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A Randomized Clinical Trial of the Management of Esophageal Coins in Children

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ABSTRACT. *Context.* **Children frequently ingest coins. When lodged in the esophagus, the coin may cause complications and must either be removed or observed to pass spontaneously.**

Objectives. **(1) To compare relatively immediate endoscopic removal to a period of observation followed by removal when necessary and (2) to evaluate the relationship between select clinical features and spontaneous passage.**

Design/Setting. **Randomized, prospective study of children <21 years old who presented to an emergency department with esophageal coins in the esophagus. Exclusion criteria were (1) history of tracheal or esophageal surgery, (2) showing symptoms, or (3) swallowing the coin >24 hours earlier. Children were randomized to either endoscopic removal (surgery) or admission for observation, with repeat radiographs ~16 hours after the initial image.**

Outcome Measures. **Proportion of patients requiring endoscopic removal, length of hospital stay, and the number of complications observed.**

Results. **Among 168 children who presented with esophageal coins lodged in the esophagus, 81 were eligible. Of those eligible, 60 enrolled, 20 refused consent, and 1 was not approached. In the observation group, 23 of 30 (77%) children required endoscopy compared with 21 of 30 (70%) in the surgical group. Total hospital length of stay was longer in the randomized-to-observation group compared with the randomized-to-surgery group (mean: 19.4 [SD: ±8.0] hours vs 10.7 [SD: ±7.1] hours, respectively). There were no complications in either group. Spontaneous passage occurred at similar rates in both groups (23% vs 30%). Spontaneous passage was more likely in older patients (66 vs 46 months) and male patients (odds ratio: 3.7; 95% confidence interval: 0.98–13.99) and more likely to occur when the coin was in the distal one third of the esophagus (56% vs 27% [95% confidence interval: 1.07–5.57]).**

Conclusions. **Because 25% to 30% of esophageal coins in children will pass spontaneously without complications, treatment of these patients may reasonably include a period of observation, in the range of 8 to 16 hours, particularly among older children and those with distally located coins.** *Pediatrics* **2005;116:614–619;** ***emergency department use, foreign body, gastrointestinal system.***

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In 1936, Jackson and Jackson[1] attributed the swallowing or aspiration of foreign bodies to "carelessness." Unfortunately, even the most conscientious parents are unable, at times, to prevent their children from placing objects into their mouths. Thus, ingested foreign bodies, most frequently coins, occur commonly in children, with 92 166 cases reported to poison centers in 2003.[2]

A large number of ingested coins lodge in the esophagus. Although many authorities recommend that symptomatic patients undergo immediate removal of these coins by 1 of several techniques,[3] considerable debate surrounds the correct management of patients in these situations. Prompt removal prevents complications from retained coins,[4] such as esophageal perforation,[5] esophageal-aortic fistula,[6] esophageal stricture formation,[7] tracheoesophageal fistula,[8] respiratory distress with or without associated cyanosis,[9] alteration in mental status,[10] and potential progression to death.[11] On rare occasions, coins have been noted to cause obstruction distal to the esophagus as well.[12] However, the procedures themselves predispose children to a different set of complications. At times, endoscopy has led to pharyngeal bleeding, bronchospasm, accidental extubation, stridor, hypoxia,[13] esophageal perforation, and mediastinitis.[14] Similarly, coin extraction with a balloon-tipped catheter has resulted in epistaxis, vomiting, respiratory distress, esophageal perforation,[15] and in at least 1 case complete airway obstruction leading to death.[14] Recent, small series of patients treated with esophageal bougienage, an alternative for treatment of esophageal coins that relies on advancement of the object into the stomach, have not described any complications as yet, but theoretical concerns exist for esophageal perforation and more distal foreign-body obstruction. Given the complications of removal listed above, a few authorities have recommend observation for an ill-defined period of time in lieu of removal of the coin in the asymptomatic patient to allow for spontaneous passage in some of the cases.[13,16]

To date, there have been no randomized, prospective investigations evaluating these 2 treatment strategies for such important outcomes as the proportion requiring endoscopy, hospital length of stay, and complications associated with either relatively im-

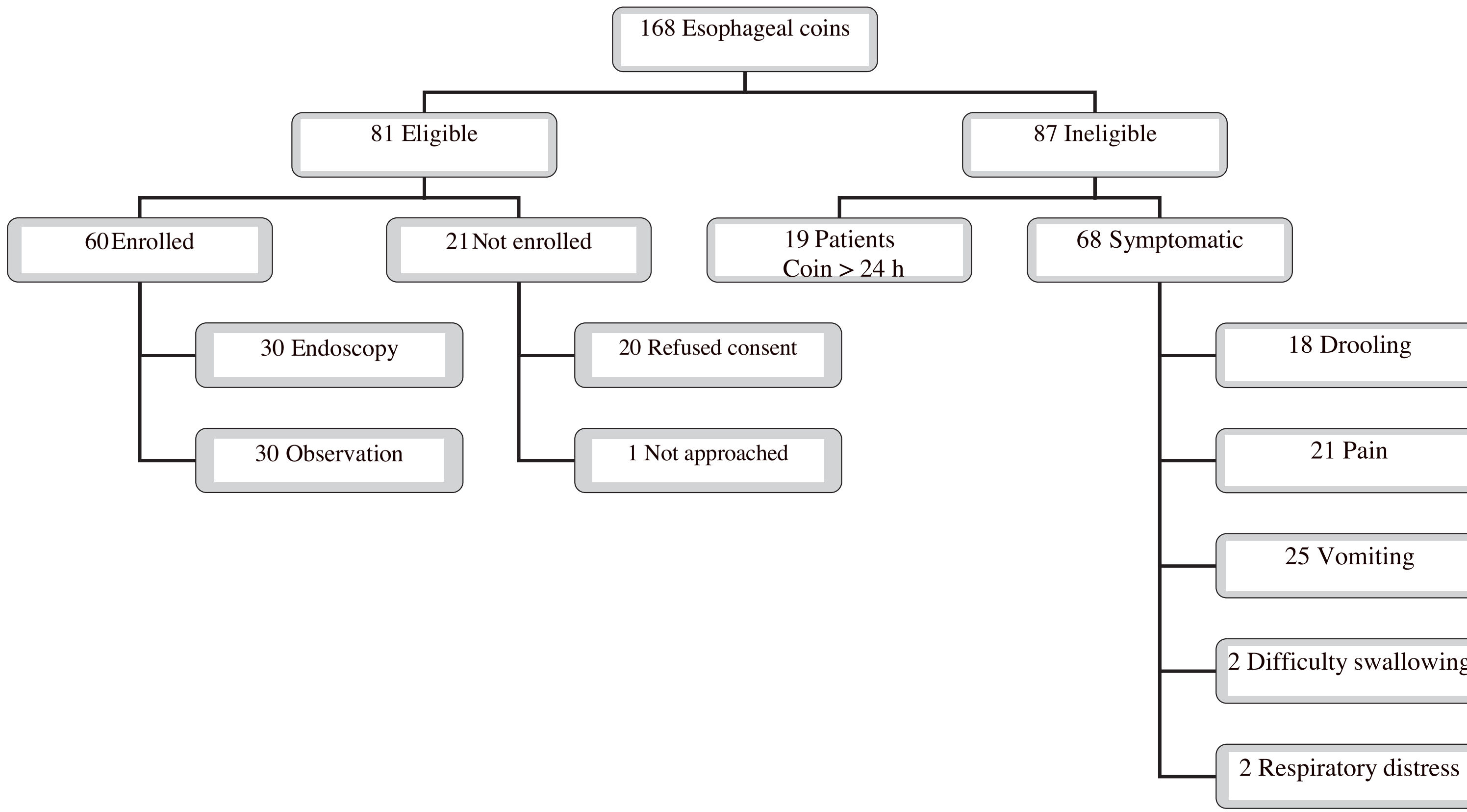

Fig 1. Enrollment among eligible patients.

TABLE 1. Demographics of all Eligible Patients ($n = 81$)

	Enrolled ($n = 60$)	Not Enrolled ($n = 21$)	P*
Mean age ± SD, mo (range)	51 ± 31 (10–55)	54 ± 34 (8–138)	NS
Female gender, %	29 (48)	9 (42)	NS
Coin type, n (%)			NS
Penny	26 (43)	14 (67)	
Nickel	4 (7)	3 (14)	
Dime	4 (7)	0	
Quarter	15 (25)	4 (19)	
Unknown	11 (18)	0	
Coin location, n (%)			NS
Proximal 1/3	20 (33)	7 (33)	
Middle 1/3	19 (32)	6 (29)	
Distal 1/3	21 (35)	8 (38)	

* Fisher's exact test. NS indicates not significant.

mediate removal or "watchful waiting." Thus, we undertook the current trial.

DESIGN/METHODS

Study Population

We performed a prospective, randomized trial in children ≤21 years of age who ingested coins that lodged in the esophagus, comparing relatively immediate endoscopic removal to observation for a defined period of time. When a physician in the emergency department at our hospital confirmed a coin in the esophagus of a child, he or she contacted the principal investigator, who approached the family for informed consent. Exclusion criteria included prior tracheal or esophageal surgery, the presence of more than minimal symptoms (respiratory distress, drooling, or choking), or an ingestion occurring >24 hours earlier or inability to ascertain the time from ingestion. When consent was obtained, patients were randomized to removal or observation groups via sealed envelope. In the endoscopy group, a surgeon (general pediatric surgeon on even days and pediatric otorhinolaryngologist on odd days) extracted the coin under general anesthesia by using rigid esophagoscopy as soon as an operating room was available. Patients transferred from another institution with a radiograph or those that had a delay in undergoing endoscopy for ≥2 hours had a second image performed before the procedure to verify coin retention in the esophagus. Those patients randomized to the observation arm were admitted to the hospital, had continuous cardiac monitoring with pulse oximetry, received intravenous fluids to maintain hydration, were kept non per os (NPO), and underwent repeat radiographic evaluation ~16 hours after ingestion followed by endoscopic removal of any coins that failed to pass spontaneously into the stomach. The primary outcome variable was the proportion of patients in each group requiring endoscopy. Secondary outcome measures included length of stay in the hospital and complication rates; potential adverse events included choking, vomiting, respiratory distress, hypoxia, coin translocation to the trachea, or esophageal perforation. Per our protocol, any complications among patients in either group were to be reported to the principal investigator immediately by the nursing staff or the physicians treating the child. Additionally, the principal investigator reviewed all hospital records from all participants to ensure that no complications occurred that were not reported. Finally, we analyzed the relationship between the size of the coin (by coin type), the location in the esophagus, and the spontaneous-passage rate into the stomach.

TABLE 2. Demographics by Randomization ($n = 60$)

	Observation ($n = 30$)	Endoscopy ($n = 30$)	P*
Mean age ± SD, mo (range)	50 ± 33 (12–155)	53 ± 30 (10–129)	NS
Female gender, n (%)	14 (47)	15 (50)	NS
Race, n (%)			NS
White	21 (70)	23 (77)	
Hispanic	5 (17)	4 (13)	
Black	4 (13)	3 (10)	
Coin type, n (%)			NS
Penny	13 (43)	13 (43)	
Nickel	1 (3)	3 (10)	
Dime	3 (10)	1 (3)	
Quarter	8 (27)	7 (23)	
Unknown	5 (17)	6 (20)	
Coin location, n (%)			.04
Proximal 1/3	7 (23)	13 (43)	
Middle 1/3	14 (47)	5 (17)	
Distal 1/3	9 (30)	12 (40)	

* Fisher's exact test. NS indicates not significant.

Data Analysis

With a sample size of 30 subjects per group, using Fisher's exact test with a .05 2-sided significance level provided 80% power to detect differences in spontaneous-passage rates between the 2 groups of 10% vs 44% or 5% vs 36%. The 2 treatment groups were compared by using an intention-to-treat analysis. t tests and Wilcoxon rank-sum tests were used to examine continuous variables, and Fisher's exact test or trend tests were used with categorical variables. Secondary analyses evaluating multiple predictors of spontaneous passage (versus requiring endoscopic removal) were conducted by using logistic regression. Kaplan-Meier survival curves were plotted to describe the time from ingestion to spontaneous passage among the study subjects. Data analysis was performed by using SAS 9.0 (SAS Institute Inc, Cary, NC).

RESULTS

Population

Between March 1, 2001, and December 1, 2003, 168 patients presented to the emergency department with esophageal coins (Fig 1). Of these, 87 were ineligible for the study; 68 were symptomatic and 19 had swallowed the coin >24 hours before presentation. Of the 81 eligible patients, 21 (26%) were not enrolled, either because of a failure to contact the principal investigator (1 of 21) or refusal of informed consent (20 of 21). Age, coin location, and coin type did not differ significantly between those eligible for the study who participated and those who refused consent or were not approached (Table 1).

Of the 60 enrolled patients, 30 were randomized

TABLE 3. Clinical Outcome ($n = 60$)

	Observation ($n = 30$)	Endoscopic Removal ($n = 30$)	P*
Undergoing endoscopy, n/N (%)	23/30 (77)	21/30 (70)	NS
Spontaneous passage, n (%)			
Proximal 1/3	1 (14)	1 (11)	
Middle 1/3	3 (43)	2 (22)	
Distal 1/3	3 (43)	6 (67)	
Mean length of stay, h (SD)	19.4 ± 10 (2.1–43)	10.7 ± 7.1 (1.5–32.3)	<.001
Complications	0	0	NS

* Wilcoxon rank-sum test. NS indicates not significant.

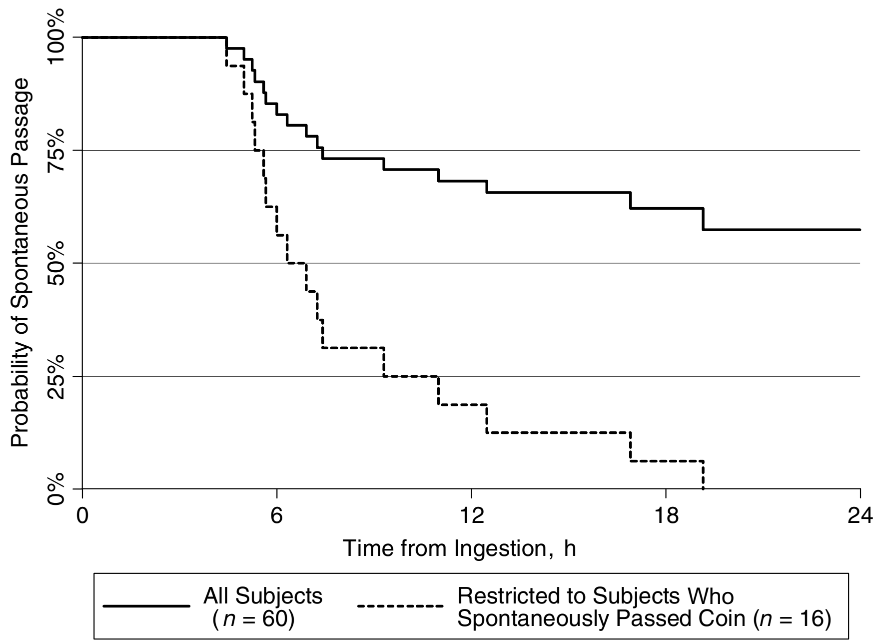

Fig 2. Estimated probability of spontaneous passage as a function of time from ingestion. The top curve (solid line) applies to all 60 subjects, assuming that subjects who received surgery had their times censored at the time of endoscopy. The bottom curve (dashed line) applies to the 16 subjects who spontaneously passed their coin.

TABLE 4. Clinical Characteristics of Children With Spontaneous Passage Versus Children Ultimately Undergoing Endoscopic Coin Removal

	Spontaneous Passage ($n = 16$)	Endoscopic Removal ($n = 44$)	P*
Mean age ± SD, mo (range)	66 ± 39.27 (12–155)	46 ± 26 (10–43)	.06
Female gender, n (%)	4 (25)	25 (57)	.04
Coin type, n (%)			NS
Penny	6 (37)	20 (45)	
Nickel	2 (13)	2 (5)	
Dime	1 (6)	3 (7)	
Quarter	2 (13)	13 (29)	
Other	5 (31)	6 (14)	
Coin location, n (%)			.06
Proximal 1/3	2 (13)	18 (41)	
Middle 1/3	5 (31)	14 (32)	
Distal 1/3	9 (56)	12 (27)	

* Fisher's exact test. NS indicates not significant.

for relatively immediate endoscopic removal and 30 for observation (Fig 1). Mean age of the patients randomized to endoscopy was 53 ± 30 months (10–129 months), and mean age of those randomized to observation was 50 ± 33 months (12–155 months). The 2 groups were similar in all other regards (Table 2) except for a slightly higher proportion of coins in the upper esophagus among patients in the observation group.

Outcome of Randomized Patients

Table 3 displays the outcomes of the 60 randomized patients. In the observation group, 23 of 30 (77%) required endoscopy compared with 21 of 30 (70%) in the group scheduled for relatively immediate endoscopy. Mean length of stay was 8.7 hours longer for those who were randomized to observation (95% confidence interval: 4.2–8.7; $P < .001$, Wilcoxon rank sum). No complications occurred in either group (0 of 60; exact 95% confidence interval: 0–5%). Spontaneous passage occurred with equal frequency in both groups (7 of 30 [23%] vs 9 of 30 [30%]; $P = .77$, Fisher's exact test). Of the patients who had spontaneous passage ($n = 16$), approximately half of the coins passed by 6 hours, and all had done so by 19 hours (Fig 2). Those patients in the endoscopy group with spontaneous passage (9 of 30) had a delay of going to endoscopy for ≥2 hours and underwent radiographic evaluation before endoscopy, per protocol.

Factors Related to Spontaneous Passage

Comparing those patients who had spontaneous passage to those who required endoscopy, age, gender, and coin location were found to trend toward statistical significance (Table 4). Spontaneous passage occurred more commonly in older patients (mean age: 66 vs 46 months), males (75% vs 43%), and those with coins located in the distal esophagus (56% vs 27%; trend $P = .02$).

To jointly assess the affects of multiple predictors of spontaneous passage in subjects, logistic regression was used. Independent variables of coin location, gender, and age were used in the model. The strongest predictors of spontaneous passage were coin location (odds ratio: 2.44, comparing proximal versus middle or middle versus distal; 95% confidence interval: 1.07–5.57; $P = .03$) and male gender (odds ratio: 3.70, comparing males versus females; 95% confidence interval: 0.98–13.99; $P = .054$). Additional adjustment for age did not reach statistical significance but did reduce the effect of both coin location (odds ratio: 2.16; $P = .08$) and male gender (odds ratio: 3.30; $P = .08$). Coin type and size were not predictive for spontaneous passage.

DISCUSSION

We found that 25% of esophageal coins passed spontaneously during an observation period of ~16 hours. This rate is similar to those reported in a retrospective study at our institution[13] and by others.[3,4,17–20] Spitz[3] reported a lower rate of spontaneous passage; however, that study was not limited to esophageal coins but included any impacted foreign body in the esophagus.

Although spontaneous passage occurred in all types of patients in our study, it was more likely in older children and with distally located coins. This finding is similar to the retrospective study from our institution[13]; however, the rates of spontaneous passage in the current study are higher for the more distally located coins. Spontaneous passage was not limited to the patients randomized to observation alone. In fact, spontaneous passage occurred with essentially equivalent frequency in those patients who were randomized to relatively immediate endoscopy. We speculate that the similar rate of passage in the 2 groups occurred in part because many esophageal coins destined to spontaneously migrate to the stomach move within a relatively short time frame, which fell within the interval required in our study to actually arrange the endoscopic procedures.

No complications occurred among our patients despite the relatively frequency with which they are described in the literature.[5,7,21–26] We suspect that the absence of complications in our population relates to the strict exclusion of children who manifest symptoms, had underlying tracheal and/or esophageal disease, or ingested coins >24 hours before presentation. Among the reports of adverse outcomes in the literature, several involved children with underlying tracheoesophageal pathology or with a history that exceeded 24 hours,[7,22] both of which may predispose to a focal area of pressure necrosis and ultimate perforation or fistula formation. Alternatively, we may not have observed any complications in our 60 patients because of limitations of the sample size.

Based on a spontaneous-passage rate of 25% to 30% and an absence of complications, we believe an 8- to 16-hour period of observation is appropriate management in children with esophageal coins assuming that the child is asymptomatic, the ingestion was recent, and the child has no underlying esophageal or tracheal abnormality. This approach would obviate the need for anesthesia and endoscopy, with no increase in risk. This approach, in the asymptomatic patient, may be particularly useful for those who present in the evening, because it would avoid the inconvenience and expense of mobilizing teams of anesthesiologists and endoscopists after hours. Additionally, patients receiving their initial evaluation at institutions not capable of performing pediatric endoscopy might avoid transfer to remote referral centers. However, depending on institutional cost and utilization issues, immediate esophagoscopy might be the least-expensive alternative.

We did not study whether children can be safely observed at home after coin ingestions; however, there have been studies that have shown this to be the case,[27,28] and we suspect it to be a reasonable strategy in the asymptomatic child. Additionally, we did not investigate methods of treatment that do not require endoscopy or anesthesia, including administration of medications to increase esophageal motility, removal in unanesthetized patients by using balloon-tipped catheters, and bougienage for advancement into the stomach. Future studies may find one or more of these alternatives equal or superior to our recommendation for a period of observation followed by endoscopy in those patients who do not experience spontaneous passage.

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TO SELL THEIR DRUGS, COMPANIES INCREASINGLY RELY ON DOCTORS

"Drug makers have seized upon an effective tool for getting their message across to doctors: other doctors. Across the U.S., thousands of doctors . . . have signed up as part-time lecturers for drug companies. At small meetings, often over lunch or dinner, these physician-pitchmen tell their peers about diseases and the drugs to treat them, often pocketing $750 or more from the sponsor. . . . In 2004, 237,000 meetings and talks sponsored by pharmaceutical companies featured doctors as speakers, compared with 134,000 meetings led by company sales representatives, according to market researcher Verispan LLC of Yardley, Pa. In 1998, events featuring sales reps and physicians were about equal at just over 60,000 each. Verispan says [that] companies formerly curried favor with doctors by taking them on free golf outings or filling up their cars with a tank of gas in exchange for listening to a sales pitch. But a voluntary marketing code adopted by the largest drug companies three years ago barred such inducements. Hiring a doctor as a speaker and providing a free meal for the attendees is still acceptable—and, data suggest, highly effective. An internal study done by Merck & Co several years ago calculated the 'return on investment' from doctor-led discussion groups was almost double the return on meetings led by the company's own sales force. . . . [S]peakers who make thousands of dollars in fees from drug companies aren't required to disclose their side job to patients, although they are expected to disclose their ties in scientific papers. Some critics see a problem . . . with the sessions at which companies train their doctor-speakers. Steven Bernstein, an internist at the University of Michigan Health System in Ann Arbor, thinks drug makers may bring more doctors to speaker training than they need because the training is itself excellent advertising. Doctors are invited, says Dr. Bernstein, to 'try to convince them to utilize these products, and second, to use them as a marketing arm for the firm's products to their colleagues.' . . . While the total number of company-sponsored doctor talks is rising, both Merck and Wyeth say they have taken steps to rely less extensively on individual speakers. Doctors speaking on Merck's behalf now do so an average of five to 10 times a year, the company says. At Wyeth, speakers can't appear more than 25 times or earn more than $25,000 giving talks each year."

Hensley S, Martinez B. *Wall Street Journal*. July 15, 2005

Noted by JFL, MD