Placebo Medication Use for Behavior Management in an Adult with Autism

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Abstract: Buspar (buspirone) is an anxiolytic medication used to reduce symptoms associated with anxiety. The current study provides a case description of a man diagnosed with autistic disorder where Buspar was prescribed on an “as needed” basis in order to decelerate tantrum behavior associated with undifferentiated anxiety. After successful reduction of tantrum behavior over time, caregivers reported a routine drug-effect time of less than 5 minutes. With consent through the individual’s employer’s governing human rights committee, a placebo pill was administered in place of the Buspar in the man’s work environment. The placebo has successfully maintained reduction of the tantrum behavior. Given that the experimental treatment is less restrictive on the individual than the previous treatment, a treatment reversal was deemed unethical. Theories of mechanism and maintenance are discussed, as well as limitations to the current study. Directions for future research and implications for adults with autism are also reviewed.

Behavioral outbursts are common comorbid symptoms in individuals diagnosed with an autism spectrum disorder. Often such behavioral outbursts are able to be systematically analyzed to determine the function of the behavior and develop subsequent treatment plans (Iwata, Dorsey, Slifer, Bauman, & Richman, 1994). However, there exist occurrences where the functional analysis does not indicate clear motivations for the problem behavior despite appropriate manipulation of the controlling antecedents and consequences, or a given setting is not able to support conducting a functional analysis whether due to the physical environment or limitations of staffing. In the latter instance, functional behavior assessments are often conducted in lieu of functional analyses to determine motivation of problem behaviors, however, findings from such assessments in regard to validity and reliability are often conflicting (Hall, 2005; Lerman & Iwata, 1993; Thompson & Iwata, 2007). The resultant or alternative consequence is often the use of psychotropic medications to manage problem behaviors and maintain treatment effects over time (Posey & McDougle, 2000). This trend appears to be even more so in the management of adults diagnosed with autism (Tsakanikos, Costello, Holt, Sturmey, & Bouras, 2007).

Given the commonplace “real world” practice of medication prescription to manage behavioral symptoms, the question arises as to whether or not behavior and anxiety management strategies can be subsequently learned over time by an individual due to the psychosomatic effects of a given psychotropic medication. That is, when a behavioral episode occurs and a medication is then administered, the temporal experience is calmness or some other (problem behavior) incompatible physical experience. Overtime, this behavioral shaping could lead to the successful removal of the medication without a return of the problem behavior due to learned coping mechanisms.

The current study describes a case where a placebo was substituted for episode-specific anxiolytic medication use. The findings provide a potential area of future study by providing preliminary support of this possibility of symptom management training from psycho-
tropic medication use over time and ultimately reducing the use of prescribed medications.

Method

Participant and Setting

The participant, a 34-year-old Caucasian man, was diagnosed with autistic disorder at the age of three by a psychologist in private practice. Diagnosis was later confirmed according to the Diagnostic and Statistical Manual, Third Edition (DSM-III; American Psychiatric Association) criteria for infantile autism at the age of 6 by a pediatric neurologist at a major children’s hospital. Additional diagnostic and standardized descriptive information (conducted by qualified and credentialed professionals on different occasions during his late adolescence and adulthood) included the following: (1) the participant received a score of 15 (cut off score of 12 for autism diagnosis) on Module 2 of the Autism Diagnostic Observation Schedule–General (ADOS-G; Lord et al., 2000); (2) a score of 25 (threshold cut off score of 15 for autism diagnosis) on the Social Communication Questionnaire (SCQ; Rutter, Bailey, & Lord, 2003); (3) a Communication domain score of $SS < 20 \ (M = 100, SD = 15$; other domains and overall Composite scores were not available during archival review) on the Vineland Adaptive Behavior Scales (VABS; Sparrow, Balla, & Cicchetti, 1984); and (4) he achieved a standard score of 40 (M = 100, SD = 15) an age equivalent of 6 years, 6 months on the Peabody Picture Vocabulary Test–Third Edition (PPVT-III; Dunn & Dunn, 1997). The derived findings from these measures are assumed to remain stable over time.

The participant demonstrated behaviors compatible with moderate to severe autism (i.e., severe deficits in communication and socialization, repetitive and perseverative behavior routines present but largely not disruptive to daily life functioning) with moderate intellectual disability levels (e.g., limited communication, sufficient adaptive behavior repertoire to meet daily needs with reduced supervision, ability to conduct and participate in routine work). He communicated verbally, however, demonstrated limited spontaneity in language used, talked in one-to-three word phrases, and was largely unintelligible to unfamiliar persons.

The participant was successfully maintained in his home setting with his parents and daily respite care providers. He attended a sheltered workshop for employment 25 hours per week where he completed repetitive daily tasks (such as commercial-product box constructions, folder and letter stuffing, etc.) in a large room in close proximity to other employees with supervising staff typically five to fifteen feet away. The workshop was operated by the state developmental disabilities board.

Target Behavior Defined and History of the Behavior

The target behavior, collectively referred to as “tantrum behavior,” was defined as a predictable escalation pattern that began with air swallowing and rapid, forced burping, profuse sweating (in the absence of strenuous exercise), shouting food-oriented words, forceful jumping and yelling, self-injurious behavior (SIB) including hitting self on the back of the neck with resultant temporary tissue damage, and occasional aggression towards others including grabbing at and pushing others. A typical behavioral episode lasted from five to thirty minutes prior to medication intervention. Past behavior predicted that if the tantrum did not receive outside intervention, the man would self-inflict extensive tissue damage with resultant emergent medical care needed. That is, if the tantrum was left to run its course, the man would require medical attention and potential hospitalization. A functional analysis of the problem behavior was not conducted in the workshop setting as the staff were not trained in proper implementation and were without appropriate equipment to do so. Instead a functional behavior assessment was conducted by the agency’s behavior specialist. Results yielded were inconclusive and the function more often than not appeared to be of an automatic-reinforcement or sensory origin without clear antecedent patterns.

The participant’s history was positive for tantrum behavior without SIB beginning at age six where block-and-ignore behavioral strategies were successfully employed. He added the SIB component at age 12 where
physical aggression was successfully redirected to aggressing towards a pillow. The behavior again increased in intensity during early adulthood where the addition of daily dosed Risperdal (risperidone) was successful in decreasing the problem behavior in both frequency and intensity. Risperdal was discontinued after four years of use due to medical complications from adverse drug side effects.

Buspar (buspirone) was introduced two months following the discontinuation of Risperdal in order to again reduce the tantrum behavior’s frequency and intensity. Buspar, selected due to its low likelihood of physical and medical side effects, was prescribed on an as-needed-basis (PRN) and a behavior plan was developed for home and work in order to warrant dosing of Buspar. If the participant began to engage in the tantrum behavior’s initial escalation stages (forced air swallowing and burping, exclamation of food words, arm flapping, pacing and profuse sweating), he was redirected to a known calming activity (repetitive stacking of interlocking blocks). If the participant did not reduce the tantrum onset symptoms after approximately 20 minutes, or if he escalated the behaviors further to SIB or other-directed aggression, he was then directed to proceed to the nurse’s station and to request “medicine.” If the participant did not deescalate the behavior within 40 minutes after ingesting the Buspar, he was again provided another Buspar pill administration. After approximately 18 months of successful psychotropic intervention and medication management of the behavior, staff across settings noticed a new behavior pattern of an almost immediate drug effect where the man was calm within two to three minutes, and always under five minutes of the medication administration.

Data Collection and Interobserver Agreement

Data were collected continuously across home and work settings by trained caregivers including workshop staff and supervisors, home respite care providers and parents. The baseline period consisted of 11 months for the home setting and 15 months for the work setting where the individual was behaviorally redirected (i.e., hit a pillow) but Buspar was not provided in order to alleviate the tantrum symptoms. It should be noted that the difference in baseline periods allowed for the introduction of Buspar in the home setting 4 months prior to its introduction in the workshop in order to assess for side effects, symptom-reduction effectiveness, and provide a multiple baseline across settings. The first intervention phase (administration of Buspar PRN protocol) lasted for 27 months in the work setting and is ongoing (at time of publication) in the home setting. The second intervention phase (administration of a placebo pill in place of Buspar PRN protocol) is documented graphically for 21 months and is ongoing (at time of publication) in the work setting. Data were recorded for frequency of the tantrum behavior onset, as well as administration of the Buspar or placebo pills. Once the placebo pill protocol was implemented, duration data were also taken on each behavioral episode.

Interobserver agreement (IOA) was not obtained during the course of the study due to difficulty in providing staffing and resources in the workshop setting, as well as limited number of persons present in the home setting. It should be noted both these identified obstacles to obtaining IOA are “real-world” barriers that again often lead to medication prescription due to the predictability of participant response under psychotropic control. However, strict medication protocol was implemented in the work setting where warrant for medication administration was verified first by direct supervisors (i.e., line staff directing the participant to request medication) and second by trained nursing staff (i.e., registered nurse who verified protocol behaviors in order to dose administration of Buspar and/or placebo), a “natural” IOA measure per se.

Procedure

Given the drastically reduced time for Buspar effectiveness noted across environments on a consistent basis, the intervention was simply to insert a placebo pill in place of the Buspar medication. The behavior and administration plan remained as previously implemented with the exception of reduced time for effectiveness. If the tantrum symptoms did not re-
mit within ten minutes post the PRN placebo pill administration, the participant was then provided the Buspar PRN administration and the Buspar administration protocol was implemented from that point forward for the remainder of the behavioral episode.

Placebo pill substitution protocol for the Buspar psychotropic medication administration was presented to and secured approval through the Ethics and Human Rights Committee of the workshop’s governing agency, the state’s developmental disabilities board.

Selection of the placebo pill considered the Buspar pill’s size, shape, color, and taste. After not being able to secure an appropriate sucrose substitute (i.e., “sugar pill”) 50 milligrams (the lowest dosage commercially available) of the vitamin supplement B_{12} was selected for placebo use. The vitamin was selected due to its similarity in color, shape and taste (including lack of coating), as well as absent anecdotal report and empirical evidence to support its use in behavior change or modification of autism symptoms.

Results

Figure 1 illustrates the placebo treatment effects across phases in the work environment. The implementation of Buspar significantly reduced the frequency of tantrums and maintained those treatment effects over 6 months. Introduction of the placebo substitution continued to successfully maintained treatment effects with the additional reduction of Buspar administration.

Figure 2 illustrates the effects of Buspar on home tantrum behavior with indication of placebo implementation in the work setting. While the home rate of tantrum behavior did not significantly change with the introduction of Buspar, the tantrum behavior underwent qualitative changes that warranted the family to continue the medication and introduce it.
into the work setting. These qualitative changes included significantly reduced tantrum duration, a quicker return to “calm” baseline state, and notably better control over the label treatment of anxiety symptoms including calm behavior in unpredictable (e.g., vacation away from home) and non-preferred (e.g., doctors’ appointments, restaurant change) settings. Overall, it should be noted that work provides a more stable and predictable environment, and thus a less anxiety-inducing place, in that the man goes at the same time every day on specified days, works in the same area performing the same class of jobs, interacts with the same people and follows the same daily work routine. The only noticeable change occurs when line staff and supervisors are absent wherein other familiar persons substitute in the absentee’s place. Home, on the other hand, is not able to provide as predictable an environment in that schedules can change without notice (e.g., periodic doctor’s appointments, respite staff cancelling without advance notice and subsequent interruption to routine daily events, weekly appointments such as speech pathology cancel without substitution of providers, etc.). As an example, even if the routine work environment closed on an inclement weather day, the effect would be seen at home where the man would stay for the remainder of the day. Therefore, qualitative changes in target behavior including most notably reduction in duration were enough to support the continuation of the medication and further implementation into other (work) environments.

For both environments, not captured in the frequency count data, was the effect of reduced severity in tantrums. After the introduction of the Buspar, the aggression towards self and others that occurred in advanced tantrum phases was significantly reduced to almost nonexistent. Therefore, while the protocol called for dosing at initial tantrum phases and once the behaviors continued for the set amount of time, they rarely escalated further into the aggression component after the introduction and stability of Buspar.

Figure 2. Frequency of tantrum behavior episodes at home across treatment phases.
Discussion

The placebo pill protocol appears to have been effective in maintaining long term problem behavior reduction in a controlled setting. While the term “placebo effect” is typically wrought with negative connotation due to notorious interference with medication trials, it appears there may be a positive place for placebo effects to harbor. These preliminary data are particularly hopeful in that anecdotal experience notes that many adults with autism are placed on medication protocols and maintained on multiple medications in order to provide behavioral control, with a growing body of evidence to shed light on this practice (Kwok, 2003). While functional analyses and behavioral manipulation would be the initial preferred manner of behavior change it does not yet appear this is the normative for adult ASD symptom management. Perhaps this case report can at least provide pilot evidence that psychotropic medications, while successful, can be faded out and replaced with impotent substitutes, leading to reduced medication use (and associated side effects and potential long term adverse effects) while maintaining the achieved quality of life for such individuals. Corollary benefits could additionally include increased access to lesser-restrictive environments and occupational settings.

The operating mechanisms of placebo effects are still largely unknown. Often they are attributed to cognitive structures such as belief and optimism, expectancy effects and interrelationship issues between provider and patient (see Sandler, 2005). However, such operating structures would not appear to hold true for this individual, or even most individuals with autism, given the diagnostic deficits in socialization and impaired interpersonal relationships. Furthermore, the participant was never told at any time that the medication was expected to make him “feel better” and instead, per written protocol, he was to request the medication himself. In wake of the widely publicized Secretin trials, the authors, while attempting to explain the open and obvious placebo effects, contended that, “It is implausible that the children with autism actually showed improved behavior [due to Secretin placebo effects] because of their own expectations of improvement” (Sandler & Bodfish, 2000). Such statements, along with the current case study participant and subsequent findings lend credence to alternate theories of placebo operating mechanisms for some groups of persons.

More recent research is investigating the role of classical conditioning in observed placebo effects (Sandler, 2005). This operating mechanism would better describe the treatment effects observed here, especially given that the man was initially dosed with the potent medication and then, post-placebo implementation, continued to receive Buspar dosing at home. Said another way, he was maintained on an intermittent reinforcement schedule for medication management of the target symptoms. Therefore, the conditioning stimulus (Buspar) was still occasionally delivering the unconditioned stimulus (psychosomatic drug experience) leading to the conditioned response (return to baseline behavioral state). It should also be reiterated that this individual likely demonstrates a true comorbid anxiety disorder diagnosis. This should be taken into consideration when generalizing or designing future research endeavors. Early on in the tantrum behavior cycle the man demonstrates severe and profuse sweating, an indication of a physiological symptom of anxiety versus a “voluntary” behavioral response. Perhaps the placebo effect lies in the combination of the physiological state of anxiety with the physiological experience of situational-specific medication and the consistent pairing of associated calmness and symptom resolution.

This report’s findings are substantially limited due to the quasi-experimental control design, as well as absent IOA measures. The study would have been further validated if a treatment reversal condition was present, or multiple baselines and placebo conditions occurred across environments. It should be reiterated that this was not a controlled study and therefore the true causality of behavioral control overtime is only suspect. However, the current findings are still hopeful in directing future investigations in the area. Forthcoming endeavors should examine the role of placebo effects in medication management for individuals with autism, as well as utilizing such effects in intervention methodologies. Such re-
search should undergo strenuous experimental control of both single-case and group designs.

References


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