Critical Review:

Behavioural Intervention for Pill Swallowing: Children and Adolescents with Medical Diagnoses

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This critical review examines whether behavioural intervention is an effective method for teaching children and adolescents with medical conditions to swallow oral medication (pill form). Eight studies, four single subject research designs and five case studies, were reviewed. Overall, research provides a suggestive level of evidence for the use of behavioural techniques in teaching children and adolescents to swallow pills. Methodological limitations and clinical implications for Speech-Language Pathologists are discussed.

Introduction

Difficulty swallowing oral medication in pill form is often reported in young children and adolescents. One third of adolescents (Hansen, Tulinius, & Hansen, 2008) and over half of children between the ages of 6 and 11 have reported difficulties with pill swallowing (Meltzer, Welch, & Ostrom, 2006). These difficulties exist and persist for a variety of reasons, including, but not limited to inexperience, taste, pill size, bodily discomfort, and affect (Hansen, Tulinius, & Hansen, 2008).

Oral administration of medication is thought to be economical, convenient, and beneficial with regards to absorption (Verma, Thakur, Deshmukh, Jha, & Verma, 2010). Given that most medications are administered orally, effective management of pill swallowing can increase adherence to medications and benefit medical treatment (Hansen, Tulinius, & Hansen, 2008). However, attempts to modify oral medications (e.g., crushing) can lead to suboptimal treatment, toxicity, and the avoidance of these medications due to adverse taste (Verma et al., 2010). Consequently, the ability to swallow pills is a vital skill for all individuals.

Pill swallowing difficulties can negatively impact medication adherence. The negative effects of poor medication adherence are most prominent and significant in children and adolescents with medical conditions. Often, children with medical conditions require the administration of oral medication, whether it be infrequently or on a daily basis. As such, poor medication adherence caused by pill swallowing difficulties may, in some cases, be life threatening (Wright, Woodcock, & Scott, 1969). Therefore, it is crucial for Speech-Language Pathologists to evaluate intervention methods, insofar as their scope of practice allows, that teach children how to safely and effectively swallow pills.

Objectives

The primary objective of this paper is to critically evaluate the literature on behavioural therapeutic techniques for pill swallowing in children and adolescents with a medical diagnosis. The secondary objective of this paper is to discuss clinical implications and provide evidence for continued research in this field.

Methods

Search Strategy

Computerized databases, including PubMed, ProQuest PsycARTICLES, and ProQuest Research Library, were searched using the following search strategy:

> [(pill swallow) OR (pill dysphagia) OR (oral medication)] AND [(treatment) OR (intervention) OR (teaching)]

Reference lists of previously searched articles were also used to obtain other relevant sources.

Selection Criteria

Studies selected for inclusion in this critical review were based on population demographics (children under the age of 21) and health status (present medical diagnosis). No limitations were placed on study design. Articles published prior to 1980 were excluded.

Data Collection

Results of the literature search, in concordance with the selection criteria above, yielded single subject research designs and case studies.

Data Analysis

Single subject research designs were evaluated using the criteria set forth by Logan, Hickman, Harris, and Heriza (2008). Case studies were evaluated using the criteria set forth by Atkins and Sampson (2002).

Results

Autism Spectrum Disorder (ASD) and Attention Deficit Hyperactivity Disorder (ADHD)

Ghuman, Cataldo, Beck, and Slifer (2004) assessed a behavioural training protocol for pill-swallowing difficulties in four children with ASD and ADHD (ages 6-9 years) using a single-subject research design. In treatment, participants were taught to swallow incrementally larger placebo pills (graded subtasks) using modeling, prompts, gestures, and visual aids. Caregivers were trained on the researchers' protocol and home practice was assigned.

Performance during the final training session demonstrated that two children (50%) learned to successfully swallow the capsules in the clinical and home setting, one child (25%) was able to swallow the capsules in the clinical setting, and one child (25%). Ghuman et al. predicted that the difficulties experienced by the latter two children could be accounted for by their learning history (e.g., coerced swallowing).

A relative strength of this study is the detail in which the behavioural training protocol is outlined, allowing for replication; however, results of the study indicated poor generalizability and no statistical analyses were performed. Furthermore, despite reporting data on overall language scores (Preschool Language Scale-3) and ADHD symptom severity, the researchers failed to report whether either of these measures could account for or help explain the reduced level of success demonstrated in 50% of the participants. Overall, this study qualifies as weak level V evidence; therefore, the interpretation of these results must be guarded.

Beck, Cataldo, Slifer, Pulbrook, and Ghuman (2005) used a single subject research design to examine the effectiveness of behavioural treatment of pill swallowing difficulties in 8 children (ages 4-9 years) with ADHD with ASD (research sample) or without ASD (clinical sample). Six of the eight children in the study had an additional learning or psychiatric diagnosis. Training protocol entailed desensitization, graded subtasks using cake decoration, verbal prompts, and contingent reinforcements.

Visual inspection of the data gathered at the final training session demonstrated that seven out of eight children had learned to swallow pills in the clinic, of which six had also generalized to the home setting.

Generalizability of the protocol across administrators (therapist to parent) and settings (clinic and home) is a major strength of this study; however, no statistical analyses were performed. Furthermore, parents in the clinical sample were instructed to continue whichever method of medication administration they were using prior to the study, whereas parents in the research sample were trained on using the study's pill-swallowing protocol. Neither the rationale behind the different approaches nor their effects were reported. This may account for the discrepancy in generalizability between groups. As such, this study qualifies as weak level V evidence and the interpretation of these results must be guarded.

Developmental Delay and Chronic Illness

Babbitt, Parrish, Brierley, and Kohr (1991) used a single subject research design (noncurrent multiple baseline across subjects) to evaluate the effectiveness of pill-swallowing training in children (ages 3.5-17.5 years) with chronic illness co-morbid with moderate to profound developmental delay. Explicit verbal instructions, graded subtasks, and contingent rewards were used during the pill swallowing protocol. Inappropriate behaviour was ignored and the child was redirected to the task. Instruction and structure were gradually faded as the children expressed success.

Pill swallowing success was recorded throughout treatment and visually analyzed. Three out of four children (75%) were able to successfully swallow their prescription-sized pills by the end of the training period and skills were maintained between 12 and 22 months post-treatment. Two cases reported not only maintenance but also subsequent improvement of the skill.

This study provides moderate level III evidence. Furthermore, strong interrater reliability (mean = 99.95%) on outcome measures and skill maintenance was reported. A lack of statistical analyses remains a major limitation. Due to the highly individualized treatment plans for each of the participants and modifications made to the protocol, replicating the study would be challenging. Furthermore, the role of the parent in training in teaching pill swallowing was unclear. Finally, the researchers failed to analyze the time required to promote generalization and assess maintenance of pill swallowing. Overall, the results of this study provide a suggestive level of evidence.

Chronic Illness

Walco (1986) reported a case study that employed a graded protocol with chunks of ice to teach a 13-year-old patient with leukemia to pill-swallow. When oral medication was presented, the patient was observed to gag and choke. Crushed medication in thickened liquids

(e.g., apple sauce or ice cream) was inconvenient due to the loss of food via chronic vomiting.

Training involved the use of ice in graded subtasks and trial swallows of the prescribed medication. Verbal cues were used to help the patient relax. Results reported that the patient was able to swallow the largest chunk of ice and the prescribed medication on day two of training. At an eighth month follow-up the patient was able to not only maintain the skill, but was able to swallow larger sized capsules.

Strengths of this case study include face validity and information regarding maintenance. However, the case study is limited in its design, leaving out key qualitative components such as the author's philosophical stance, systematic analysis of data, possible triangulation, and information regarding generalizability. Furthermore, despite an adequate rationale, a major flaw of the study was using ice as a training stimulus. Allowing ice to dissolve may lead to a learned behaviour that would result in dissolving medications; this can be counterproductive since strong tastes can cause aversive reactions to swallowing oral medications. Overall, this study provides an equivocal level of evidence.

Pelco, Kissel, Parrish, and Miltenberger (1987) described two case studies that evaluated behavioural interventions for pill swallowing difficulties in four-year-old children with chronic illnesses (hyperammonemia or severe asthma). For the child with hyperammonemia a pill-swallowing protocol that employed verbal instruction, relaxation, modeling, shaping, and contingent reinforcement. Visual analysis of post-treatment data demonstrated that the child was able to swallow pills without any difficulties. For the child with severe asthma the aforementioned strategies were combined with physical guidance and resulted in the ability to pill-swallow. According to parent report, gains in both children were maintained six months post-intervention.

Strengths of these case studies include a credible argument for the use of the case study design, employment of quality control measures (100% interrater reliability), and a detailed and explicit research approach. Furthermore, researchers were able to support pill-swallowing success by demonstrating a subsequent improvement in ammonia levels for the child diagnosed with hyperammonemia. This cross-check provides strong evidence for the medical benefits of their chosen protocol. Some limitations of the study include omitted position statements and the lack of a first cut conceptual framework. Overall, these case studies provide a suggestive level of evidence for behavioural treatment of pill swallowing.

Sallows (1980) used a single subject research design to examine the effectiveness of a behavioural pill-swallowing therapy technique that utilized modeling, graded subtasks, verbal praise for effort, and self-directed learning with a 16-year-old girl with acute lymphocytic leukemia. Sallows reported data on mean number of swallows and pills per trial during treatment sessions (10 sessions spanning seven weeks). Visual inspection of the data demonstrated progress as defined by the decrease in the mean number of swallows per trial (22.5 to 1.13). Visual inspection also elucidated that the improvement was not due to changes in the number of pills per trial. Self-report at five months, two years, and four years post-treatment demonstrated maintenance of skills.

A detailed protocol allowing for replication is a relative strength of the study, whereas lack of statistical analyses remains a major limitation. Furthermore, Sallows purports that *in vivo* practice contributes to pill swallowing success to a greater extent than other techniques, such as giving information, passive modeling, and self-directed learning; however, the data to support the claims was not reported. Additionally, gagging was reported to be the primary concern but was not measured. Overall, this study qualifies as weak level V evidence. Taken together with the clinical feasibility of the methodology and positive results, this paper presents with a suggestive level of evidence.

Funk, Mullins, & Olson (1984) reported a case study on teaching pill swallowing in 9-year-old boy with acute lymphocytic leukemia. The therapy had incorporated relaxation exercises, modeling, and shaping procedures (e.g., graded subtasks). After three weekly sessions and weeklong home practice the patient was able to swallow the target size medication. At a three-month follow-up the patient was not only able to maintain his ability to swallow the target-size medication but also able to swallow larger sized pills.

This study qualifies as weak level V evidence. Despite having face validity and follow-up information regarding maintenance and generalization, the study is limited by a lack of information regarding the author's philosophical stance, systematic analysis of data, possible triangulation, and identification of issues for future research. Overall, this study provides an equivocal level of evidence.

Garvie, Lensing & Rai (2007) retrospectively assessed the efficacy of pill-swallowing training in 23 patients, aged 4 to 21 years, living with HIV/AIDS. The protocol used a combination of modeling, graded subtasks, and patient-directed session length. The researchers

reviewed patient charts to gather data on medication adherence and subsequent health benefits (viral load suppression and CD4 T-cell% improvements). Appropriate analysis, which included the Mantel-Haenzel χ^2 test, Wilcoxon signed-rank test, and calculation of Spearman's rank correlation coefficient, revealed significant improvements in adherence from baseline to six months post-pill-swallowing training completion (p=.038) and CD4+ T-cell% (p=.004). A trend demonstrating improvements in viral load suppression six months post-pill-swallowing training was noted. Results revealed that the number of sessions required to complete training increased with age (p=.001).

A major strength of the study was the crosschecking of reported pill adherence with measures of improvements in immune function. Limitations of the study include a small sample size, a lack of a control group, variable timing of data collection, and incomplete data sets. Furthermore, patients with known adherence difficulties receive additional support from allied health professionals; as such, the effects of other support sources remain unaccounted for. Overall, this case study qualifies as level V evidence; however, its use of statistical analyses and significant findings provides a suggestive level of evidence for the medical benefits and efficacy of pill-swallowing training.

Discussion

This critical review examined the efficacy of behavioural intervention in treating pill swallowing difficulties in children and adolescents with medical conditions. Overall, there was a suggestive level of evidence indicating that behavioural intervention is a valid and feasible option for addressing pill-swallowing difficulties and that further investigation is required to create timely, economical, and effective therapies.

Many methodological issues arose when comparing the studies in this review. Firstly, a distinct lack of statistical evaluation of the data was observed. Specifically, seven out of eight studies did not perform statistical analyses on any of their data; analyses were primarily conducted visually. Secondly, each study used a different operational definition of pill swallowing success, making comparisons across studies difficult to ascertain. The qualitative and subjective nature of the studies further perpetuates this difficulty. Therefore, due to risk of subjective bias, it can be challenging to put these therapies into practice.

Many of the participants used across the studies presented with diagnoses or medical histories that call into question whether their language skills were typically developing. It is well known that prolonged hospital stays during early childhood and diagnoses of ASD and ADHD can have an adverse effect on language development. Therefore, receptive language skills, specifically the ability to follow directions (one step, two step, etc.) may have been affected and consequently impacted the participants' ability to master pill-swallowing skills. Despite reporting some data on overall language skills, most studies did not evaluate the effect of the child's language skills on their ability to master the task.

One of the many challenges that exist in comparing studies with multiple medical diagnoses is assessing motivation. It is likely that, depending on the diagnosis, course of treatment (e.g., chemotherapy) and the effect of the medication itself (e.g., Dexedrine) may have adverse effects on an individual's overall motivation. In fact, Hankinson & Slifer (2013) assessed oral medication adherence in a 17-year-old female with a diagnosis of mixed connective tissue disease, a diagnosis of renal disease, and self-identified low positive affect and motivation. Despite subclinical depressive symptoms, pill-swallowing training had to be combined with psychological counseling (i.e., cognitive-behavioural therapy) in order to increase adherence. As such, motivation can have a crucial role in pill swallowing training and consequent medication adherence.

Additionally, different medical diagnoses require pills that vary in dimensions beyond pill size (e.g., coating, shape, and taste). Different training stimuli were used across the studies (e.g., ice, cake decorations, placebo capsules, etc.) and success was often measured not by the successful swallow of the training stimuli, but by the ability to swallow their own prescription medication. This may affect generalizability of skills across settings and medications. Furthermore, individuals with chronic illness, such as cancer, may suffer from xerostomia (dry mouth) or sialorrhea (excessive drooling) causing added difficulties when learning to swallow pills. These limitations must be accounted for when translating these methods into clinical practice.

A final challenge arises from the age of participants. As Garvie et al. (2007) noted, older children require a larger number of intervention sessions in order to master the skill. This is further corroborated by Hankinson & Slifer (2013); their participant required over 15 sessions and psychological counseling in order to achieve the desired outcome. Most studies within the review did not explore the effect of age on pill-swallowing training; however, taken together, these studies provide evidence for future exploration of differential therapeutic approaches between children and adolescents.

Conclusion

The research evaluated in this critical review provides a suggestive level of evidence for the use of behavioural intervention for pill swallowing difficulties, indicating a need for further research.

Clinical Implications

First and foremost, the behavioural interventions discussed substantiate the role of Speech-Language Pathologists in treating pill-swallowing difficulties. Secondly, the suggestive level of evidence provided by these studies offers variations of protocols that are replicable and can be easily integrated into practice. It is therefore left to the clinician to design the most appropriate intervention based on each individual client. Finally, clinicians should consider the effect of language, age and motivation when designing therapy for children and adolescents.

Future Recommendations

Ongoing examination of the efficacy of behaviourally based interventions and the roles of language, age, and motivation in pill-swallowing training are highly recommended, specifically through the use of randomized controlled trials, larger sample sizes, and systematic evaluation of data. Future research is needed to delineate which therapeutic techniques and session designs are best suited for children versus adolescents.

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