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Original Article

Hypnosis to Reduce Distress in Children Undergoing Anorectal Manometry: A Randomized Controlled Pilot Trial

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Background/Aims
To assess the effectiveness and feasibility of a brief session of hypnosis to reduce distress in children with functional constipation undergoing anorectal manometry (ARM).

Methods
A partially-blinded randomized controlled pilot trial was conducted in children 4-18 years old scheduled for ARM. Children were randomized to receive a brief session of hypnosis prior to ARM or standard care. Non-blinded and blinded observers rated the child's level of distress using the Observation Scale of Behavioral Distress and a 4-point-Likert scale, respectively. Differences between groups were analyzed using Fisher's exact test or Mann-Whitney *U* test as appropriate.

Results
Data from 32 children (15 hypnosis and 17 standard care) were analyzed. Prior to insertion of the catheter, the observed mean levels of distress were lower in the hypnosis group according to both the non-blinded observer (median 0.0 [interquartile range {IQR} 0.0-0.3] vs 1.4 [IQR 0.3-2.4]; $P = 0.009$) and the blinded observer (median 0.0 [IQR 0.0-0.0] vs 0.5 [IQR 0.0-1.0]; $P = 0.044$). During ARM, observed and reported levels of distress did not differ significantly. In the hypnosis group, 92.9% of parents and children reported that hypnosis helped the child to relax. There were no significant differences in resting pressure, squeeze pressure, or duration of the procedure between both groups.

Conclusion
A brief session of hypnosis for children before ARM is an easily incorporable intervention that lowers distress levels prior to the procedure and is positively perceived by children and parents.
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Key Words
Anxiety; Child; Constipation; Hypnosis; Manometry

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Introduction

Anorectal manometry (ARM) is a test used in the diagnostic work-up of children with severe constipation to identify patients with Hirschsprung disease, internal anal sphincter achalasia, anal sphincter hypertonia and pelvic floor dyssynergia.[1-3] During ARM, neuromuscular function of the anorectum is assessed using a manometry catheter that is inserted in the rectum through the anus. The procedure is considered safe and not painful. However, rectal insertion of the manometry catheter can be frightening and high levels of anxiety and distress have been described in both children undergoing ARM and their parents.[4] Distress and anxiety at the time of the procedure can generate negative memories, which can lead to recurring distress at subsequent medical procedures.[5-7] Additionally, fear and lack of cooperation during the test may prevent completion of the procedure and may require repeating the test with sedation. ARM is preferably performed awake to allow for assessment of rectal sensation and defecation dynamics.[2] Anesthetic agents can influence the anal sphincter resting pressure and performing the study under anesthesia involves additional risks and costs.[8,9]

A growing body of evidence indicates hypnosis may be effective to reduce distress, anxiety, and pain in children during hospital procedures.[10-13] Hypnosis is defined by the American Psychological Association as "a state of consciousness involving focused attention and reduced peripheral awareness characterized by an enhanced capacity for response to suggestion."[14]

The aim of this randomized controlled pilot study is to examine the feasibility and effectiveness of a brief session of hypnosis on reducing the level of distress in children undergoing ARM. We hypothesized that hypnosis would be an easily incorporable intervention which may lower distress levels in children during ARM.

Materials and Methods

A partially-blinded randomized controlled pilot study was conducted at a tertiary children's hospital. The local Institutional Review Board approved the study protocol (IRB15-00864). The trial was registered at clinicaltrials.gov with identification number NCT04471857. All parents gave written consent and all children older than 9 years of age provided assent.

Participants

We included children 4-18 years of age who were scheduled to undergo awake ARM. Exclusion criteria were a lack of proficiency in the English language, known organic cause of constipation, and conditions that could potentially compromise administration of hypnosis. The latter included, diagnoses of a psychiatric or behavioral disorder, developmental delay, or severe physical illness defined according to the American Society for Anesthesiologists (ASA) classification as an ASA score ≥ 3.[15] We excluded children with behavioral disorders based on the hypothesis that these children would be more likely to be uncooperative with the hypnosis intervention and that maladaptive behavior could influence other outcomes in this study. In order to identify children with undiagnosed behavioral disorders, all parents completed the Behavior Assessment System for Children, Third Edition, Parent Rating Scale (BASC-3).[16] Following completion of the study protocol, we evaluated BASC-3 scores. Children with evidence of high levels of maladaptive behavior or emotional and behavioral disturbances as determined by the BASC-3 web-based scoring, were excluded from the statistical analysis.

On the day of the ARM procedure, after obtaining consent and assent, one of the parents of the child completed a form with questions about the child's medical history, prior experience with ARM, and current symptoms and treatment. After baseline data collection, children were allocated to the hypnosis group or standard care group using a computer-generated randomization sequence (SAS for Windows, version 8.2; SAS Institute Inc., Cary, NC, USA). ARM was performed with a high-resolution solid-state catheter (UniTip High Resolution Catheter, model number K12959-L5-1038-D from Unisensor AG; Attikon, Zürich, Switzerland) and executed according to the protocol of the department. Every ARM was performed by the same motility nurse, who has extensive experience performing motility procedures, and the same hypnotherapist, an advanced nurse practitioner with training in clinical hypnosis. Parents were allowed to be present during the procedure.

Hypnosis Intervention

Prior to ARM, when lying on the procedure bed in the intervention room, children in the hypnosis group received a brief hypnosis session from a certified hypnotherapist. The hypnotherapist was an advanced nurse practitioner trained in clinical hypnosis during a 3-day pediatric clinical hypnosis course held by the National Pediatric Hypnosis Training Institute. The hypnosis session lasted from 1 to 3 minutes and included an induction phase, which was adapted according to the child's age, interests, and cognitive and social development. References to child's well-being and comfort were included in the induction. The induction involved progressive

relaxation and further focusing or deepening of the hypnotic state by the conventional means, such as mentally going to a special place. The session ended with a post-hypnotic suggestion stimulating the child to think of their special place during the ARM, which would provide comfort during the procedure. The session was meant to result in immediate relaxation and if the child seemed distressed during the procedure the hypnotherapist would refer back to that initial moment and stimulate the child to relax again.

Outcome Measures

Both a non-blinded and a blinded observer rated the child's distress during ARM. The non-blinded observer was present in the procedure room. The blinded observer was positioned in a separate room and was able to observe the child during the procedure through a one-way mirror. The hypnotherapist assisted during both ARMs with and without hypnotherapy, and stood behind a curtain so that the blinded observer could not see what the hypnotherapist was doing and thus could not know to which group the children were allocated. The room study set-up is shown in Figure 1.

Child distress was measured during 3 phases:

(1) Phase 1 (before ARM): The period that the child was on the table until the introduction of the catheter

(2) Phase 2 (passive ARM): The period between introduction of the catheter into the rectum until first active instruction or question directed to the child (measuring the resting pressure)

(3) Phase 3 (active ARM): The period during which the child was asked questions and was instructed to cooperate and actively follow instructions until the catheter was removed (measuring sensitivity, the recto-anal inhibitory reflex, squeeze pressure, and defecation dynamics)

The non-blinded observer used the Observation Scale of Behavioral Distress (OSBD) to assess the distress of the child during the ARM (Supplementary Material 1).[17] The OSBD is a validated tool also used in other studies investigating the effect of hypnosis on distress in children during medical procedures.[18] It records the presence or absence of 13 operationally-defined behaviors with scores ranging from 1 to 4, which indicate discomfort at 15-second intervals throughout the procedure. The total scores were summed up for each phase and then divided by the number of 15-second intervals in that phase to obtain a mean distress score.

The blinded observer rated the child's distress on a 4-point Likert scale ranging from 0 (not anxious at all) to 3 (extremely anxious). Ratings were based on facial features, crying, and physical movements (see Supplementary Material 2). During each phase of the ARM procedure, the blinded observer reported the highest (ie, peak), most common (ie, stress level during the majority of the time), and the lowest level of distress. We compared the highest and most common levels of distress between groups, as we believed these levels of distress were most clinically relevant.

After the ARM, the parent and child were separately asked to rate the amount of distress of the child (unpleasantness, nervousness, and anxiety) during the ARM on a 5-point Likert scale ranging from 0 (not at all) to 4 (very much). They also rated painfulness of the procedure on an analogous scale of 0 (no pain) to 10 (extremely painful). Children and parents of children who received hypnosis were asked if they believed that it helped the child to relax on a 5-point Likert scale ranging from 0 (not at all) to 4 (very much).

After the procedure, the motility nurse reported if all parts of the procedure could be performed properly and rated the degree of difficulty of the procedure on a 5-point Likert scale ranging from 0 (not at all) to 4 (very much). In addition, the hypnotherapist rated the degree of difficulty of the hypnosis on a similar 5-point Likert scale ranging from 0 (not at all) to 4 (very much). We also reviewed manometric data of all ARM studies.

Statistical Methods

Statistical analyses were conducted with SPSS for Windows, version 24 (IBM Corp, Armonk, NY, USA). As there were no

Figure 1. Room setup: view from position of non-blinded observer. The patient would be on the bed facing the mirror, the hypnotherapist would sit on the chair on the right side of the bed, the motility nurse would stand behind computer on the same side. The parent would sit on a chair on the left side of the bed. The blinded observer would be behind one-way mirror on the left.

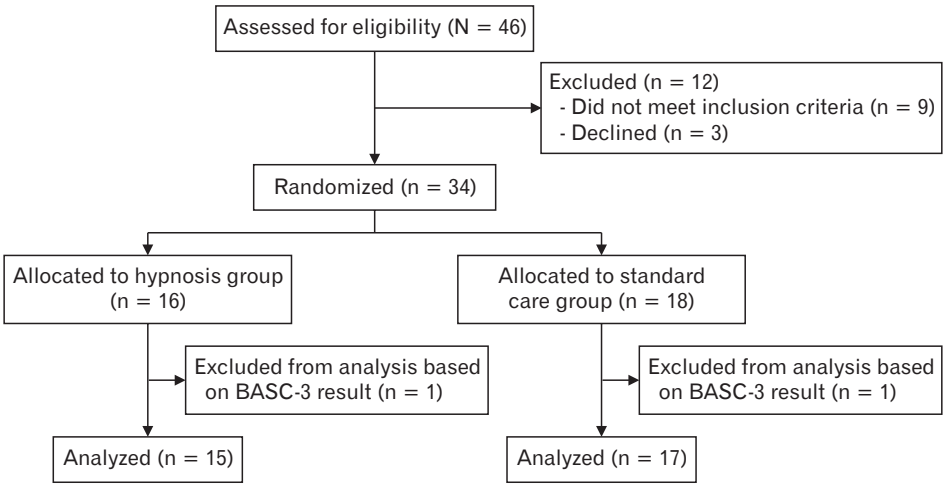

Figure 2. Patient flow diagram. BASC-3, Behavior Assessment System for Children, Third Edition.

preliminary data available, we were not able to perform a sample size calculation. We estimated that a sample size of 40 patients would allow us to compare data between groups and provide sufficient information to determine the feasibility of this intervention. However, as our goal sample size was not based on preliminary data, we terminated enrollment early during the Coronavirus disease 19 (COVID-19) pandemic. Data are presented using medians and interquartile ranges. Differences between groups were analyzed using Fisher's exact test or Mann-Whitney *U* test as appropriate. A *P*-value of < 0.05 was considered statistically significant.

Results

Forty-six patients were screened for eligibility (Fig. 2). Twelve were excluded from participation, of whom 9 did not meet inclusion criteria (5 behavioral disorder, 3 developmental delay, 1 organic cause of constipation) and 3 declined participation. Thirty-four patients were enrolled and randomized: 16 underwent hypnosis and 18 were allocated to the standard care group. Two subjects (Hypnosis [n = 1]; Standard care [n = 1]) were excluded from analysis due to high levels of maladaptive behavior and emotional and behavioral disturbances on the BASC-3 scale. Table 1 shows baseline characteristics of the participants. The median age of included subjects was 8.2 years (interquartile range [IQR] 6.1-10.2; range 4-14 years) and the majority (59.4%) were female. More children in the hypnosis group had a history of frequent enema usage (46.7% vs 5.9%, $P = 0.013$). However, at time of the ARM there were no differences in the use of oral or rectal laxatives.

Table 1. Baseline Characteristics

Baseline characteristics	Hypnosis group (n = 15)	Standard care group (n = 17)	*P*-value
Age (yr)	8.5 (6.5-10.1)	8.2 (6.1-9.7)	0.911
Sex (female)	8 (53.3)	11 (64.7)	0.720
Previous anorectal manometry	1 (6.6)	0 (0.0)	0.469
History of frequent enema usage	7 (46.7)	1 (5.9)	0.013
Duration of symptoms (mo)	60 (33-78)	60 (48-72)	0.710
Current symptoms			
Bowel movements per week	4.3 (1.0-7.0)	6.5 (1.5-7.0)	0.667
Fecal incontinence	7 (46.7)	13 (76.5)	0.144
Large stools	10 (66.7)	9 (52.9)	0.716
Painful stools	11 (73.3)	6 (35.3)	0.073
Hard stools	8 (53.3)	9 (52.9)	> 0.999
Withholding behavior	5 (33.3)	11 (64.7)	0.141
Abdominal pain	11 (73.3)	8 (47.1)	0.273
Current treatment			
Oral laxatives	14 (93.3)	16 (94.1)	> 0.999
Rectal laxatives	5 (33.3)	4 (23.5)	0.699

P-value < 0.05 was considered statistically significant.
Data are presented as median (interquartile range) or n (%).

Observational Ratings of Distress

The non-blinded observer ratings generated a mean distress score during each phase. In 6 participants (hypnosis [n = 3]; standard care [n = 3]) the study protocol was unintentionally violated by the non-blinded observer; the non-blinded observer had started recording distress levels only after insertion of the manometry catheter. This resulted in missing data for phase 1 in these participants.

Table 2. Observed Levels of Distress

Outcomes by study phase	Hypnosis (n = 15)	Standard care (n = 17)	*P*-value
Blinded observer[a] (peak level of distress)			
Phase 1	1 (0-2)	1 (0-2)	0.502
Phase 2	0 (0-1)	1 (0-1)	0.370
Phase 3	1 (1-2)	1 (1-1)	> 0.999
Blinded observer[a] (common level of distress)			
Phase 1	0 (0-0)	0.5 (0-1)	0.044
Phase 2	0 (0-0)	0 (0-1)	0.455
Phase 3	0 (0-0)	0 (0-1)	0.478
Non-blinded observer[b] (mean level of distress)			
Phase 1[c]	0.0 (0.0-0.3)	1.4 (0.3-2.4)	0.009
Phase 2[d]	0.3 (0.0-1.5)	1.6 (0.0-2.4)	0.309
Phase 3[d]	0.2 (0.0-0.7)	0.4 (0.2-2.0)	0.423

[a]Blinded observer used a 4-point Likert scale from 0 (no distress) to 3 (extreme distress).
[b]Non-blinded observer used the Observation Scale of Behavioral Distress (higher values correspond to higher levers of distress).
[c]Six missing (hypnosis [n = 3]; standard care [n = 3]).
[d]One missing (standard care).
P-value < 0.05 was considered statistically significant.
Data are presented as median (interquartile range).

Table 3. Outcomes by Study Condition

Outcomes	Hypnosis (n =15)	Standard care (n = 17)	*P*-value
Child report[a]			
Pain during procedure[b]	2 (0.0-6.5)	3 (1.0-5.5)	0.637
Afraid during procedure[c]	3 (1.0-3.5)	3 (1.5-3.5)	0.892
Nervous during procedure[c]	1 (0.0-3.0)	3 (2.0-3.5)	0.093
Hypnosis helped relax	13 (92.9)	N/A	
Parent report[d]			
Pain during procedure[b]	2 (1.0-3.0)	2 (0.0-2.5)	0.496
Unpleasant procedure[c]	2 (0.0-2.5)	3 (1.5-3.0)	0.325
Anxious during procedure[c]	2 (1.0-3.0)	3 (3.0-4.0)	0.056
Nervous during procedure[c]	3 (1.0-3.0)	3 (3.0-4.0)	0.116
Hypnosis helped relax	13 (92.9)	N/A	
Procedural outcomes			
Difficulty procedure[c]	0 (0-1)	1 (0-2)	0.382
Duration (min)	14 (12-21)	17 (14-19)	0.597
Resting pressure (mmHg)	73 (68-87)	78 (67-84)	0.941
Squeeze pressure (mmHg)	231 (140-231)	200 (173-282)	0.455
First sensation (balloon volume [mL])[e]	20 (10-50)	30 (20-45)	0.525
Urge sensation (balloon volume [mL])[e]	50 (30-60)	50 (25-105)	0.914
Discomfort sensation (balloon volume [mL])[e]	80 (60-90)	90 (85-150)	0.142

[a]One missing (standard care), one child (hypnosis) did not answer if hypnosis helped.
[b]Pain scores ranged from 0 (no pain at all) to 10 (extreme pain).
[c]Scores ranged from 0 (not at all) to 4 (very much).
[d]Two missing (Standard care), 1 parent (hypnosis) did not answer if hypnosis helped.
[e]Not reported: first sensation (hypnosis [n = 1]), (standard care [n = 1]); urge (hypnosis [n = 2]), (standard care [n = 1]); discomfort (hypnosis [n = 2]), and (standard care [n = 2]).
N/A, not applicable.
Data are presented as median (interquartile range) or n (%).

The hypnosis group had a lower mean distress score during phase 1 (median 0.0 [IQR 0.0-0.3] vs 1.4 [IQR 0.3-2.4]; $P = 0.009$). No differences were found between groups during the other phases.

The blinded observer reported lower levels of distress during phase 1 in the hypnosis group compared to the standard care group (median 0.0 [IQR 0.0-0.0] vs 0.5 [IQR 0.0-1.0], $P = 0.044$). No differences were found between groups for common levels of distress during the other phases, nor for peak levels of distress during any of the phases.

Parent and Child Reported Levels of Distress

Child and parent reported levels of distress and medical staff ratings of procedure difficulty are shown in Table 2. We found no differences in reported outcome measures between the hypnosis and standard care group. Most children (92.9%) and parents (92.9%) in the hypnosis group reported that the hypnosis had a relaxing effect.

Procedural Outcomes

Two patients were not able to fully complete the ARM procedure, 1 in the hypnosis group and 1 in the standard care group. One child refused to squeeze or push or answer questions about rectal sensation, the other child did not answer questions about rectal sensation. The procedure was rated "somewhat difficult" to "difficult" in 4 patients (23.5%) in the standard care group compared to 1 patient (6.7%) in the hypnosis group. The hypnosis was rated "somewhat difficult" to "difficult" in 5 patients (33.3%) in the hypnosis group. There were no statistically significant differences in procedural outcomes between groups (Table 3).

Discussion

To the best of our knowledge, this is the first study to evaluate the effect of hypnosis during ARM. The results of this study show that a brief session of hypnosis can reduce distress prior to the start of ARM but does not seem to affect the overall distress during the procedure. Both measures of distress reported by the non-blinded

and blinded observer showed lower distress scores in the hypnosis group prior to insertion of the ARM catheter.

Additionally, 92.9% of parents and children in the hypnosis group believed that the hypnosis had helped the child to relax. Even though there was an extra intervention in the hypnosis group, the ARM procedure in this group was not prolonged.

Other studies evaluating the effect of hypnosis in children during uncomfortable medical procedures such as needle-related procedures and transesophageal echocardiography have reported lower levels of distress during these procedures.[10,12,13] There are several possible explanations for why our findings differ from those studies. One important difference is that during ARM, children are asked to answer specific questions and actively follow instructions, such as squeezing and pushing. This requires the child to be focused on what is happening during the procedure, rather than being able to be distracted from the environment and focused on his or her own "safe place." Thus, in our study phase 3 of the ARM may have made the child less susceptible to hypnosis. Additionally, in our protocol, the hypnotherapist was sitting at the backside of the patient and was assisting during the ARM by inserting and holding the catheter. We chose this protocol to minimize the number of people in the room, which could cause extra distress for the child, and we wanted to design this study in a way feasible for daily practice. However, the position and multitasking of the hypnotherapist may have lessened the hypnotic effect during ARM.

Distress during ARM is a commonly encountered challenge in daily practice for which no standard approach is available at the moment. Recently, the effect of a preparatory child-centric educational video on child distress during ARM was assessed in a prospective randomized controlled trial.[19] This study showed that use of a psychoeducational video was effective in decreasing child and parental reported anxiety and child's heart rate and blood pressure prior to the procedure, as well as reported levels of distress upon completion of the procedure by a non-blinded observer. Although this study used a combination of objective and validated tools (heart rate, systolic blood pressure, and the Procedure Behavior Check List) to assess distress before and after ARM, distress during the procedure was not specifically measured. The combination of both an educational video and hypnosis may be valuable in reducing distress even more, especially since we noticed that most children scored points on the "information seeking" category of the OSBD, meaning they were asking questions regarding the medical procedure such as "what is going to happen next?". If children are more prepared for what will happen, they may feel safer and let themselves be distracted from the procedure more easily.

The effect of hypnosis has not yet been described during other procedures in the field of pediatric gastroenterology. It has, however, been described as an effective therapeutic intervention for children with functional gastrointestinal disorders, especially for functional abdominal pain.[20,21] This indicates that hypnosis could be used for a multitude of clinical applications in pediatric gastroenterology practice. The use of hypnosis during ARM did not require extra personnel and did not prolong the duration of the procedure, making it feasible to apply in daily practice. We believe the reason that the hypnosis intervention did not prolong the procedure is because the session was short, did not interfere with the ARM, and eased the introduction of the catheter.

Although the intervention led to lower levels of distress prior to ARM and is easily incorporable in daily practice, our study did not show that it reduced distress during the ARM according to our blinded and non-blinded observer. This may be secondary to our overall observed low mean levels of distress. The blinded observer used a tool that was not previously validated to evaluate distress because we did not find a validated child distress tool that did not require vocal input. Moreover, the tool only had a small range (4-point Likert scale). On its own, this may have negatively influenced the reliability of our distress measurements, but when combined with the validated distress measurement of the non-blinded observer, we believe this was a good combination to ensure reliability and decrease the possibility of bias in measuring distress.

Although both observers did not detect an effect of the hypnosis during the procedure, 93% of parents and children reported that the hypnosis helped the child to relax. If the use of hypnosis is safe, feasible, and is positively experienced by children and parents, one could argue that it would do no harm to offer it to patients. In our experience, the insertion of the manometry catheter is the most stressful event during ARM and hypnosis may reduce distress during this specific component.

Strengths of this study include the randomization of subjects, the presence of a control group, the use of a blinded observer, and the use of validated tools when available. In addition, the team of hypnotherapist and motility nurse was always the same to ensure consistent intervention for each subject. However, several factors can be identified as limitations to our study. First, since there were no preliminary data available to estimate the effect of the intervention, we could not perform a reasonable power analysis. Therefore, the study may have been underpowered and we may have not been able to detect the full effect of the intervention. Second, to ensure feasibility of the intervention we trained one of our own nurses to perform the hypnosis intervention. However, the nurse was not a

specialized experienced hypnotherapist which may have affected our results. Third, in our study protocol, we allowed the parents to be present in the procedure room. Parental behavior is known to be an important factor on the level of distress and coping of the child and has been shown to modulate a child's distress levels.[22,23] Parental behaviors may therefore have influenced our results. Moreover, parents who agreed to participate in this study were not blinded to the intervention and may have been "believers" in hypnosis. They may have biased themselves and their child by knowing that there was the possibility of an extra intervention to help the child relax. In addition, more children in the hypnosis group had a history of frequent enema usage. Although at the time of the ARM, rectal medication usage did not differ between groups, a history of frequent enema usage could have influenced the anticipated fear of the child. Depending on prior experiences, this could have increased or decreased anticipated fear of the rectal catheter. Finally, this study only enrolled children without psychiatric or behavioral disorders and our results are therefore not generalizable to all children undergoing ARM. However, by excluding these patients we were able to evaluate the effect of hypnosis in a homogenous population, in the future it would be valuable to determine if the intervention would be beneficial for children with behavioral disorders as well.

In conclusion, the results of this randomized controlled pilot trial show that a brief session of hypnosis may lower distress levels of children prior to, but not during ARM. According to most of the children and parents of children in our study who received the intervention, hypnosis helped the child to relax. Hypnosis during ARM is a feasible intervention that can easily be implemented in daily clinical practice without prolonging the procedure.

Supplementary Materials

Note: To access the supplementary materials mentioned in this article, visit the online version of *Journal of Neurogastroenterology and Motility* at http://www.jnmjournal.org/, and at https://doi.org/10.5056/jnm20274.

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