

Prospective Observational Study

Caudal Normal Saline Injections for the Treatment of Post-Dural Puncture Headache

Susanne Abdulla, MD, Walied Abdulla, MD, Dr.med.habil,
and Regina Eckhardt, Dr.rer.med

From: Department of Anaesthesiology and Intensive Care Medicine Klinikum Bernburg, Teaching Hospital, Martin Luther University Halle-Wittenberg, Bernburg, Germany

Dr. S. Abdulla is a clinical researcher with the Department of Anaesthesiology and Intensive Care Medicine Klinikum Bernburg, Germany.

Dr. W. Abdulla is a Professor of Anesthesiology with the Department of Anaesthesiology and Intensive Care Medicine Klinikum Bernburg Teaching Hospital, Martin Luther University Halle-Wittenberg, Bernburg, Germany.

Dr. Eckhardt is a consultant and medical researcher.

Corresponding author:
Prof. Walied Abdulla
Department of Anaesthesiology and Intensive Care Medicine
Klinikum Bernburg
Kustrener Str. 98, D-06406
Bernburg, Germany
E-mail: walied.abdulla@t-online.de

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Background: Post-dural puncture headache (PDPH) is the most common complication of procedures in which the dura mater is penetrated.

Objectives: To evaluate the effectiveness of caudal saline injections as a therapeutic approach for handling post-dural puncture headache.

Study Design: Prospective observational study between 1995 and 2010.

Setting: Associated teaching hospital.

Methods: A 5-cm 20-gauge short-beveled needle, connected by extension tube to a 20-mL syringe filled with normal saline was used for injection. During injection in increments (limited by patient discomfort), the patients were asked continually to quantify their pain experience on a visual analog scale (VAS) and on a 0-3 verbal categorical rating scale (VRS) after 50, 80 and 100 mL of infusion over a 20 minute period.

Limitations: This study is limited by its sample size, observational design, and lack of long-term outcomes.

Results: PDPH occurred in 60 of 1,716 patients undergoing dural puncture (3.5%). It was significantly more common in women and occurred more often in young adults. The rate was highest in the spinal catheter group (13%) and lowest in the Sprotte needle group (0.98%). Fifty-six patients underwent caudal saline injections which were repeated in sessions of 1-2 times a day for 1-2 days. Most patients (n = 48) needed 3 or 4 (n=18) sessions. Mean volumes during the 4 sessions were 120.0 mL, 114.9 mL, 106.5 mL, and 97.8 mL. Four patients were finally treated with a blood patch.

Conclusions: The use of fine gauge pencil-point needles may reduce the incidence of PDPH. The technique of repeated caudal saline injections is easy, rapid, and effective in providing the patient with almost immediate headache relief. In cases where this treatment fails, a blood patch should be considered. Observations from this study suggest that randomized, controlled, double-blind studies may be warranted.

Key words: Post-dural puncture headache (PDPH), dural puncture, spinal anesthesia, caudal saline injection

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The syndrome of post-dural puncture headache (PDPH) is the most common complication of commonly used procedures in which the dura mater is penetrated, such as diagnostic lumbar

punctures and spinal anesthesia, as well as during epidural injections with inadvertent dural punctures (1-25). PDPH was first described in 1898 by August Bier, who experienced this condition first-hand after

experimentation with spinal anesthesia with co-pioneer August Hildebrandt (26).

Modern anesthetic and interventional pain management techniques have reduced the incidence of PDPH considerably (27). However, PDPH and its treatment still remains a serious problem, especially in those cases requiring an epidural blood patch (28). This procedure has a success rate of about 70–98% and can be repeated if it fails to resolve the symptoms after the first attempt (29,30). Complications are rare, but include radicular pain from nerve root irritation or displacement, cranial nerve palsies, meningeal irritation, elevated intracranial pressure, paraparesis, cauda equina syndrome, infection, and subdural hematoma (29,31-35). It has been found that the success rate is lower if it is performed within the first 24 hours of lumbar puncture (36). In addition, its effectiveness is decreased if dura mater puncture is caused by a large-bore needle (37).

The immediate resolution of the headache with a blood patch is attributable to thecal compression raising the cerebrospinal fluid (CSF) pressure (29,30). An epidural injection of saline would, in theory, produce the same mass effect, and restore normal CSF dynamics. Therefore, the epidural placement of a saline bolus or infusions, which are relatively inert and sterile, has been advocated as an alternative to an epidural blood patch (29).

In 1972, Crawford reported the infusion of 1.0 to 1.5 L of Hartmann's solution over 24 hours as an effective measure for the treatment of PDPH (38). He placed an epidural catheter in the lumbar region and through it saline was infused over a 24-hour period. However, in patients whose epidural space was difficult to identify, an accidental dural puncture could take place depending on the experience of the anesthesiologist.

Therefore, caudal injection of normal saline might be preferable rather than epidural infusion at the same puncture spot where deformation of the spinal column might exist (39,40). This approach for the treatment of PDPH had already been recommended in 1956 (41). The procedure, however, was not generally acknowledged at that time and was soon forgotten. The discomfort of repeated caudal injections surely played a major role. Another reason might have been the increasing popularity of the epidural blood patch, which was introduced in 1960 by Gormley (42) into clinical practice and popularized in 1970 by DiGiovanni and Dunbar (43).

A decade ago, epidural saline infusion as an alternative strategy for dealing with PDPH was compared with epidural blood patch in 8 patients, with success

rates of 75% versus 100% (44). In a 2006 United States anesthesiologists survey of the treatment of PDPH, epidural saline boluses or infusions were employed infrequently, but considered to be an option by 32% of respondents (45).

The goal of this prospective observational study is to evaluate the effectiveness of caudal saline injections as a therapeutic approach for handling PDPH at an associated teaching hospital during a 15-year period. Efficacy should be judged both according to the extent of relief obtained directly after normal saline injection and according to the persistence of relief after treatment, as well as the number of necessary injections.

MATERIALS AND METHODS

Between March 1995 and March 2010, all patients treated in our hospital with caudal normal saline injection for incapacitating PDPH following spinal or epidural anesthesia provided for abdominal and bone surgery and analgesia for therapeutic interventions were included in our prospective observational study. Approval from our institutional review board was obtained in advance.

For each patient, the following data were recorded: age, height, weight, and sex; technique of dural puncture utilized, including type and gauge of needle or catheter, and level of placement; difficulties encountered in performing dural puncture; clinical symptoms; and the volume of normal saline injected caudally until back, buttock, or leg discomfort or pain appeared; the total saline injected was also recorded. The anesthesia record was also reviewed for evidence of inadequate anesthesia, defined as insufficient block for the planned surgical procedure.

Patients were informed about the risks and benefits of regional anesthesia and/or analgesia and the occurrence of PDPH with its classic symptoms, such as photophobia, nausea, vomiting, neck stiffness, tinnitus, diplopia, and dizziness in addition to severe cephalgia. They were instructed to inform the anesthesiologist in case of PDPH, when conservative treatment failed to improve the patient's symptoms. Conservative treatment consisted of the advice to take 24 hours bed rest and drink at least 2 L of fluid a day. In addition, reassuring the patient that the headache would likely resolve within a week was a usual practice; the use of painkillers was not prohibited.

Diagnosis criteria of severe PDPH were a clinical history of dural puncture associated with severe postural symptoms in patients who were disabled in their

daily activities and needed to stay in bed for most of the day. To use caudal normal saline injections as a therapeutic approach, patients should have an unbearable headache, refractory to any conservative treatment and aggravated by changing from the supine to the upright position as well as coughing and straining and the headache should not be more than 3 days after dural puncture. Furthermore, patients should be aged 18 years or older. Patients with defective hemostasis or suspected infection at the site of injection and patients with a body temperature over 38°C or a history of headache and/or difficult anatomic conditions were not eligible for injection of normal saline.

After discussing the risks and benefits with the patient and obtaining informed consent, the caudal normal saline injection was conducted by trained anesthesiologists under strict surgical aseptic conditions with the patient in the prone position with a pillow under the pelvis. The puncture site was first infiltrated with 1% lidocaine as a local anesthetic by palpating the tip of the coccyx with the finger and moving cephalad about 4 to 5 cm until the fingertip was over the sacral hiatus with prominent sacral cornua palpable on each side by moving the fingertip from side to side. For caudal injection, a 5-cm 20-gauge short-beveled needle, connected by extension tube to a 20-mL syringe filled with normal saline was used. The caudal space was first identified through the sacral hiatus, and the sacral hiatus was entered using the "loss of resistance" technique.

During the injection of normal saline in increments (limited by patient discomfort), the patients were asked continually to quantify their pain experience on a visual analog scale (VAS) between 0 and 10, with 0 representing no pain and 10 the worst imaginable pain. Likewise, pain was assessed by the patient on a 0-3 verbal categorical rating scale (VRS) (0 = none, 1 = mild, 2 = moderate, 3 = severe). Mild headache is defined as postural headache slightly restricting head and neck movement. The patient is not confined to bed and there are no associated symptoms. Moderate headache was defined as postural headache confining the patient to bed without associated symptoms. Severe headache was defined as postural headache causing the patient to be bedridden and associated symptoms. The associated symptoms were nausea, vomiting, dizziness, hearing loss, hyperacusis, tinnitus, photophobia, diplopia, stiffness of the neck and scapular pain. The patients' verbal responses were documented after 50, 80 and 100 mL of saline infusion over a 20-minute period. The saline infusion/injection was continued until patients indicated a remain-

ing tolerable level of headache by 10% to 20% on the visual analog scale (VAS) or mild on the verbal rating scale (VRS). Depending on the subjective condition of the patient, the maximum amount of infused normal saline was restricted to 220 mL for a single injection in all cases. The total saline infusion volume until the disappearance of headache was noted, the puncture needle removed, and the infusion site secured with sterile plaster. The patient was then asked to stay in the supine position for 15 minutes; effectiveness was evaluated by asking the patient to stand up and walk. The results of caudal normal saline injection on clinical signs were then classified into complete relief, incomplete relief of symptoms, or failure. Complete relief was defined as disappearance of all symptoms after injection. Incomplete relief of symptoms included clinically improved patients who probably were in need of further treatment with normal saline within the next 12 hours in order to resume normal daily activity. Failure included all patients with persistent severe PDPH after normal saline injection. If severe headache returned, a further saline injection was offered. In case of repeated failure, an epidural blood patch was offered to the patient. After each injection, patients in the hospital were asked to report to the ward or as outpatient to phone back if there was a return of any sort of pain. Patient satisfaction with the effectiveness of pain relief was recorded at the end of the caudal injection by using a 4-point scale which shows the verbal expressed satisfaction of assigned numerical values: 1 = worse, 2 = moderate, 3 = good, 4 = very good.

Results were predominantly descriptive and expressed as mean \pm standard deviations or medians plus minimum and maximum.

RESULTS

After reviewing our anesthesia database for dural punctures during regional anesthesia and/or analgesia, a total number of 1,716 patients were found to have undergone dural puncture during a 15-year period. In 60 (3.5%) of those patients, dural puncture led to PDPH. Four patients were excluded from caudal normal saline injections because of a history of headache ($n = 2$) or difficult anatomic conditions with severe ossifications and obesity ($n = 2$). Therefore, only 56 patients underwent caudal injections of normal saline for the treatment of PDPH and were analyzed. For 3 patients with unclear clinical and neurological symptoms, a cranial computed tomography (CT) scan was required in order to exclude other possible causes of headache. Thirty-

four (61%) were female and 22 (39%) were male. The age ranged between 26 and 63 years, with a mean age of 46 years. Table 1 shows clinical characteristics of the 56 patients and Fig. 1 shows the age distribution of the patients.

Twenty cases of PDPH were due to spinal anesthesia using a spinal needle of type Terumo (Terumo GmbH; Eschborn, Germany) (22-gauge) in 4 cases (4.5% out of 89 patients), Atraucan (Braun; Melsungen, Germany) (26-gauge) in 8 cases (3.8% out of 212 patients) and Pencan (Braun; Melsungen, Germany) (27-gauge)

in 8 cases (0.98% out of 811 patients); 36 cases (13%) occurred after use of spinal catheters Spinocath (Braun; Melsungen, Germany) (24-gauge) for spinal anesthesia in 276 patients and 4 cases (1.2%) were inadvertent dural punctures during epidural catheter placement minipack using a Tuohy needle (Smiths Medical-Portex; Grasbrunn, Germany) (16 gauge) (Table 2).

Information concerning technical difficulties encountered in performing spinal or peridural puncture could be ascertained in only 38 out of 56 patients (68%). Symptoms of PDPH occurred 8 to 16 hours after surgery; the patients were referred to our department for treatment 1-3 days after dural puncture. Headache occurred in all 56 cases (100%), neck pain in 52 (93%), vestibular signs (nausea and vomiting) in 26 (46%), cochlear symptoms in 22 (39%), and ocular symptoms in 25 (45%).

After a caudal injection of 50 mL of saline infusion in the first session, 48% (n = 27) of the patients reported a 50% reduction in headache. For the majority of the patients (n = 51, 91%), an 80 mL saline infusion created a 70% headache intensity decrease, and in 30 patients (54%) 100 mL induced pain relief of 85%. The mean volume of normal saline injected was 120 ± 16.2 mL in the first session, 114.9 ± 14.9 mL in the second session, 106.5 ± 15.2 mL in the third session and 97.8 ± 14.8 mL in the fourth session (Table 3).

One patient recovered completely from PDPH after the first session with normal saline injections. After the second session, 5 patients completely recovered from PDPH. Two patients who were considered as treatment failures after the second session preferred to be treated with an epidural blood patch because of their severe headache. In both cases the total amount of saline required exceeded 140 mL and 180 mL respectively, and a blood patch was finally successful in relieving PDPH. After the third session, 30 patients immediately improved, followed by complete resolution of symptoms within the following 24 hours. Eighteen patients needed 4 sessions to recover from PDPH. In 2 patients headache returned after 4 sessions; they were then successfully treated with a blood patch. Thus, all but 4 of the patients had a satisfactory outcome. Discomfort occurred in 45 patients (80%) after administration of the total amount of normal saline, and pain which was always preceded by discomfort occurred only in 8 cases (14%).

The duration of effect until the next normal saline injection was administered amounted to 8 ± 3 hours (median 8; range 1-24 hours) after the first injection,

Table 1. Patient characteristics and clinical data of the 56 patients (data are presented as mean ± standard deviation).

Patients	n = 56
Gender	
female	n = 34
male	n = 22
Age (yr)	46.7 ± 7.4
Body height (cm)	173 ± 5.2
Body weight (kg)	70.9 ± 6.2

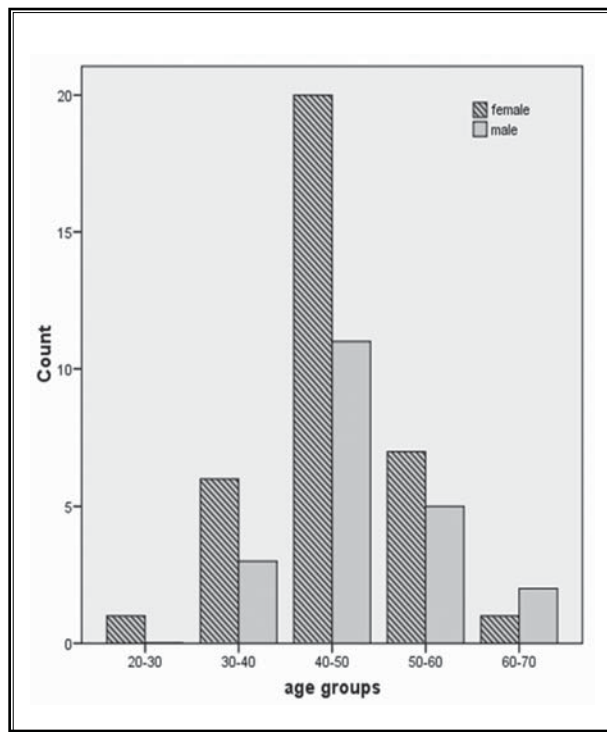


Fig. 1. Frequency of PDPH in various age groups

Caudal Normal Saline for PDPH

Table 2. *Needles and catheters (type, manufacturer, size), total number of patients (n = 1716) and total number of PDPH (n = 60)*

Spinal needle	Manufacturer	Gauge	Total Patients (n)	Total PDPH (n)	PDPH (%)
Terumo*	Terumo Corp	22	89	4	4.5
Atraucan*	Braun	26	212	8	3.8
Pencan* (Sprotte)	Braun	27	811	8	0.98
Spinal catheter Spinocath*	Braun	24 (29 N.)*	276	36	13
Peridural catheter minipack*	Smiths Medical-Portex	16	328	4	1.2

* 24 = Gauge of outside catheter, and 29 = Gauge of inside needle

Table 3. *Normal saline injections: frequency and amount of fluid required*

Statistical data	Volume 1st Saline injection n = 56	Volume 2nd Saline injection n = 55	Volume 3rd Saline injection n = 48	Volume 4th Saline injection n = 18
Mean	120.0	114.9	106.5	97.8
Standard Deviation	16.2	14.9	15.2	14.8
Median	120	120	100	100
Minimum	100	80	80	80
Maximum	220	180	140	120

10 ± 4.9 hours (median 8; range 1-24 hours) after the second injection, 18.7 ± 7.4 hours (median 24; range 8-24 hours) and 23 ± 3.3 hours (median 24; range 10-24 hours) after the third injection.

Discussion

The syndrome of post-dural puncture headache (PDPH) is a well-established complication of procedures in which the dura mater of the spinal cord is punctured. However, the incidence of PDPH after spinal anesthesia varies greatly among studies. It is related to the size and design of the spinal needle used, the experience of the personnel performing the dural puncture, and the age and sex of the patient (6,29, 46,47).

Patients included in our prospective observational study during a 15-year period were suffering from dull or throbbing headache which started in the frontal or occipital head region and became generalized, radiating into the neck and shoulder area and associated with neck stiffness. The overall rate of headache was 3.5% (60 of 1,716). The PDPH rate was highest in the spinal

catheter group (13%) and lowest in the Sprotte needle group (0.98%).

Among 60 cases with PDPH, the alarmingly high incidence of PDPH of 60% in the spinal catheter group was attributable to the use of a large gauge catheter and cutting edge needle inside. Between March 1995 and August 1999, catheter spinal anesthesia and/or analgesia were mainly performed at our institution. In addition, 7% of PDPH was induced by inadvertent dural punctures during epidural catheter placement using a Tuohy needle (16-gauge). The remaining 20 PDPHs (33%) were recorded among 1,112 patients who underwent lumbar puncture using spinal needles for surgical and other interventions. The overall incidence of PDPH in the 3 spinal needle groups was 1.8%. Between 1995 and 1999 the Terumo and Atraucan needles were often used. Thereafter lumbar puncture was performed mainly with Sprotte needles (Pencan). The PDPH rate was significantly lower in the Sprotte group compared with both Terumo and Atraucan groups, and it was also significantly lower in the Atraucan group as

compared to the Terumo group. In fact, the use of fine gauge pencil-point needles, such as the Sprotte needle, may produce a greater reduction in the incidence of PDPH, which varies with the type of procedure and patients involved (48,49). The theoretical advantage of the Sprotte needle was its tapered "pencil-point" tip with lateral displacement of the distal orifice; this was intended to bring about an atraumatic splitting of the dural fibers rather than the cutting action of the Quincke spinal needle, which is similar to the common venipuncture needle in design (50). In addition, the correct size of the needle for any dural puncture is the smallest gauge that allows the operator to perform the intended procedure with a reasonable success rate.

In accordance with the literature, PDPH occurred more often in young and middle-aged adults and was significantly more common in women than in men (61% versus 39%, respectively) (51). Five decades before, Vandam and Dripps (47) reported that the highest incidence of PDPH was in the second and third decades, with a gradual decline thereafter. They also identified a greater incidence in women. Young patients with a lower body mass index seemed to have the highest risk of developing headaches after dural puncture (52). In the elderly, a less stretchable dura mater, due to either atherosclerosis or age-related mechanical changes in the epidural space, might explain why the incidence is low in this age group.

Once the diagnosis of PDPH was made, caudal normal saline injections were considered for obtaining relief, particularly when headache persisted and was disabling to the patient, or when nausea, vomiting, visual disturbance, or tinnitus occurred. Normal saline is a relatively inert and sterile solution. Caudal saline injection appears to be an attractive alternative, as patients with PDPH are often unwilling to accept another "injection in the back at the same puncture spot." In addition, patients with a history of lumbar spine surgery or significant spinal deformities may also benefit from this approach as opposed to an interlaminar blood patch. However, normal saline would be more prone to dissipation through tissue planes and to rapid re-absorption than would whole blood (50). Therefore, normal saline would be expected to disperse quickly from the epidural space, allowing re-expansion of the subarachnoid space and return of the headache. Repeated caudal saline injections obviously avoid this problem. Some investigators have reported that early treatment with normal saline can be more effective when injections are repeated since symptoms are more

severe as the CSF leak is greater (39-41). However, other authors recommend 24 hours of conservative therapy since the natural history of PDPH is one of spontaneous resolution (53,54). Traditional methods, such as bed rest, lowered head position, administering oral opioid and nonopioid analgesics, increasing oral fluid intake, applying an abdominal pressure girdle to raise the intra-abdominal pressure and with it, the epidural pressure, and reassuring the patient that the headache will likely resolve within a week, have been shown to be marginally effective. Although conservative therapy has been the practice for over 100 years, it has now largely been discarded because of patient discomfort. In addition, it is time-consuming and has virtually no benefit for the patient.

When normal saline was caudally injected in our patients, headache diminished, beginning in the occipital area. After injection of 80 mL saline, pain intensity decreased on average by almost 70%, but all patients still claimed to have remaining frontal and retrobulbar pain. One hundred mL saline reduced pain, on average, 85%. The remaining pain indicated by the patients amounted to 10-20% of the initial symptoms on the VAS or mild on the VRS. Caudal saline injections, if treated successfully, should be repeated in sessions of 1-2 times a day for 1-2 days before occurrence of headache with its symptoms. The injecting process was stopped as soon as the patient indicated satisfactory relief of PDPH. However, the reported effectiveness in the literature remains highly variable because some investigators consider only total relief from symptoms as success, whereas others include incomplete relief of symptoms (41,55-57). In our study, the effectiveness of caudal saline injection to treat PDPH was high because both complete and incomplete relief of symptoms were considered as a success. It was also noticed that patients complained of unpleasant sensations of warmth and tightness down the legs during the injections. There were no other specific side-effects particularly due to repeated entry into the caudal canal apart from the inconvenience to the patient while performing the procedure. However, there are reports in the literature that visual impairment caused by retinal hemorrhage is a rare but significant complication following epidural fluid injection and epiduroscopy (58). The retrobulbar pain mentioned in our study must be interpreted with some caution. It might be caused by increasing ocular pressure or be explained, at least in part, by the symptoms of PDPH. However, retrobulbar pain should be kept in mind while performing this procedure as a first-

line treatment for PDPH because any potential benefits that may arise from caudal normal saline injections would be lost by retinal hemorrhage during overzealous injections (58).

In the 4 cases where normal saline injections failed to be effective, the standard procedure of blood patch was performed successfully. The mechanism of relieving PDPH by a blood patch is thought to be related to a dual mode of action not possessed by saline injections, namely compression of the thecal space as well as clotting and occluding the dural perforation by preventing further CSF leak (29). There is only one study comparing both techniques in 16 randomly assigned patients (44): epidural saline injection resolved PDPH in 75% of patients, compared to a 100% success rate with epidural blood patch. Transient dysesthesia of the lower extremities occurred in both groups, while back pain at 24 hours after the treatment was experienced significantly more often in the blood patch group (44). However, larger randomized studies are needed to compare the risk-benefit ratio of both approaches.

This article has certain limitations due to the observational nature of the study (59-66). For obvious ethical reasons, blinding was not possible. In addition, there is no comparison group to truly compare outcome and

efficacy of normal saline injections versus other forms of treatment like blood patch or spontaneous improvement without a therapeutic intervention in PDPH. Even then, the value of results is pertinent, due to the fact that complications are most commonly evaluated in observational studies. However, additional randomized, prospective, controlled studies are required to clearly establish the benefits and value that can be obtained with this treatment. Finally, we were unable to analyze long-term outcomes after treatment with normal saline because it was up to the patient to phone back if there was a return of any sort of pain.

CONCLUSIONS

Caudal saline injection for PDPH should be administered by anesthesiologists experienced in this technique. It is also important that the injection be given slowly and repeated if needed. According to our clinical experience and research, it is easy, rapid, and effective in providing the patient with almost immediate headache relief. In cases where this treatment fails, a blood patch should be considered. The observations from this study suggest, however, that randomized, controlled, double-blind studies may be warranted.

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