

Effectiveness of Pediatric Pill Swallowing Interventions: A Systematic Review

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abstract

BACKGROUND AND OBJECTIVE: Pediatric patients commonly have difficulty swallowing pills. Targeted interventions have shown to improve medication administration and treatment compliance. The objective was to evaluate studies performed on pill swallowing interventions in the pediatric population since 1987.

METHODS: We performed a comprehensive PubMed search and a bibliography review to identify articles for our review. We selected articles published in English between December 1986 and December 2013 that included >10 participants aged 0 to 21 years with pill swallowing difficulties without a comorbid condition affecting their swallowing. Reviewers extracted the relevant information and rated the quality of each study as “poor,” “fair,” or “good” based on the sample size and study design.

RESULTS: We identified 4 cohort studies and 1 case series that met our criteria. All 5 studies found their intervention to be successful in teaching children how to swallow pills. Interventions included behavioral therapies, flavored throat spray, verbal instructions, specialized pill cup, and head posture training. Quality ratings differed between the articles, with 3 articles rated as “fair,” 1 article as “good,” and 1 article as “poor.”

CONCLUSIONS: Pill swallowing difficulties are a barrier that can be overcome with a variety of successful interventions. Addressing this problem and researching more effective ways of implementing these interventions can help improve medication administration and compliance in the pediatric population.

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The pediatric population has a unique set of barriers to oral medication compliance and administration. One common barrier is children's inability to swallow pills. Factors that can affect a child's success in swallowing pills include developmental stage, fear, anxiety, intolerance of unpleasant flavors, and failure to appreciate the risks associated with noncompliance. In 2008, a survey was done of 304 parents with children aged 0 to 26 years.¹ This survey found that 30% to 40% of parents had children who rejected or refused a pill or liquid medication, and >50% had children who were unable to swallow a standard size pill or small capsule.¹ The majority of the children in the survey were otherwise healthy, with only 10.9% documented to have a chronic illness.¹ Other studies have found that struggles in pill swallowing can extend into adolescence and can have significant detrimental effects for those with chronic illnesses.^{2,3} In 2008, Hansen et al² interviewed 89 healthy adolescents aged 11 to 20 years about their struggles with swallowing tablets. More than one-third of the adolescents reported difficulties with swallowing pills caused by factors such as taste, size, feelings, and bodily discomfort.² Another study, done in 2010 by Hommel and Baldassano,³ found that difficulty swallowing pills was one of the most common identified barriers in treatment adherence for adolescents with inflammatory bowel disease. The commonality of pill swallowing problems in children and its potential to have a detrimental effect on compliance and administration highlight the importance of targeted interventions to help children swallow pills.

In 1987, Pelco et al⁴ reviewed the relevant literature on interventions to address pill swallowing difficulties in children. The authors found 5 studies that used behavioral techniques such as instruction, modeling, positive and negative reinforcement, and shaping

to help children swallow pills.⁴⁻⁹ All studies reported routine pill acceptance shortly after their intervention, and 3 studies reported continued pill acceptance 3 to 6 months after the intervention.⁴⁻⁹ Unfortunately, all studies mentioned in the review had small sample sizes, ranging from 1 to 6 children.⁴⁻⁹ Thus, knowledge about the effectiveness of the tested interventions was limited.

Since the 1987 review, a variety of interventions have been studied to help children swallow pills. These interventions include behavioral therapies, flavored throat spray, simple verbal instructions, a specialized pill cup, and head posture practices.¹⁰⁻¹⁴ The main objective of this systematic review is to evaluate the published literature since 1987 that focuses on pill swallowing interventions, and our main outcome of interest is how effective these interventions are in helping pediatric patients successfully and consistently swallow pills.

METHODS

Data Sources and Search Strategy

We performed a comprehensive PubMed search to identify all relevant articles for our main objective for this article. Our final search strategy included the following Medical Subject Headings terms (*) and keywords: "(Deglutition* OR Swallowing) AND (Child* OR Children OR Pediatric OR Pediatrics*) AND (Oral administration* OR Capsule OR Capsules* OR Tablet OR Tablets* OR Pill OR Pills)." To ensure that our search strategy was adequate, we identified 2 sentinel articles from a previous literature search.^{11,12} Both of these articles were found in our search results. We reviewed titles of all identified articles to find those that studied our topic of interest and met our inclusion criteria as described below. These results were filtered with abstract reviews and screening of full-text articles. Last, we reviewed reference lists of the final articles to

find any additional studies that met our inclusion criteria.

Study Selection and Data Abstraction

Figure 1 presents our flow diagram of study retrieval and selection. We restricted our search strategy to include articles that were published in English between December 1986, just before the last review, and December 2013.⁴ Our population of interest included pediatric patients ages 0 to 21 with pill swallowing difficulty. We excluded articles that focused on children with a diagnosis of dysphagia or any other condition associated with swallowing dysfunction such as severe developmental disabilities. We included all types of pill swallowing interventions and focused on randomized control trials and cohort studies. We excluded case-control studies and included only studies with >10 subjects.

Our main outcome of interest was whether participants who received the intervention successfully and consistently swallowed pills. In addition, we were interested in the long-term effects of the intervention, such as improved medication adherence after the study was complete. We extracted the necessary data from the included articles. We recorded the year of publication, study question, study population, study design, main intervention, and overall results or conclusions for each of the final articles.

Next, we performed a quality assessment for each of the articles by evaluating their internal validity. For each study, reviewers graded the sampling strategy, strength of outcome measurement, and consistency of intervention delivery based on prespecified criteria as good, fair, or poor. Sampling strategy was rated based on how well the authors sampled their population of interest to minimize bias. Strength of outcome measurement was assessed as how reliable the study was at

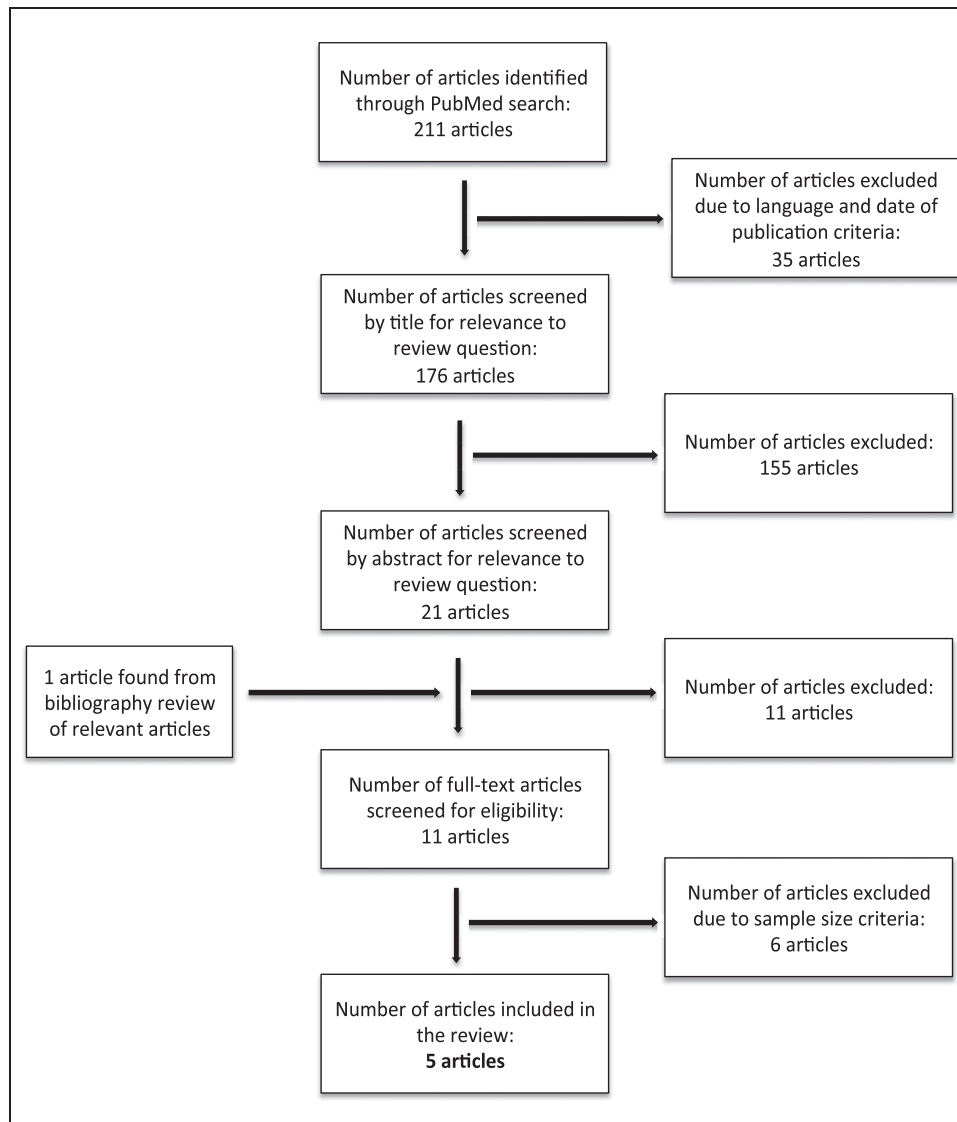


FIGURE 1
Study selection flowchart.

capturing whether a child was able to successfully and consistently swallow pills. A 1-time demonstration of swallowing a pill was believed to be a weaker measure of outcome than studies that ensured the child was able to successfully swallow pills on multiple occasions. Consistency of intervention delivery was evaluated based on the level of detail provided regarding the protocol used during the study.

Ratings for each item were converted into numeric values (good = 2, fair = 1, poor = 0). Each item was weighted equally, excluding items judged to be

not applicable based on study design. Final quality grades were assigned for each article, based on the average score of all items we rated. An article with an average score of 1.5 or higher was considered to be of good quality, 1.0 to 1.49 was considered to be of fair quality, and <1.0 was considered to be of poor quality with considerable methodological limitations.

RESULTS

Search Results

We initially identified 211 articles from the PubMed search (Fig 1). We

excluded 35 articles not published in English, 155 articles after screening the titles for relevance, and 11 articles after reviewing the abstracts for relevance. We excluded 6 studies with a sample size of <10 participants. We added one article via a bibliography review, so our final list for this review consisted of 5 articles (Fig 1).¹⁰⁻¹⁴

Study Design and Study Populations

The main characteristics of our final 5 articles are summarized in Table 1. We found no randomized trials. The included studies consisted of 3

prospective cohort studies, 1 case series, and 1 retrospective cohort study. Two of the articles specifically studied children with a diagnosis of HIV.^{10,11} Czyzewski et al¹⁰ studied 29 children with HIV aged 3 to 13 years who were either new to pill swallowing or had reported difficulties swallowing pills. Garvie et al¹¹ studied 23 children with HIV aged 4 to 21 years who either had difficulty swallowing their current medication regimen or were preparing for a change in their medication formulary. Meltzer et al¹⁴ studied a cohort of 124 children aged 6 to 11 years who were healthy or had a dermatologic or a respiratory condition. In this cohort, 67 children reported that they were unable to swallow a pill at the start of the study. Diamond and Lavalley¹² studied 11 adolescents aged 9 to 17 years who self-reported difficulty swallowing tablets or capsules. Kaplan et al¹³ studied 41 children aged 2 to 17 who were never able to successfully swallow medications. Most of the children in this study were referred from an advertisement in a tertiary care pediatric hospital. The remainder of the children in this study were either siblings or friends of the clinic patients or were the hospital staff's children.

Study Interventions

All articles studied the effects of various interventions on improving pill swallowing abilities in children (Table 1). The Czyzewski et al¹⁰ and Garvie et al¹¹ studies used a behavioral intervention that included shaping and modeling. The study by Meltzer et al¹⁴ provided scripted swallowing instructions with an ordinary cup or pill cup depending on the child's needs. Diamond and Lavalley¹² studied the effects of a lubricated flavored spray that helps children swallow by coating the back of their mouths and tongues. Kaplan et al¹³ taught children 5 different head positions and provided a brief education about the esophagus along

with reassurance to improve pill swallowing skills.

Study Results

In general, all of the studied interventions improved pill swallowing abilities in the majority of their study population (Table 1). Czyzewski et al¹⁰ found that 17 of the 29 children in their study were able to swallow large capsules and maintain adherence to their medication regimen for ≥ 6 months after the behavioral intervention. In the Meltzer et al¹⁴ article, 47 of the 67 children who were initially unable to swallow pills learned the skill via scripted instructions with an ordinary cup, and 9 additional children learned the skill via scripted instructions with a pill cup. Garvie et al¹¹ found that 22 of the 23 children in their study not only learned to successfully swallow pills after the behavioral intervention but also had significant improvements in their CD4 counts and viral load at 6 months. In the study by Diamond and Lavalley,¹² the lubricated flavored spray was found to be effective in helping 7 of the 11 adolescent participants swallow a small candy. Finally, in the Kaplan et al¹³ study, 33 of the 41 children completed the 2-week practice protocol after being taught 5 different head positions. All 33 of these children were able to successfully swallow pills after completing their practice regimen.

Quality of Studies

Quality characteristics of the selected studies are summarized in Table 2. Overall, 1 study was rated as "good," 3 studies were rated as "fair," and 1 study was rated as "poor." There were a number of common limitations for the selected articles in this review. First, all selected articles were observational studies and did not have a control group. Another limitation was the lack of consistency in measuring whether participants continued to be successful at swallowing pills after the study was

completed. The follow-up period after the study ranged from 0 to 6 months. Garvie et al¹¹ studied postintervention adherence via pill counting, CD4+ T-cell percentage, and viral load at 3 and 6 months. Kaplan et al¹³ conducted follow-up phone calls after 30 days to see whether their participants were able to use their new skill for prescribed medications. Czyzewski et al¹⁰ mentioned compliance with protease inhibitor regimen for at least 6 months, but the exact method by which they obtained these data were not described. The lack of consistency between the articles made it difficult to compare the long-term effectiveness of the various interventions. Last, all articles had small sample sizes. Our largest study had only 67 children who actually needed and received the intervention.¹⁴ Therefore, the conclusions drawn in these articles must be taken with caution.

The Diamond and Lavalley¹² study was rated as "poor," with an average quality rating score of 0.33 because of its very small convenience sample, poor measurement of outcome, and lack of consistency in the use of the intervention. The Czyzewski et al,¹⁰ Meltzer et al,¹⁴ and Garvie et al¹¹ studies were rated as "fair," with an average quality rating score of 1.33 for each study. The Czyzewski et al¹⁰ study used a convenience sample of children being considered for an HIV medication trial and did not provide details on the method used to assess pill swallowing success. However, a major strength of the study was the detailed intervention protocol to ensure standardization. The Meltzer et al¹⁴ study had a large and diverse sample of pediatric patients, but the study's outcome assessments for ease and success of swallowing medications were not reliable. The Garvie et al¹¹ study had robust measurements for adherence to medication and pill swallowing success. Unfortunately, their sampling

TABLE 1 Summary of Selected Articles

Author and Year	Study Design	Study Population	Intervention Type	Results
Cyzewski et al (2000)	Case series	29 children with HIV aged 3–13 y	Behavioral intervention via shaping technique and modeling	17 children were able to swallow large capsules and maintained adherence to their protease inhibitor for ≥ 6 mo
		Children were either new to pill swallowing or had reported difficulties with swallowing pills	Trainers were clinical psychology interns and trainees Sessions usually lasted <30 min	Most successful cases (14/17) needed only 1 training session
Meltzer et al (2006)	Prospective cohort study	124 children aged 6–11 y who were healthy or had a dermatologic or respiratory condition	Scripted swallowing technique instructions with ordinary cup or pill cup	From the cohort of 67 children noted to have pill swallowing difficulties:
		67 of the 124 children reported that they could not swallow pills at the start of the study		47 children learned with instructions and ordinary cup 9 children learned with instructions and pill cup
Garvie et al (2007)	Retrospective cohort study	23 children with HIV aged 4–21 y	Behavioral intervention via shaping technique and modeling	22 children were able to successfully swallow pills with training
		Children were referred for difficulties with adherence to medication regimen or for desire to change formulary	Trainers were clinical pediatric psychologists Sessions were ≤ 30 min	Modal number of sessions needed = 1 Significant improvements in adherence, CD4 counts, and viral load were seen from baseline to 6 mo
Diamond and Lavallee (2010)	Prospective cohort study	11 adolescents aged 9–17 y	Lubricated flavored spray that coats the back of the mouth and tongue	7 children were able to swallow a small candy successfully with spray
		Participants who self-reported past difficulty with swallowing tablets or capsules		The majority of successful children needed only 1 attempt with spray
Kaplan et al (2010)	Prospective cohort study	41 children aged 2–17 y	Teaching of 5 head positions (center, up, down, left, and right) along with 2 min of reassurance and education about the esophagus	All 33 children who completed the 2-wk practice regimen were able to successfully swallow pills
		Participants were referred from an advertisement in a tertiary care pediatric hospital, were siblings or friends of clinic patients, or were the hospital staff's children	The first session was usually 45 min	29/33 were able to swallow pills in all 5 positions
		All children were never able to successfully swallow a pill in the past	The session was followed by 2 wk of daily practice with candy	8 children withdrew from the study because of lack of practice, with 4/8 children being too ill to continue with the study

strategy was a major concern in this study, given its retrospective design and lack of information on how their participants were selected to be referred. In addition, the article did

not provide information on how they chose the 2-year time period in which they did the chart review. The Kaplan et al¹³ study was the only article that was rated as “good,” with an average

quality rating score of 1.67, because of its standardized method for both intervention delivery and outcome measurement. Specific examples can be found in Table 2.

TABLE 2 Quality Assessment of Selected Articles With Examples

Author and Year	Study Design	Sample Size	Sampling Strategy and Quality Score	Strength of Outcome Measurement and Quality Score	Consistency of Intervention Delivery and Quality Score	Quality (Average Score)
Czyzewski et al (2000)	Case series, no control group	29	1 Convenience sample of children being considered for an HIV medication trial	1 No description of methods in article, thus authors assigned middle rating	2 Detailed protocol on behavioral therapy for trainer administering intervention	Fair (1.33)
Meltzer et al (2006)	Prospective cohort study, no control group	124 (67)	2 Large and diverse sample of pediatric patients from clinical research center	0 One-time demonstration of swallowing a tablet in each round; objective ease of swallowing assessment	2 Scripted instructions with one clinical research coordinator performing intervention	Fair (1.33)
Garvie et al (2007)	Retrospective cohort study, no control group	23	0 Convenience sample of patients with HIV referred for pill swallowing training	2 Success at swallowing 2 placebos with ease in each round, up to target gel size	2 Modified version of protocol by Czyzewski et al with detailed steps	Fair (1.33)
Diamond and Lavallee (2010)	Prospective cohort study, no control group	11	0 Convenience sample of adolescents with self-reported difficulty swallowing pills	0 Success was defined as a 1-time demonstration of swallowing a small candy after 1 or multiple attempts	1 Inconsistent intervention administration with variable number of sprays and gulps	Poor (0.33)
Kaplan et al (2010)	Prospective cohort study, no control group	41	1 Patients referred via ad or through relationship with clinic patients or staff because of past difficulty swallowing pills	2 Success measured during follow-up session after 14 d of practice, testing all 5 head positions along with parental report	2 Detailed protocol consisting of teaching head positions, reassurance, and education about the esophagus	Good (1.67)

DISCUSSION

In the last 26 years, from 1987 to 2013, there have only been 5 published studies on pill swallowing interventions that meet our criteria for inclusion. This paucity of data demonstrates the need for more high-quality studies on this topic. Nevertheless, our review does show that the failure to swallow pills is a barrier that can be overcome in the pediatric population. All selected articles in this review demonstrated that their intervention was successful in improving pill swallowing abilities in more than half of their study population. Furthermore, the articles showcased a number of different strategies that a health care provider can use to facilitate the development of pill swallowing skills. The

interventions in this review include behavioral therapy, flavored throat spray, specialized pill cup, simple verbal instructions, and head posture training. A major reason for the success of all the interventions is that every study recognized and specifically addressed problems with pill swallowing. As a result, there was a conscious effort to help children with their difficulties in swallowing pills.

In addition, this review provides insight into the appropriate age range for swallowing pills. Parents who are concerned that their children are too young to swallow pills can be assured that some of the interventions have been studied in children as young as 2 years old.¹³ In fact, 1 study found that younger children (age 4–5 years)

needed less training sessions than older children to learn how to swallow pills.¹¹ The authors of the study indicated this was probably because younger patients are pill naive before pill swallowing training and therefore have fewer negative experiences when learning to swallow pills than older patients who had previous negative experiences with pills.¹¹ Therefore, teaching children how to swallow pills at an earlier age can help prevent a barrier to medication adherence and can be easier than waiting until they are older.

In addition to the common limitations for the selected articles in this review, there were a few limitations in the design of our systematic review. First, we searched only 1 database

(PubMed) for articles on pill swallowing interventions. In addition, we limited our search to articles that were published in English and that had >10 participants. All of these factors could have resulted in us excluding important articles pertaining to our main topic of review. Furthermore, we excluded studies focusing on children with a comorbid condition that affected their swallowing skills, such as severe developmental disabilities. Consequently, the generalizability of this review is limited to children who do not have dysphagia and are developmentally appropriate. Lastly, our method of appraising the quality of the studies could be vulnerable to bias. However, our review had multiple authors independently appraise these articles, thus reducing this potential concern.

CONCLUSIONS

The failure to swallow pills is a common and important barrier to medication administration for children and their parents. Therefore, addressing pediatric pill swallowing difficulties via targeted interventions has the potential to improve both medication administration and treatment compliance. These interventions can include behavioral therapy, flavored throat spray, specialized pill cup, simple verbal instructions, and head posture training. Unfortunately, studies that evaluate the effectiveness of various pill swallowing interventions are limited by their small sample sizes,

observational study design, and lack of controls. Nevertheless, all the interventions were successful in improving pill swallowing abilities, proving that this is a barrier that can be overcome. At this time, research on the most efficient way to prospectively identify children with pill swallowing difficulties and implement targeted interventions before it is medically necessary for them to swallow pills should be a priority.

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