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A Comparison of Two Different Ear Curettes-Satisfaction, Pain, and Bleeding

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Abstract

Introduction: The objective of this study was to determine whether a novel flexible ear curette was preferred to a traditional stiff curette for ear curettage, and to analyze differences in clinical outcomes.

Methods: Patients between the ages of 0 to 21 years were randomized to EasiEar™ or Bionix™ ear curettes and further block randomized by age group. Patient pain during the exam, physician satisfaction with the curette, and bleeding (scrape or drop or more of blood) during the exam were determined.

Results: 82 patients were enrolled. 62 patients were enrolled in the 0-5 year's old age group, and 20 patients were enrolled in the 6-21 years age group. There was no significant difference in patient pain (0-5: p=0.4273; 6-21: p=0.6009). Clinicians were significantly more satisfied with the EasiEar™ curette (0-5: p <0.0001; 6-21: p=0.0002). One scraping occurred in each curette group.

Conclusion: Although use of EasiEar™ curettes does not significantly decrease patient pain, there was a significant improvement in physician satisfaction with its use.

Keywords: Ear Curettes; Patient pain; Physician; Blood

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Introduction

Cerumen is a combination of secretions from the sebaceous and modified aprocine sweat glands, produced in the outer one third of the ear canal [1]. In the US, approximately 150,000 cerumen removals take place each week [2]. Febrile patients who present to the Emergency Department (ED) often require an ear examination and subsequent cerumen removal to determine the fever's source. Similarly, 29% of the 2 million children presenting to the ED with acute otitis media require cerumen removal [3,4]. Excess cerumen can impede assessment of the ear canal/tympanic membrane or audio vestibular system, or both [5]. Cerumen impaction affects approximately 10% of children in the US [6]. Cerumen removal in the ED usually occurs manually, with the use of curettes, or through irrigation.

Historically, ear curettes were made from metal. The plastic ear curette was invented as a cheaper, disposable option. Plastic ear curettes, such as the Bionix™ (Bionix Medical Technologies, Toledo, OH) ear curette are widely available and are the current standard for curettage. They are economical and come in multiple sizes and styles. However, plastic curettes are also stiff and often difficult to maneuver in the ear canal. They often have rigid edges, which can cause scraping, bleeding, and in extreme cases, perforation of the tympanic membrane. Risks associated with using an ear curette include pain, bleeding, infection, tinnitus, ear canal abrasion, tympanic membrane perforation, infection of the ear, or hearing loss [3]. A survey of 312 general practitioners regarding cerumen removal practices found that 38% of practitioners reported complications during cerumen removal, including pain, perforation of tympanic membrane, otitis externa, failure of wax removal, damage to external auditory canal or vertigo [7].

A new curette, EasiEar™ (Splash Medical Devices, LLC, Atlanta, GA), was developed to help reduce problems caused by traditional metal and plastic curettes. EasiEar™ was designed with a single continuous round spring wire. The smooth surface was proposed to lessen abrasive pain and trauma to the patient. The wire loop has a low profile for maneuverability within the ear canal, and the spring handle was designed to provide shock absorption during use.

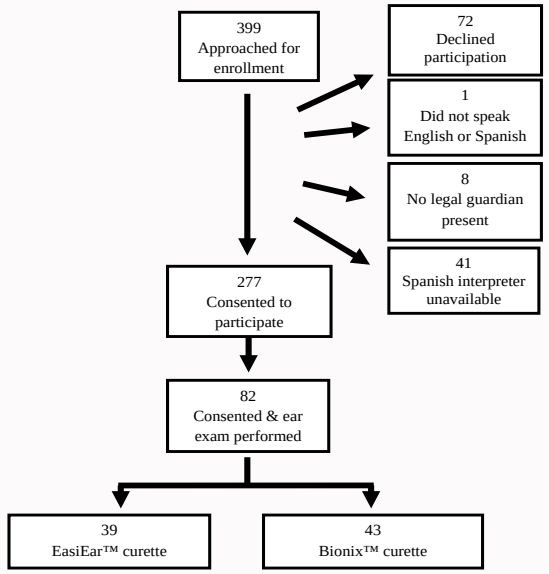

Figure 1: Diagram of Patients Approached and Enrolled.

The primary objective of this study was to assesspatient pain during ear examination and cerumen removal using a Bionix™ ear curette versus an EasiEar™ curette. The secondary objectives were to evaluate the practitioners' clinical satisfaction and the occurrence of adverse events.

Methods

This was a randomized controlled study to examine patient pain and clinical satisfaction with two different types of ear curettes during cerumen removal. Patients were recruited from a large [blinded for review] metropolitan hospital Emergency Department and an [blinded for review] metropolitan pediatric office between September 2014 and May 2015. Patients were approached for enrollment if the following inclusion criteria were met: (1) Patient was between the ages of 0 and 21 years old (2) Patient was undergoing an ear examination requiring cerumen removal. Exclusion criteria included not speaking English or Spanish and resuscitation/trauma room patients. This study was reviewed and approved by the institutional review board of the hospital.

To avoid impeding patient flow in the ED, any patient presenting with an ear complaint, fever, or cold and flu like symptoms was approached for enrollment before their physical examination. Once informed consent was obtained, patients were randomly assigned an opaque packet including either EasiEar™ or Bionix™ ear curettes. Patients were block randomized by age group into two age categories, ages 0-5 years and ages 6+ years, using a random number generator (www.random.org). The actual ear curette was enclosed in a smaller opaque envelope within the larger packet for blinding prior to opening the packet. The attending physician or nurse practitioner then performed ear curettage using the assigned ear curette. Consent, assent, and HIPAA forms were shredded for patients who did not require ear curettage.

Following the procedure, physicians or nurse practitioners were asked which ear they cleaned, if any bleeding occurred (none, scant (blood or red scrape visualized), frank blood (drop or more)), if their clinical goal was met, and how satisfied they were with the curette (a five point scale where 1 was worst clinical utility and 5 was best clinical utility). Patients over the age of 6 years were asked to rate their pain level during the procedure, using the Bieri FPS-R pain scale [8]. For patients under the age of 6 years, their caregivers were asked to rate patient pain using a 10cm Visual Analog Scale, where 0 was "did not hurt at all" and 10 was "worst pain my child has ever felt."

Using α=0.05 and β=0.8, this study was powered at n =120, determined by a self-reported pain difference of 25% being considered to be clinically relevant [8]. Because no previous studies evaluated pain with curettage, we planned an interim analysis after 80 patients. An unpaired student's t-test was calculated to determine differences in patient pain and satisfaction when ear curettage was performed using an EasiEar™ versus a Bionix™ curette.

Results

A total of 399 patients were screened forenrollment. Of these, 277 parents or legally-authorized representatives consented for the study, whereas 72 declined participation, 1 did not speak English or Spanish, 41 did not have a Spanish interpreter available, 8 did not have a legal guardian present, and 195 patients did not require ear curettage. Of the 82 patients who were consented and enrolled, 39 received the EasiEar™ curette for curettage and 43 received the Bionix™ ear curette (Figure 1).

One patient in the Bionix curette 0-5 year old group was actually 6 years old. Pain for the patient was determined using the 10cm VAS instead of the FACES pain scale. The majority of the legally-authorized representatives who declined participation did so because they did not want to participate in research.

No significant difference was revealed for patient pain in either the 0-5 years old (EasiEar™: 1.65, SD=2.03; Bionix™: 2.08, SD=2.19; t=0.80, p=0.4273) nor the 6-21 years old (EasiEar™: 2.30, SD=1.49; Bionix™: 2.67, SD=1.50; t=0.53, p=0.6009) groups (Table 1).

Pain for patients ages 0-5 years old was determined by the caregiver, using a 10cm VAS. For the 6-21 years old age group, pain was determined by asking the patient to rate his/her pain using the Bieri FPS-R pain scale.

Clinicians rated the EasiEar™ with significantly better utility scores thanBionix™ ear curettes in both the 0-5 years old (EasiEar™: 4.86, SD=0.35; Bionix™: 3.30, SD=1.02; t=7.86, p = <0.0001) and the 6-21 years old (EasiEar™: 4.80, SD=0.63; Bionix™: 2.70, SD=1.25; t =4.74, p=0.0002) groups (Table 2).

Physicians and nurse practitioners were asked to rate satisfaction with the ear curette using a five point scale, where 1 was worst clinical utility and 5 was best clinical utility.

Table 1: Patient Pain during Curettage.

Ages	EasiEar™		Bionix™		p
	Mean	SD	Mean	SD	
0-5	1.648	2.031	2.079	2.188	0.4273
6-21	2.30	1.49	2.67	1.50	0.6009

Table 2: Clinical Satisfaction during Curettage.

Ages	EasiEar™		Bionix™		p
	Mean	SD	Mean	SD	
0-5	4.86	0.35	3.30	1.02	<0.0001
6-21	4.80	0.63	2.70	1.25	0.0002

Only two clinicians reported any adverse events during curettage. Both patients experienced scant bleeding, defined as visualization of blood or a red scrape. Of the two patients, one received curettage with an EasiEar™ curette (2.6%) and the other with a Bionix™ (2.3%) curette.

The results of the interim analysis revealed that enrollment could be stopped after n=82 without enrolling the remaining 38 patients.

Conclusion

In the US, approximately 8 million cerumen removal procedures are performed annually [3]. Previous studies have recognized that adverse events occur during curettage, but there is little published data on how frequently this happens, and patient pain during curettage has not been quantified.

Although we were initially interested in comparing bleeding caused by ear curettes, we were unable to evaluate it because only 2 of the enrolled patients experienced any sort of adverse event. Our incidence of bleeding during curettage was less than what has been reported in previous studies [7].

Important limitations include the self-report of bleeding and complications because ears were not re-examined by another physician after curettage for confirmation. As such, it is possible that adverse events were under-reported.

Patients who were enrolled in the study often presented to the ED or their pediatrician's office for well-check visits or with various primary complaints. Ear curettage was often a secondary procedure, which did not necessarily relate to their purpose in seeking medical care. It is possible that patients were not able to differentiate between the pain they felt during curettage and their discomfort in general. Therefore, it is possible that patients did not rate their pain only based on the curettage.

Clinicians were not asked why they chose a specific satisfaction rating. One possible explanation for their preference of EasiEar™ curettes is increased mobility during curettage.Despite a statistically insignificant difference in patient pain, patients in both age groups reported lower pain, on average, with EasiEar™ curettes than with Bionix™ curettes. It is possible that this subtle difference led to increased clinical satisfaction with the EasiEar™ curette.Our findings suggest that EasiEar™ curettes are an effective alternative to Bionix™ curettes.

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