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A pilot study to improve venipuncture compliance in children and adolescents with Autism Spectrum Disorders

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Abstract

Objective—Medical procedures, particularly venipuncture (the puncture of a vein especially for the withdrawal of blood), can cause serious distress and behavior disturbance for many children. Noncompliance to blood draws can have significant ramifications in both research and clinical settings. The negative reactions may be exacerbated in individuals with autism spectrum disorders (ASD). Even so, there has been little research into the prevalence of the problem or effective intervention procedures. In response to these concerns, we developed and evaluated the Blood Draw Intervention Program (BDIP). The program was designed to be easy to use, require little provider or family time, effectively reduce negative behaviors and increase blood draw compliance.

Method—In a quasi-randomized trial over the course of approximately 18 months, 58 of 210 families with children with ASD participating in a larger study of phenotypic and genotypic factors reported significant concerns about blood draws and elected to use the BDIP.

Results—Completion of the program increased blood draw compliance rates from 85.4% to 96.6 % (OR = 4.80, 95% CI = 1.12, 20.59 p = 0.03).

Conclusion—Results indicate the efficacy of the program in a research setting and suggest a potential clinical application. The current intervention, unlike many others for the same or similar difficulties proposed in the past, was successful without requiring extensive time, training, or effort on the part of providers, parents or their children, nor did it require large scale institutional changes.

Keywords

autism spectrum disorders (ASD); venipuncture; systematic desensitization

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Preliminary results from this study have been presented at the International Meeting for Autism Research 2009 and the Society for Developmental Behavioral Pediatrics 2009 annual conference.

Venipuncture, one of the most common medical procedures in children, is also one of the most feared aspects of hospital visits for children. [1] In the process of conducting a larger study about autism spectrum disorders (ASD) which required venipuncture, we found that a significant number of families we contacted were reticent to participate because of their concerns that their child with ASD would not be able to complete the blood draw due to anxiety, fear, and/or behavioral noncompliance. Children are not restrained or sedated for blood draws in our research program. Of the families who did enroll, there was only an 85.4% completion rate for the blood draw for their children with ASD. On becoming aware of this issue, we reviewed the data and found that despite the frequency of venipuncture and its importance in medical and research settings there was little information available on the prevalence and level of difficulty in typical or atypical populations. There was also little information on the efficacy of specific therapeutic interventions to increase compliance to blood draws.

Previous research as well as direct parental report has shown that children can exhibit a distress response in medical settings. This can include displays of fear, anxiety or acting out behaviors. [2] Only a small number of studies, however, have documented the presence and extent of distress in typically developing children undergoing venipuncture procedures.[1, 3-5] Upon observation, Humphrey, Boon, Chiquit van Linden van den Heuvell, and van de Wiel (1992) found that 83% of pre-school aged children and 51% of primary school aged children experienced “high levels of distress,” defined as a rating of 3 or higher on a 5 point outsider-observer scale. Additionally, a high proportion of this distress bordered on “unacceptable distress” due to the participant’s loss of self-control.[6] In such cases, parents and providers frequently resort to physical restraint or sedation in order to complete the procedure[1].

To date, we could not find any studies describing the reaction of individuals with ASD to venipuncture. There have been a small number of studies that assessed general medical fears in individuals with developmental delay and/or ASD. In one study, individuals with developmental difficulty (DD) were found to have more common and more frequent negative emotions towards medical procedures than typical peers.[7] Evans, Canavera, Kleinpeter, Maccubin, and Taga (2005) used parent report and found that children with ASD have greater medical fears as compared to chronologically and developmentally age-matched peers.[8] MacNeil, Lopes, and Minnes (2009) found that children with ASD have significantly higher levels of anxiety related to medical procedures than did community-based populations.[9]

Strategies to increase compliance

In attempts to alleviate or prevent a child’s distress during medical procedures, researchers have employed a number of different strategies, many of which are based on cognitive behavioral therapy (CBT). CBT is a psychotherapeutic approach aimed to help people develop coping strategies for psychological and situational problems. [10] Common CBT methods include breathing exercises, relaxation techniques, modeling, positive reinforcement, imagery, behavior rehearsal, parent and provider coaching, filmed modeling, and systematic desensitization. Multiple studies have documented the efficacy of CBT procedures in areas of medical coping. [1112, 13] A report by the American Society of Anesthesiologists task force on acute pain management gives support for the use of family training on behavioral techniques for pain management. [14] Other behavioral strategies, outside the realm of CBT, are also increasingly used. These include interventions such as preparation with social stories and picture schedules, which are evidence based practices in working with children who have ASD.[15-17]

Support for the effective use of behavioral strategies specifically in venipuncture procedures is limited to a study by Thurgate and Heppell (2005). They employed a CBT-based protocol combining relaxation training and graded exposure (i.e., systematic desensitization) and did not perform venipuncture until the child signaled they were ready. This process took anywhere from half an hour to several weeks. By using these techniques they decreased the preparation time before a blood draw in a case study of a typically developing child, and established their unit as a local referral center for children with needle phobia. [2]

In response to the lack of empirically-supported information to help individuals with ASD and their families with venipuncture procedures, our laboratory developed a program designed specifically with this population in mind. The Blood Draw Intervention Program (BDIP) is simple, easy to use, and individualized. In addition, it is practiced at home before the blood draw and therefore does not increase the duration of the visit.

METHODS

Participants

Children participating in this study were enrolled from a larger investigation as part of the Simons Simplex Collection (SSC) or the Boston Autism Consortium (AC); both studies were looking at the phenotypic and genotypic factors in ASD. As part of their enrollment in the SSC and AC, diagnostic and cognitive assessments were conducted and a blood draw was attempted. All families who were enrolled before the BDIP was implemented served as a control group (n= 239). For the next 18 months, each subsequent family (n= 210) was offered enrollment in the BDIP. 58 families decided to use the program due to their concerns about their child's ability to complete the blood draw. The age range of participants is 0-20.9 years of age.

Children involved in this current study had a diagnosis of ASD confirmed using DSM-IV-TR criteria, the Autism Diagnostic Observation Schedule (ADOS), [18] and the Autism Diagnostic Interview-Revised (ADI-R).[19] The latter two assessments were performed by research reliable examiners. The use of these two measures combined is the current gold standard for the diagnosis of ASD. Children with ASD were all also administered an age and developmentally appropriate cognitive measure: The Mullen Scales of Early Learning, [20] the Differential Ability Scales, 2nd Edition, [21] or the Wechsler Abbreviated Scale of Intelligence. [22] Severity of ASD symptoms were calculated using the Calibrated Severity Scale (CSS). [23]

Materials

The BDIP consisted of five components (details available from the first author). The first included instructions for the parents, with an outline explaining how to practice with their child. The second section included a set of instructions for the child. These instructions were written in the first person and were designed to reflect what was written in the parent instructions, but in more simplistic language and format. The third section of the kit was a social story based on the guidelines of Gray and White (2002).[24] The social story was individualized for each child, integrating a parent-chosen salient reward as a motivator. The fourth section was a Boardmaker picture schedule. The Mayer-Johnson® program Boardmaker provides an inventory of picture communication symbols representing words and concepts, and is often used by special educators and speech and language pathologists for augmentative and alternative communication and other skill development. The picture schedule depicted how a reward would be achieved for good behavior and completion of the blood draw, whereas tantrums and negative behaviors would not yield a reward. Finally, the

fifth section included a packet of venipuncture materials (rubber gloves, alcohol swabs, band-aids, an elastic tourniquet, and a 5ml plastic syringe without a needle).

Procedure

For the intervention group, parents were sent detailed instructions on how to use the five components of the BDIP. Each step of the practice session was outlined in the instructions and aimed to gradually increase exposure to the feared stimuli, approaching the ultimate goal of interaction without anxiety. Parents were encouraged to practice a few times a day for at least two weeks before the research venipuncture. Practice sessions lasted approximately 5-10 minutes. The practice was broken down into sessions, each describing a portion of the blood draw. Initially, children were encouraged to play with the kit of materials, inspecting and examining them as they felt comfortable. If at any point the child seemed anxious, parents were urged to drop back to a previous session and work until the child appeared comfortable with that particular material or portion of the blood draw process. Before practicing on a child's own body, parents were encouraged to have their child practice on a parent, sibling, or stuffed animal to lessen initial anxiety. The intervention schedule was flexible, and it was suggested that parents tailor it to their child. The culmination of the practice sessions was a parent-administered pretend venipuncture, incorporating all previously mastered steps. A phone number was included in the packet for parents to call if they had any questions about the procedure.

At the research blood draw all families, whether or not they were using the BDIP, were asked to answer a comprehensive medical history form, allowing time for the child to acclimate to his or her surroundings. When the family was ready to have their blood drawn, the genetic counselors ensured that the nurse was prepared, to minimize the amount of time the family was potentially waiting in the blood draw room. The number of people in the room varied, as did the order in which family members had their blood drawn, depending on the specific family's request. Trained nurses employed standard phlebotomy procedures, and drew approximately 30 milliliters (2 tablespoons) of blood from all family members. If a parent requested use of a topical anesthetic, Eutectic Mixture of Local Anesthetics (EMLA) cream was available for use thirty minutes prior to the draw. It was not standard practice, however, to use or offer this product because in past clinical experience the application of the cream was an aversive experience for many children with ASD. In addition, the cream requires a half hour to be effective, thereby signaling to the child what was going to happen and lengthening anticipatory distress.

Statistical Analyses

The primary analysis of this study looked at the impact of the BDIP on successful blood draw. A binomial logistic regression model with successful blood draw as the dependent variable and group as the independent variable was used to look at this relationship. Successful blood draw was defined as whether or not the patient was able to provide a sufficient blood sample for genetic testing; group was defined to be a dichotomous variable that identified whether the patient was in the control group or whether the patient participated in the BDIP. This analysis was conducted using an intent to treat approach. In the intent to treat approach all families who were offered the BDIP were included in the intervention group and those subjects who were seen through the larger research study prior to the inception of the BDIP served as the control group.

Binomial logistic regression models were also used in secondary analyses to look at the relationship between the BDIP and successful blood draw using an efficacy approach. In the efficacy approach only those subjects who agreed to participate in the BDIP were included in the intervention group, while those subjects who refused participation were excluded from

the analysis. The control group in this analysis again consisted of those subjects who were seen through the larger research study prior to the inception of the BDIP. Binomial logistic regression was also used in secondary analyses to look at the relationship between successful blood draw and age, gender, CSS, full scale IQ score, verbal IQ score, and non-verbal IQ score. Data for all subjects were included in these secondary analyses.

All analyses were conducted using the statistical software package R (version 2.8.1, R Foundation for Statistical Computing, Vienna, Austria). Tests with a significance level of less than 0.05 were considered significant.

RESULTS

Prior to inception of the BDIP, 239 children were seen through a larger research study on the phenotype and genotype of ASD. Of those 239 children, 204 (85.4%) were able to provide a sufficient sample for genetic testing. Noncompliance among this group was due either to family refusal to attempt a blood draw on their child due to concerns about their anxiety or behavior or an array of behavioral difficulties at the visit which prevented the nurses from successful venipuncture, such as tantruming and bolting from the room. After the BDIP was developed any family who endorsed concerns about their child's ability to complete venipuncture was offered the BDIP. 210 families were offered the intervention. Of the 210 families, 199 (94.8%) had a child who was able to provide a sufficient blood sample for genetic testing. Of the 210 families who were offered the intervention, 58 families completed the BDIP (28%). Of these children, 56 (96.6%) were able to provide a sufficient blood sample. The outcome rate for the 152 subjects who did complete the BDIP was 143 out of 152 (94.1%). The control group and the BDIP group did not differ with respect to age, Calibrated Severity Scale score (CSS), gender, full scale IQ score, non-verbal IQ score, or verbal IQ score. Characteristics of the children by group can be found in Table 1.

According to both the intent to treat approach analysis and the efficacy approach analysis, the blood draw kit increased the odds of successful blood draw (OR = 3.10, 95% CI = 1.53, 6.28 and OR = 4.80, 95% CI = 1.12, 20.59 p = 0.030, respectively). Age, CSS, gender, full scale IQ score, non-verbal IQ score, and verbal IQ score were not associated with successful blood draw (table 2). Furthermore, the impact of the BDIP was not moderated by age, CSS, gender, full scale IQ, non-verbal IQ, or verbal IQ.

DISCUSSION

Over a quarter of parents in our cohort used the BDIP. This indicated that many parents had significant concerns about the emotional and behavioral reactions of their children in a blood draw setting and were worried about their ultimate ability to complete blood draws. Use of the BDIP was associated with a significant increase in the compliance rate for blood draw procedures within our research population. Children who completed the intervention were five times more likely to complete the blood draw.

Post-blood draw comments by parents and children indicated that overall they appreciated the service being offered. A few families mentioned that they liked the flexibility of the protocol which allowed them to adapt the practice schedule to fit their lives and their child's learning style. Feedback from a small number of parents also indicated that our intervention protocol was not particularly challenging or time consuming for busy families. With average practice sessions lasting less than 10 minutes per day, families were able to incorporate this design easily into their schedule.

Our family reports regarding ease of implementation contrast with those of Love et al. (1990) which suggested hours of parental time spent practicing and coaching for other

specific fears.[13] Other researchers, such as Duff (2003) have suggested that there need to be significant, difficult to implement changes in clinical practice in order to improve venipunture compliance. [1] The current intervention, by contrast, was successful without requiring extensive time, training, or effort on the part of parents or their children, nor did it require institutional changes.

Results from our intervention indicate the program's successful use in a research environment. However, venipuncture occurs within a variety of settings, including outpatient clinics, inpatient surgery, as well as primary care. Due to the training component and parent involvement, this program has the potential for dissemination among a wide range of private practices, hospitals, and centers specializing in the medical care of children with ASD. Future research should look to extend the intervention to a broader audience, in clinical as well as research arenas. Primary care settings are where most children are first exposed to procedures involving needles and trials within this context should be explored. [25]

Potential limitations of our study include that this may not be a representative sample of the population of children with ASD. Families in our study were primarily recruited from patients seen in a specialty clinic of a large, urban hospital, which may not represent other settings. Our quasi-experimental design did not randomly assign participants to groups, and groups were based on the availability of the intervention however there were no critical differences between the two groups that we would expect to change the level of venipuncture refusal. Families overly concerned about their child's anxiety towards venipuncture may have chosen to decline participation. However, the fact that we discussed this issue openly with families may have encouraged families to participate who might have refused participation before the BDIP was offered, thus making our results even more remarkable. Additionally, this intervention is not appropriate in an inpatient setting where blood draws are needed acutely. However, these families could be informed of the positive effects of using the kit and perhaps be encouraged to practice with their child to potentially reduce anxiety for subsequent blood draws. There were no measures of anxiety for the children before and after they used the blood draw kit, so it is unknown if those feelings as well as the final outcome also improved. Finally, prents were not interviewed to find out how often or for what length of time theypracticed with the kit, which may have impacted whether the child engaged in the blood draw.

Humphrey et al.'s (1992) finding that younger children experience more venipuncture distress than older counterparts may indicate a need for intervention programs to target a young age group.[6] Intervention at an age when a child's understanding and experience of pain, discomfort, and unfamiliar medical procedures is naive can shape their framework for all future procedures. Given that many parents who used the BDIP indicated their child had prior difficulty with venipuncture, use of this program in a preventative way may decrease rates of new occurrences of distress and negative behaviors.

Through direct observation we have seen many children with ASD display high levels of anxiety towards venipuncture procedures, which has often been exacerbated by negative experiences during these procedures. Behavioral techniques are effective for the reduction of distress to painful medical procedures in typically developing children; [12, 26] however, such paradigms have not been disseminated in a practical, easy-to-use format for providers and families of individuals with ASD. For these reasons we created and implemented an intervention protocol designed to replace these negative strategies with appropriate coping mechanisms and behavioral techniques to assist children with ASD in completing venipuncture without excessive distress. Long-term benefits of the program remain to be seen, and future research should look into maintenance of effects, to see if the skill set acquired for this brief amount of time alters coping systems for future venipuncture. We

focused on a population with ASD, as relevant to our larger study, but the techniques adapted are supported in the literature for children with a range of concerns as well as typically developing children. Future studies should look to replicate our findings, to help determine if psychological approaches such as systematic desensitization and aspects of cognitive behavioral therapy may be effective in addressing additional issues for the population of children with ASD.

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References

1. Duff A. Incorporating psychological approaches into routine paediatric venipuncture. Archives of Disease in Childhood. 2003; 88
2. Thurgate C, Heppel S. Needle phobia: Changing venepuncture practice in ambulatory care. Paediatric Nursing. 2005; 17:15–8. [PubMed: 16315811]
3. Cohen L, Blount RL, Cohen R, Johnson V. Dimensions of pediatric procedural distress: Children's anxiety and pain during immunizations. Journal of clinical psychology in medical settings. 2004; 11:41–7.
4. Ost I. Acquisition of blood injection phobia and anxiety response patterns in clinical patients. Behavior Research and Therapy. 1991; 29:323–32.
5. Duff A, Brownlee K. The mangaement of emotional disterss during venipuncture. Netherlands Journal of Medicine. 1999; 54
6. Humphrey G, Boon C, Chiquit van Linden an den Heuvell G, van de Wiel H. The occurrence of high levels of acute behavioral distress in children and adolescents undergoing routine venipunctures. Pediatrics. 1992; 90:87–91. [PubMed: 1614786]
7. Matson J, Rivet T. Characteristics of challenging behaviours in adults with autistic disorder, PDD-NOS, and intellectual disability. Journal of Intellectual and Developmental Disability. 2008; 33:323–9. [PubMed: 19039692]
8. Evans D, Canavera K, Kleinpeter F, Maccubin E, Taga K. The fears, phobias and anxieties of children with Autism Spectrum Disorders and Down SYndrome: Comparisons with developmentally and chronologically age matched children. Child Psychiatry and Human Development. 2005; 36:3–26. [PubMed: 16049642]
9. MacNeil B, Lopes V, Mines P. Anxiety in children and adolescents with Autism Spectrum Disorders. Reserach in Autism Spectrum Disorders. 2009; 3:1–21.
10. Anderson S, Morris J. Cognitive behavior therapy for people with Asperger Syndrome. Behavioural and Cognitive Psychotherapy. 2006; 34:293–303.
11. Elliot C, Olson R. The management of children's distress in response to painful medical treatment for burn injuries. Behaviour Research and Therapy. 1983; 21:675–83. [PubMed: 6661152]
12. Jay S, Elliot C, Ozolins M, Olson R, Pruitt S. Behavioral management of children's distress during painful medical procedures. Behavioral Reserach and Therapy. 1985; 23
13. Love S, Matson J, West D. Mothers as effective therapists for autistic children's phobias. Journal of Applied Behavioral Analysis. 1990; 3:379–85.
14. American Society of Anesthesiologists. Practice guidelines for acute pain management in the perioperative setting. Anesthesiology. 2004; 100:8.
15. Ali S, Fredirickson N. Investigtating the evidence of social stories. Educational Psychology in Practice. 2006; 22:355–77.
16. National Autism Standards Project. [December, 18, 2009] 2009. http://www.nationalautismcenter.org/affiliates/reports.php

17. Dettmer S, Simpson R, Myles B, Ganz J. The use of visual supports to facilitate transitions of students with autism. Focus on Autism and Other Developmental Disabilities. 2000; 15:163–9.
18. Lord, C.; Rutter, M.; DiLavore, P.; Risi, S. Autism Diagnostic Observation Schedule (ADOS). Los Angeles, CA: Western Psychological Services; 2002.
19. Rutter, M.; LeCouteur, A.; Lord, C. The Autism Diagnostic Interview - Revised. Los Angeles, CA: Western Psychological Services; 2003.
20. E, M. Mullen Scales of Early Learning. Circle Pines, MN: Pearson Assessments; 1995.
21. Elliott, C. Differential Ability Scales (DAS-II). San Antonio, TX: Harcourt Assessments; 2007.
22. Weschler, D. Weschler Abbreviated Scale of Intelligence (WASI). San Antonio, TX: Harcourt Assessments; 1999.
23. Gotham K, Pickles Lord C. Standardizing ADOS scores for a measure of severity in autism spectrum disorders. Journal of Autism and Developmental Disorders. 2009; 39:693–705. [PubMed: 19082876]
24. Gray, C.; White, A. My social stories book. Gateshead, Great Britain: Arthenaeum Press; 2002.
25. Gaskell S, Binns F, Heyhoe M, Jackson B. Taking the sting out of needles: Education for staff in primary care. Paediatric Nursing. 2005; 17:24–8. [PubMed: 15906895]
26. Blount RL, Bachanas PJ, Powers SW, Cotter MC, Franklin A, Chaplin W. Training children to cope and parents to coach them during routine immunizations: Effects on child, parent and staff behaviors. Behavior Therapy. 1992; 23:689–705.

Table 1

Sample Characteristics (N = 449)

	Group		*p*
	Control (N = 239)	**BDIP (N = 210)**	
Gender			
Male, n (%)	196 (82.0)	180 (85.7)	.31
Female, n (%)	43 (18.0)	30 (14.3)	
Age (yr), mean (SD)	8.09 (3.41)	7.90(4.00)	.59
Severity score, mean (SD)	6.21 (2.58)	6.54 (2.28)	.17
Full Scale IQ, mean (SD)	83.77 (33.90)	80.50(33.30)	.48
Nonverbal IQ, mean (SD)	85.65 (32.30)	84.78(33.15)	.85
Verbal IQ, mean (SD)	79.55 (41.72)	75.39 (36.11)	.43

BDIP, Blood Draw Intervention Program.

Table 2

Odds of Successful Blood Draw

Characteristic	Odds Ratio (95% CI)	*p*
Group—intent-to-treat approach	3.10 (1.53, 6.28)	.002
Group—efficacy approach	4.80 (1.12, 20.59)	.03
Age	1.08 (0.99, 1.19)	.09
CSS	0.95 (0.84, 1.08)	.45
Full Scale IQ	1.00 (0.98, 1.01)	.82
Nonverbal IQ	1.00 (0.98, 1.02)	.91
Verbal IQ	1.00 (0.98, 1.01)	.50
Gender	0.82 (0.38, 1.77)	.60

CI, confidence interval; CSS, Calibrated Severity Scale.