BRIEF REPORT

A Pilot Study of the Pediatric Oral Medications Screener (POMS)

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ABSTRACT

OBJECTIVE: Oral medications are commonly used to treat acute and chronic conditions, but formal evaluation of a child's pill-swallowing ability rarely occurs. In this pilot study, the Pediatric Oral Medication Screener (POMS) was used to physically assess a child's pill swallowing ability and identify children who would benefit from a targeted intervention.

METHODS: We identified children 3 to 17 years old admitted to a general pediatric service over a 3-month period in 2014. Patients were asked to swallow several different-sized placebo formulations. If subjects did not meet age-based goals, they were referred for pill swallowing interventions (POMS+). Follow-up parental surveys were performed for patients completing the intervention.

RESULTS: The prospective pilot study recruited 34 patients. Twenty-eight patients (82%) passed the screening, and a majority of this group started or continued taking pill medications. Six did not pass the screen. Three of the 6 completed the intervention, improved their pill swallowing ability, and were taking oral pill medications at discharge. Parent prediction of pill swallowing was accurate only 56% of the time. Follow-up survey of the 3 families who completed POMS+ reported satisfaction with the program, and 2 of the patients had continued success with swallowing pills 5 months later.

CONCLUSIONS: The POMS was effective at identifying children who could benefit from an intervention to improve pill-swallowing ability. Our analysis demonstrated that POMS has the potential to improve patient satisfaction and discharge planning.

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Pill-swallowing competence is a recognized barrier to compliance with prescribed treatment regimens in children. However, in the past 26 years there have been few studies to evaluate pill-swallowing interventions in children, especially in a prospective and standardized way.[1] In 2010, pediatric outpatient prescriptions totaled 263.6 million in the United States.[2] Nonadherence with a treatment regimen is correlated with increased health care utilization, costs, and increased antibiotic resistance.[3] Pill swallowing has been identified as a major barrier to medication adherence in chronic conditions such as inflammatory bowel disease and HIV infection, but previously healthy children can have similar difficulties that impede their medical care.[4,5] Inability to swallow pills can result in expensive, hard-to-find formulations, treatment failures,[6] and patient and family stress and anxiety. Improved oral medication skills could reduce the need for prolonged intravenous therapies and the associated risks and costs.[7] More studies are demonstrating early transition from IV to oral therapy as having equivalent outcomes when compared with prolonged IV therapy for several common conditions: uncomplicated osteomyelitis and community-acquired pneumonia, postdebridement mastoiditis, acute pyelonephritis, and febrile urinary tract infections in infants.[8–12]

Evidence emphasizes the importance of oral medication compliance; however, no accepted method of assessing oral medication skills is incorporated into pediatric discharge planning. The objective of this study was to develop and test the Pediatric Oral Medication Screener (POMS), a screening tool coupled with an intervention to assess and improve children's pill-swallowing ability.

METHODS

This study was approved by the University of North Carolina Institutional Review Board.

Pilot Study

We identified potential study subjects by reviewing the electronic health records of children ages 3 to 17 admitted to a general pediatric service from April to June 2014 at an academic children's hospital with an estimated length of stay of ≥3 days. Exclusion criteria were altered mental status, developmental delay, neuromuscular abnormality, head or neck lesion, history of dysphagia, severe medical illness, and current NPO status. A survey was conducted asking each parent to report their perception of their child's anxiety about taking medicines, any past difficulties taking oral medications, any previous or current psychiatric or psychological services, and the pill size they thought their child could swallow. Subjects rated how they felt about taking oral medications by using a 5-point scale.

A research assistant presented to patients the placebo formulations, consisting of a liquid solution and 3 varied pill sizes. The suspension was a 2:1 mixture of Ora-Plus oral suspending vehicle and Ora-Sweet sugar-free syrup (Perrigo Co., Allegan, MI). The pills consisted of 1-grain (5-mm diameter) and 5-grain (10-mm diameter) pressed tablets (Rxhomeo.com, Dover, DE) and "0" size empty gelatin capsule (22 mm × 7 mm) (Capsule Connection LLC, Prescott, AZ). Standards for each age group were set for goal medication use based on historical provider expectations because these data are limited. Children ages 3 to 5 years were expected to swallow the liquid substitute only, ages 6 to 10 years the liquid as well as the small and medium tablet, and ages 11 to 17 years all formulations. If the patient successfully met preset age criteria within a 15-minute time limit, the patient passed and completed the study. If unsuccessful, the patient was referred for the intervention phase (POMS+). After 1 or 2 sessions the patient was rescreened with the original placebo formulations to determine whether improvements were made. The families who finished the intervention completed a follow-up telephone survey 4 to 5 months after the screening.

Interventions

Two trained child life specialists performed standardized POMS+ interventions. Children ages ≤8 years were approached with the following interventions in order until 1 was successful: medical play, procedural support and practice, relaxation training, different head positions, and then a pill cup. Children ages ≥9 years started with procedural support followed by the other interventions. These intervention techniques are part of child life training and are described in Table 1.

Statistical Analysis

We compared patients who passed the initial POMS screening with patients who did not pass were done by using either a type 2 2-tailed, 2-sample *t* test or a Fisher's exact test.

TABLE 1 POMS+ Interventions Performed by Child Life Therapists

Medical play	Playing doctor, role playing and fun cups and straws used to desensitize pill swallowing, create safe environment through play, provide a sense of control, and desensitize medical equipment
Procedural support and practice	Developmentally appropriate information that includes pill-swallowing games, reward charts, and practice with different-sized candies (Nerds, Tic-Tacs, M&M's, and Mike and Ikes)
Relaxation training	Distraction, progressive muscle relaxation, guided imagery, diaphragmatic breathing, and emotional self-regulation to help manage stress and reduce anxiety
Different head positions	Head forward position or tilted back
Pill cup	The Pill Taker's Cup, Oralflo Pill Cup
Discharge planning	Teaching to reduce concerns about returning to the community by improving the patient's skills with problem-solving, planning, and coping strategies with written handouts to practice

RESULTS

Initial Screening

Thirty-four of the 52 patients approached (64%) consented to screening, and 28 of the 34 (82%) passed the initial pediatric oral medication screening (POMS). Six patients (18%) did not meet their preset age criteria and were referred to POMS+ interventions with child life specialists. Figure 1 presents the age distribution of patients who passed and did not pass, and the data show no obvious age predilection. Three children under the age of 6 years were able to swallow the small tablet or the capsule in addition to the liquid substitute. Table 2 demonstrates similar age and gender distributions between the 2 groups (pass and not pass). Of note, there was a significantly higher parent-reported anxiety rating for children who did not pass versus children who did ($P = .03$) but not a significantly higher child-reported anxiety rating. In addition, 13 children reported previous medication difficulties, and 5 of these children did not pass the screen. Children who did not pass also had a higher rate of use of psychiatric and psychological services compared with the group that passed the screening ($P = .02$).

Lack of Reliability of Parent Report

The accuracy of parental report compared with the child's performance was assessed. Parents correctly predicted the pill size their child could swallow in only 56% (19/34) of cases. Parents underestimated their child's ability 32% of the time (11/34) and overestimated their child's ability to swallow pills 12% of the time (4/34). Twenty-one percent of parents reported their child's anxiety when taking medications at a level of 4 or 5 (5 being *extremely anxious*). Children reported lower anxiety, with only 12% indicating an anxiety level of 4 or 5.

Outcomes for Children Who Passed the Screen

Twenty-eight patients passed the initial screening, and 68% of them went home on new or previously prescribed pill medications. One went home on no oral medications, 1 went home on chew tabs, and 7 went home on liquid medications or had previously been prescribed liquid medications (age range 3–11 years).

Intervention

Six children (18%) were screened and did not meet age-specific pill-swallowing capabilities, prompting referral for the POMS+ intervention. Three of these 6 patients withdrew before the intervention phase because of self-reported anxiety. All 3 patients who did complete the intervention improved their pill-swallowing ability, with a positive impact on their care, and were discharged from the hospital on oral pill medications. One patient was a 16-year-old girl with meningitis and a cerebellar abscess, who was able to swallow all 3 pills sizes, which she was unable to do before the intervention. An 8-year-old boy with a retropharyngeal abscess and a 6-year-old girl admitted for ureterostomy revision both improved from being able to take only liquid medication before the intervention to being able to swallow medium-sized pills. As a result of their improvement, 1 patient went home on oral medication without a peripherally inserted central catheter line, and 1 patient transitioned to oral medications without using her G-tube. Follow-up survey of these 3 families demonstrated satisfaction with the program, and 2 families reported continued ability to swallow pills 5 months after the intervention.

Needs of the Program

This screening and intervention program was carried out with 1 researcher and 2 child life specialists. Time per patient for screening was <15 minutes, and only those who did not pass were referred to the intervention phase, with child life consisting of 1 or 2 10- to 30-minute sessions.

DISCUSSION

In this pilot study, screening children with the POMS led to improved pill swallowing, which positively affected the treatment of

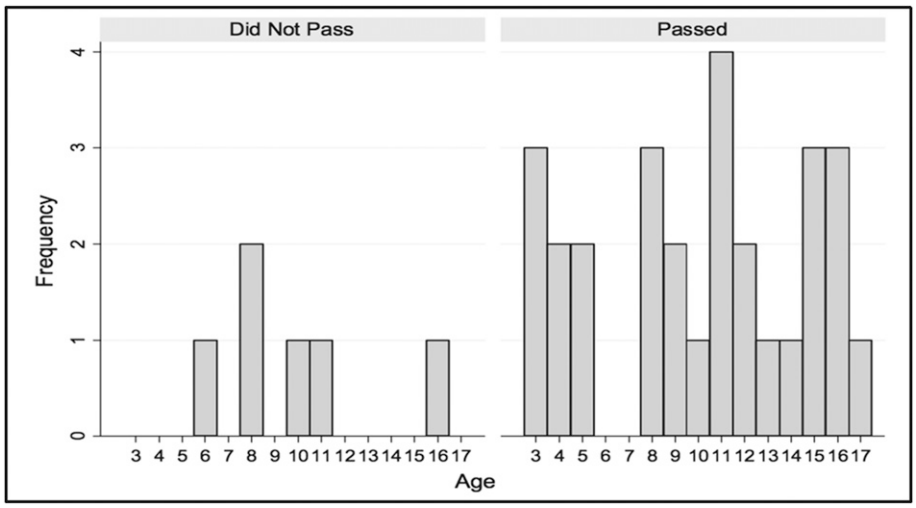

FIGURE 1 Age distribution of patients ($n = 34$) who did not pass versus passed screening with POMS.

TABLE 2 Demographics and Questionnaire Results of Screened Patients

	All Patients ($n = 34$)	Passed ($n = 28$)	Did Not Pass ($n = 6$)	P
Average age, y	10.09	10.14	9.83	.88*
% Male	38.24	40.74	16.67	.37
Average parent-reported anxiety rating (1–5)[a]	2.15	1.89	3.33	.03*
Average child-reported anxiety rating (1–5)[a]	2.06	1.88	2.83	.10*
No. with previous oral medication difficulties	13	8	5	.02
No. who self-reported that screening was helpful	33	27	6	.99
No. who self-reported history of psych services	8	4	4	.02

* P based on a 2-tailed 2-sample t test (assuming equal variance); rest of P values based on Fisher's exact test.
[a] Rating of 5 corresponds to *high anxiety.*

the patients who completed the study. Although this is a small pilot, our results demonstrate the feasibility and potential benefit of prospectively screening children for pill-swallowing difficulty in the inpatient setting with limited resources and personnel time. A major rationale for routine screening is the lack of reliable predictors of pill-swallowing ability, including parental report.

The use of oral medications for complete treatment courses or for transition after short courses of IV medication is receiving increasing emphasis. In addition, the use of chronic oral medications to treat type 2 diabetes, hypertension, and hyperlipidemia in pediatric patients is increasing.[8–10,12,13] Therefore, factors that influence the timing and success of transitioning from IV to oral medications will become even more important. For some medications, liquid formulations are not a viable alternative because of unfavorable taste, large volumes for the given doses, or excessive difficulty getting medications compounded. Whole pill doses have less toxicity than other forms of medication, and tablets are the easiest to produce, transport, and store and thus better for the health care system.[14] Despite these benefits, there is a recognized gap in the production of pediatric-appropriate pharmaceuticals.[14,15]

With the exception of HIV, there are no inpatient or outpatient systems in place to evaluate or improve pediatric pill swallowing. The ability to swallow oral medications is a skill that can be improved, and several cohort studies report those techniques.[5,6,16] In these studies, patients are reported to have the developmental and physical capacity to swallow medication but are hindered by poor behavior, anxiety, or lack of exposure. One of the motivations for piloting our POMS program in the hospital is that these children and parents are motivated to work toward discharge, and they often have time to practice these skills in the inpatient setting. We seek to improve patient outcomes and believe a potential benefit of this program would be to prevent readmission for failed oral medication regimens. Given that neither doctors nor nurses were directly involved with screening or intervention, our prospective study demonstrates that POMS could be instituted with only minimal cost and limited training. The techniques used for the intervention are part of a child life specialist's repertoire. A future goal is to create a single manufactured unit that contains all the placebo formulations, training information, and printed materials in 1 packet.

Intangible benefits of the screening and intervention program are patient and family satisfaction and the continued evidence in support of child life therapists wherever children are treated. This intervention uses a variety of techniques to address both anxiety surrounding swallowing pills and any physical difficulties children have.

Our results generate meaningful future research questions. More children than we predicted passed the screen on the first attempt, and this result must be studied more. We offer 2 possible explanations; the first is that providers have expectations of pill-swallowing ability that are far too dogmatic. In our study, there were children aged 3 to 5 years who swallowed all pill sizes with no difficulty. Even children <3 years old have shown the ability and sometimes preference to swallow small tablets in various studies.[17,18] Follow-up prospective studies using POMS will allow neurologically intact children to proceed through as many of the pill-swallowing steps as they can without prejudged, age-based stopping points. The second potential explanation is that our placebo pill and capsule sizes are too small. One mother remarked in follow-up that the patient had learned to swallow pills, but his discharge medication was larger than the study medications. The size 1 pill is equivalent to an 81-mg aspirin tablet, and the size 5 pill is equivalent to a 325-mg aspirin tablet. The size 0 capsule is a medium-sized capsule. We are conducting a follow-up analysis of commonly prescribed pediatric pill medications to determine whether larger tablet and capsule formulations for screening would better match the medications children are taking in the hospital and at home.

Our results should be examined in light of certain limitations. This pilot study had a small patient sample, used to demonstrate feasibility. As discussed earlier, our age-based benchmarks were arbitrary and based on historical expectations. Additional open-ended screening in a larger pediatric population would allow us to refine these benchmarks with real performance data. We restricted our initial screening to general pediatric patients only. Lastly, participation bias may have existed. Families who agreed to participate may have known their child would have no

difficulties with pills, and families who declined may have known the child would probably have difficulties. If this program were instituted as hospital standard of care, it would normalize the process of learning to take pills for parents and children and potentially lead to even better outcomes. However, these limitations should not overshadow the results achieved in this pilot sample of children.

CONCLUSIONS

This pilot study demonstrates the feasibility of using the POMS to prospectively evaluate pill swallowing in children and to provide the necessary tools to improve this skill, which can ultimately lead to improved outcomes. The use of POMS was associated with a positive experience for the children and families who participated. Future goals include having all pediatric patients screened upon admission to the hospital, with expansion to other institutions and the outpatient environment.

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