001).

Finally, completion and accuracy of RTDC pain diaries with minimal missing responses are crucial because incorrect or missing values may make participants’ data unusable or invalid (17,19). Completion and accuracy rates are also influenced by the type of RTDC approach method that is used. Palermo et al (20) compared the accuracy of electronic and paper diaries used by children with arthritis and headaches. The paper diary group made significantly more errors and omissions than the electronic diary group. All diary entries (100%) returned by children in the electronic diary group contained no errors of omission, while only 51% of the diaries returned by children in the paper diary group had no errors.

Similarly, in our diary studies, we found that the e-Ouch electronic pain diary entries contained no errors of omission in two samples of adolescents with arthritis who were asked to complete the diaries for two and three weeks, respectively. However, adolescents made errors in the order of their recalled least, average and worst pain ratings, as well as errors in marking the visual analogue scale (VAS) scores using a paper-based recalled pain inventory (4). Other researchers, who studied chronic pain in adults, found that paper diaries contain numerous out-of-range or illegible data (with rates as high as 80%), which in turn limits their usefulness in clinical research (21).

While there are many advantages to using RTDC approaches to assess chronic pain, data derived from electronic and paper diaries may be distorted due to the effects of reactivity. Reactivity has been defined as the degree to which the intensity, frequency and/or quality of a target variable (eg, pain intensity) will change when being observed, monitored or assessed (5,22). The issue of measurement reactivity has important implications for the external validity of RTDC studies in terms of whether the findings can be generalized to persons who do not spend their days monitoring their pain so often and so exactly. However, measurement reactivity associated with self-monitoring has not been shown to be a significant problem in adults with chronic pain (6,22).

**Mechanics of RTDC approaches**

One of the first considerations in designing a study using a RTDC approach to assess pain is to develop a sampling scheme that adequately represents the domain of the experience being studied (14). General sampling approaches include interval-, signal- and event-contingent approaches. Interval-contingent assessment involves the completion of assessments at preselected times of the day (eg, morning, afternoon and evening) or across days (eg, end-of-day ratings). Limitations of this approach are that assessments may not be representative of the participant’s day, an inflexible schedule may result in poor participant compliance and the timing of assessments can be anticipated by the participant, which may lead to certain response biases. Signal-contingent recordings involve using a prompting device (eg, pager or PDA) that emits a signal at prespecified or random intervals to alert the respondent to make a recording about their immediate experience. However, this approach may result in important episodes being missed and frequent random prompting may increase response burden. Event-contingent assessments are those completed when a particular event occurs (eg, migraine). This method requires participant vigilance in the constant monitoring of specific events, as well as compliance with the simultaneous recording of events and participant responses. Consequently, it is often impossible to determine the validity of the report (14,23). Decisions regarding the sampling design should ultimately be based on the principles of representative sampling and nature of the pain problem being examined (eg, is the pain constant or does it fluctuate within and across days?) (23).

The second consideration when designing a RTDC study is the frequency and duration of self-monitoring. There is no simple answer to how many samples per day should be obtained or for how long (24). Jensen and McFarland (13) found that the most reliable and valid estimates of average weekly pain were obtained from a composite pain intensity score calculated from an average of 12 ratings across four days. Similarly, we found that 12 ratings across four days provided valid estimates of average weekly pain in youth with arthritis (4). Increasing the number of measurements per day increases the temporal resolution and statistical reliability of the data. Increasing the number of days that measurements are made may increase the generalizability of data and allow for observation of a greater range of responses. However, these advantages need to be weighed against the disadvantages of increasing participant burden and potentially reducing participant compliance (5,25). Although compliance results of electronic diaries are reportedly superior to those of paper diaries (6,20), frequent monitoring may still be burdensome for participants (25,26). Compliance is one of the most crucial components of the successful execution of RTDC methods; therefore, it is important to consider the number of daily entries and duration of recording while minimizing the response burden of children with chronic pain.

The third consideration when designing a RTDC study is the actual method used by participants to record their responses. In most RTDC studies, researchers collected data using paper diaries. Even when a ‘high-tech’ device (eg, wristwatch or
generally more familiar with and confident in the use of com-
imies hold particular promise for use in children because they are
honestly express their pain. Furthermore, electronic pain diar-
diaries may also provide children with a means to easily and
convenience and ease of data transfer to a stationary personal
prevention of backfilling or entry of invalid responses; and
concealment of previously recorded responses from subjects;
branches and tailor-made sequential or hierarchical strategies;
question layouts and response categories; design of question
stamping of entries to track participant compliance; flexible
signals and programmable alarm functions to prompt the indi-
mable PDAs has many advantages, including built-in reminder
access and, therefore, rely heavily on time-contingent sched-
ules (ie, end-of-day reporting).

**ELECTRONIC PAIN DIARIES**
The development of PDA technologies offers new possibilities
for the measurement of chronic pain in children. PDAs are
small, portable devices that are capable of presenting text and/or
graphics to subjects, recording and electronically storing sub-
jects’ responses, and transmitting stored data to a computer to
be analyzed (22). Electronic diaries have been used with
patients of all ages, including children as young as six years of
age and adolescents, for the measurement of a wide variety of
symptoms and behaviours (8). However, to date, research stud-
es evaluating electronic pain diaries have primarily been con-
ducted in adults with chronic pain (5).

Advantages and disadvantages of electronic pain diaries
Advances in PDA technologies have allowed researchers to
implement electronic RTDC pain protocols. Using program-
nable PDAs has many advantages, including built-in reminder
signals and programmable alarm functions to prompt the indi-
vidual at predefined intervals; reliable time and duration
stamping of entries to track participant compliance; flexible
question layouts and response categories; design of question
branches and tailor-made sequential or hierarchical strategies;
concealment of previously recorded responses from subjects;
prevention of backfilling or entry of invalid responses; and
convenience and ease of data transfer to a stationary personal
computer for summary, review and analysis (5,23). PDA pain
diaries may also provide children with a means to easily and
honestly express their pain. Furthermore, electronic pain diar-
ies hold particular promise for use in children because they are
generally more familiar with and confident in the use of com-
puterized technologies than adults (27).

Despite the advantages of using PDAs or mobile telephones
to implement RTDC protocols, there are also limitations.
Substantial financial commitment is required to conduct
RTDC studies that use the highest level of technological
innovation. The price of PDAs and cell phones exceeds the
cost of written methods, but is not unreasonably high in light
of the flexibility of data acquisition, high technical reliability
and exact timing provided by PDA technology (23). PDAs also
require user training; however, children often require less train-
ing than adults because they tend to have more familiarity and
competence with computerized technologies (25). Finally,
RTDC methods can place a significant burden on both investi-
gators and research participants; the programming and develop-
ment are costly to implement, require high levels of technical
skill and are labour-intensive. Moreover, the sheer volume of
data and its complexity can pose significant logistical and ana-
lytical challenges to investigators (23,25). RTDC methods also
demand significant effort and cooperation from participants,
and may not be suitable for those with cognitive, sensory or
motor impairments (25).

While electronic diaries have been found to outperform
written diaries in terms of compliance, data accuracy and sub-
ject acceptability (5), technical malfunction is one of the main
disadvantages of the PDA-based RTDC methods. Dale and
Hagen (28) conducted a systematic review of nine randomized
and quasi-randomized controlled trials comparing electronic
and written diaries in terms of feasibility, compliance, data
accuracy and acceptability. Five studies reported on feasibility,
and all reported technical difficulties with PDA technology.
For example, in Palermo et al’s study (20), 14% of the PDAs
stopped working because of technical problems, with all data
being lost and/or unusable. The authors also reported several
power failures with the units and other PDA malfunctions.
Furthermore, one unit was damaged, three stylus pens were
broken or lost, and two of the AC adapters needed to be
replaced (20). Mechanisms need to be in place to ensure regu-
lar backup of data, that batteries are adequately charged and
technical problems can be resolved quickly when they occur
(24 h support). For these reasons, it is crucial to undertake
formal usability and feasibility testing of RTDC electronic
diaries to uncover these technical difficulties before implementing
them in research or clinical practice.

**LITERATURE ON THE USE OF ELECTRONIC
PAIN DIARIES IN CHILDREN**
The use of electronic diaries for pain assessment in children is
relatively new and there is little existing related research. Walker
and Sorrells (29) were the first researchers to evaluate the use of
an electronic diary for the assessment of daily gastrointestinal
(GI) symptoms and function in children in a small pilot study.
Eleven parent-child (six to 10 years of age) dyads referred to a
tertiary care centre for evaluation of constipation and abdominal
pain were provided with hand-held computers and modems.
They completed end-of-day diary entries for a seven-day period.
They were asked to respond to questions as a team regarding the
level of the children’s GI symptoms and the extent to which
symptoms interfered with the day’s activities. On completion of
the diary use period, parents responded to a telephone interview
evaluating the procedure. Parents reported that the children
understood most of the questions and that the responses entered
were accurate. Parents and children were enthusiastic about the
data collection method. However, some technical problems
arose with the units (ie, trouble logging in, modem and PDA
malfunctions, dead batteries or lost units). This study provided
the first evidence that this method demonstrated promise in
evaluating pain in children with GI problems.

Palermo et al (20) compared the compliance, accuracy and
acceptability of multidimensional electronic and paper pain
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...diaries in 60 children, eight to 16 years of age, who had recurrent (ie, headaches) and chronic (ie, juvenile idiopathic arthritis [JIA]) pain. Children were randomly assigned to use either a PDA pain diary that was administered via a home visit or a paper diary that was administered during a regularly scheduled clinic visit. The diaries were designed to capture pain occurrence (ie, morning, afternoon and evening), location and intensity ratings using a faces pain scale; distress ratings (ie, emotional upset) using a five-point adjective scale; occurrence of other somatic symptoms; and activity limitations. Compliance was significantly higher in children who used the electronic diary (83%) than those who used the paper diary (47%). Age, ethnicity and baseline pain severity and frequency did not influence compliance rates, although boys were significantly more compliant with the electronic diary than the paper diary. Paper diary entries had significantly more errors and omissions than those in the electronic diaries. While only one-half of the sample completed the acceptability questionnaire, children found the electronic diary easy to use, efficient and accurate. A significant methodological limitation was that the diary protocols were markedly different and the children receiving the electronic diaries had more contact with the researchers throughout the course of the study, which may have affected their compliance and acceptability ratings.

We recently developed a multidimensional electronic pain diary using a phased approach (4,30,31). First, the prototype was developed and the usability was tested in adolescents with JIA (30). A qualitative usability testing approach with semistructured, audiostaped interviews with two iterative cycles was used. A purposive sample of 10 adolescents per cycle was drawn from a rheumatology clinic in a university-affiliated pediatric tertiary care centre. Participants were provided with a brief demonstration of the electronic diary and then asked to use the diary while ‘thinking aloud’ to record the pain they experienced when they woke up that morning, during that afternoon and from the previous evening. Adolescents were then asked a series of open-ended questions addressing ease of use of the diary. Qualitative thematic analysis was used to generate categories and emerging themes from interview data. All of the adolescents stated that the e-Ouch diary was very easy to learn, use and understand, and was satisfying to complete. Participants took less than 9 min to complete all three of the diary entries with minimal errors. The usability evaluation revealed aspects of the interface that were suboptimal (eg, VAS slider) and impeded the performance of certain tasks. Adolescents generated ideas on how the diary interface could be improved. A multifaceted usability approach provided important insight regarding the use of technology by adolescents with arthritis and, more specifically, for understanding how adolescents can more effectively use an electronic chronic pain diary (30).

In the next phase, the e-Ouch multidimensional electronic pain diary was pilot tested in terms of compliance and acceptability in adolescents with arthritis (31). Two iterative phases in a descriptive study design were used. A purposive sample of 13 adolescents with mild to severe pain and disability was drawn from a large rheumatology clinic in a university-affiliated pediatric tertiary care centre in Canada over a four-week period in December 2004. Participants were signalled with an alarm to use the diary three times per day for a two-week period. Adolescents also completed an electronic diary acceptability questionnaire. Overall mean compliance for phases 1 and 2 was 72.9% and 70.5%, respectively. Compliance was affected by the timing of data collection and technical difficulties. Children rated the diary as highly acceptable and easy to use. Phase 1 testing revealed aspects of the software program that affected compliance, which were subsequently altered and tested in phase 2. No further changes were made following phase 2 testing. Pilot testing was the crucial first step in facilitating the future evaluation of the construct validity and feasibility of this measure in children with chronic arthritis (31).

We then conducted two descriptive studies to evaluate the construct validity and feasibility of the e-Ouch electronic pain diary in adolescents with JIA (4). Participants were drawn from a large metropolitan rheumatology clinic in a university-affiliated pediatric tertiary care centre. In study 1, 76 adolescents with active arthritis recorded their pain three times a day for two weeks using the e-Ouch. In study 2, 36 adolescents recorded their pain three times a day for one week before and two weeks after joint injections. Adolescents in both studies completed multiple measures to determine the construct validity and feasibility of the e-Ouch. Adolescents reported mild levels of pain intensity, unpleasantness and interference, as well as stiffness and mild to moderate levels of fatigue. e-Ouch average weekly pain unpleasantness and interference scores were higher in adolescents with higher pain intensity scores. Correlations among average weekly pain ratings on the e-Ouch and scores from recalled least, average and worst weekly pain; health-related quality of life and pain coping; and disease activity were as predicted. Pain ratings were significantly lower following joint injections, with effect sizes in the low to moderate and moderate to high ranges at the first and second week postinjection, respectively. To our knowledge, this was the first study to evaluate the construct validity of an electronic pain diary in adolescents with JIA (4).

**FUTURE RESEARCH**

While holding great promise, there are many challenges with RTDC approaches that need to be addressed before their potential is fully recognized. Future research is needed to determine the optimal number of items (eg, five to 20 questions) and the time to complete electronic diary entries (eg, brief; taking less than 5 min to complete), schedule for use with children and youth to avoid interference with school (eg, preset times tailored to participants’ schedules), modes of data entry (VAS, versus word-based entry, graphic icons for word descriptors, or body outlines where patients can shade percentage body area in pain or rate pain intensity in various painful body locations) and amount of training and support required to enhance acceptability and compliance with this measurement approach. Research is also needed to explore the issue of reactivity with RTDC electronic diaries in children. Finally, electronic pain diaries using RTDC approaches need to be tested to determine their usability, feasibility and psychometric properties in children and youth.

Future research is also warranted to explore how we can meld RTDC electronic diary approaches with proactive advice. An example of this would be incorporating decision-making...
support systems into the diaries and or integrating them into electronic health interventions (eg, a patient would receive a prompt on a PDA or cell phone to take some therapeutic actions if pain exceeded some predetermined threshold).

Sorbi et al (32) recently reported on a mobile Web-based monitoring and coaching program for adults with migraines. Adults were asked to record their pain on electronic hand-held pain diaries and received Internet-based coaching and health information on managing migraines. Clearly, this is a burgeoning area of research that extends beyond electronic diaries to include other electronic health technologies, such as the Internet and cell phones (for short message service and/or text messaging). These are the types of interventions that need to be further explored to see whether they can assist youth with chronic pain in being engaged in self-care during the difficult period of adolescence and transition to adulthood.

CONCLUSION

RTDC methods hold significant promise for clinical practice and research on chronic pain in children due to the primary importance of self-report methods of pain assessment and the inherent limitations of retrospective self-report. Moreover, there are numerous limitations for using the traditional methods of questionnaires and paper diaries to obtain RTDC data. For these reasons, PDA technologies for facilitating RTDC make electronic methods increasingly powerful and practical for research and clinical care in children. Future research in this area will enable clinicians and researchers to better understand the chronic pain experience of children, and more optimally treat it.

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