Clinical outcomes and feasibility of ear cleaning with a bellows pipette and 2% acetic acid for chronic suppurative otitis media in Luanda, Angola: a prospective observational study

Short title: Bellows pipette and acetic acid for CSOM in Angola

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Abstract

Chronic suppurative otitis media (CSOM) is an important cause of preventable hearing impairment, particularly in settings with limited access to specialist ear care. Effective topical treatment requires removal of purulent material from the external auditory canal. We assessed the short-term clinical outcomes and feasibility of a manually operated bellows pipette for aspiration of ear discharge, followed by irrigation with 2% acetic acid or diluted vinegar, among patients with CSOM at a tertiary hospital, Josina Machel, in Luanda, Angola. In this prospective observational study, we enrolled 100 patients with

persistent otorrhoea and tympanic membrane perforation. Patients or caregivers were instructed to aspirate visible discharge and irrigate the affected ear twice daily; clinical reassessment was planned on days 5 and 10. The primary outcome was complete resolution of otorrhoea in all affected ears at the final recorded assessment. Of 100 enrolled patients, 91 had an assessable final outcome. Complete resolution of otorrhoea was documented in 82 patients (82.0% of all enrolled patients; 90.1% of patients with an assessable outcome); otorrhoea persisted in eight patients, and one patient had a mixed bilateral outcome. Nine patients could not be assessed at the final visit. At day 10, 62 of 90 patients with classifiable observations (68.9%) were free of otorrhoea. Among 94 patients with available usability data, nine (9.6%) had a recorded problem during treatment, including technical difficulty or limited cooperation, mild pain, vertigo, fever or otalgia, non-adherence, and an anatomical obstruction. In an exploratory analysis, otorrhoea lasting more than one year was more frequent among patients with persistent otorrhoea than among those with complete resolution (100% versus 57.5%, Fisher's exact test, p=0.021). In this resource-constrained setting, a simple bellows-pipette cleaning method combined with 2% acetic acid was feasible and was associated with a high proportion of short-term otorrhoea resolution. These observational findings support further evaluation os this approach, ideally in controlled studies.

Introduction

Chronic suppurative otitis media (CSOM) is characterized by persistent or recurrent ear discharge through a perforated tympanic membrane and remains an important cause of hearing impairment and serious complications in many low- and middle-income settings [1–4]. In Angola, previous studies have documented a substantial burden of suppurative otitis media and bacterial pathogens associated with chronic ear discharge [3,5,6]. Access to otolaryngology services is limited for many patients, while recurrent treatment and travel to specialist facilities can impose substantial practical and financial burdens. Aural toilet is a central component of CSOM management because accumulated pus and debris may impede contact between topical agents and infected tissue. Conventional microsuction requires an electrically powered suction system, appropriate

cannulas, trained personnel, and access to clinical facilities. In children, suction can also be distressing because of noise and discomfort. Primary ear-care guidance therefore includes simple cleaning approaches that can be delivered in resource-constrained environments [1,7].

Topical antiseptics provide a potentially low-cost alternative or adjunct to topical antibiotics. Acetic acid lowers local pH and has antimicrobial activity. Previous studies have reported resolution of otorrhoea after repeated acetic-acid irrigation, although the overall evidence base for topical antiseptics in CSOM remains limited and heterogeneous [8–10]. In parallel, antimicrobial resistance is an important concern in chronic ear disease in Angola and elsewhere, reinforcing the need to evaluate non-antibiotic approaches where clinically appropriate [5,6].

A manually operated bellows pipette that can aspirate discharge from the external auditorycanal without electricity and can subsequently deliver a small volume of irrigating solution was developed. The device incorporated a depth-limiting feature to prevent deep insertion(Figure 1). The present study evaluated the feasibility, short-term clinical course, and final otorrhoea outcome when the bellows pipette was used with 2% acetic acid or equivalently diluted vinegar in patients with CSOM treated at Hospital Josina Machel in Luanda. Because there was no concurrent control group, the study was designed to describe outcomes rather than establish comparative efficacy.

EarClean bellow pipette; Safety Testing, CE Marking and Ethical Approval

The EarClean bellow pipette was tested to assess the pressures and fluid flow generated during manual compression and release. Testing demonstrated that no hazardous pressures were generated when the pipette was used with its narrow nozzle, which prevents an airtight seal in the ear canal [11].

The pipette and its plastic materials also underwent the required safety and material analyses to demonstrate conformity with the EU Medical Device Regulation (MDR). EarClean was subsequently CE-marked as a Class I medical device, allowing its marketing and sale within the European Union for its stated intended use.

The clinical use of EarClean for treating chronic suppurative otitis media (CSOM) in Angola, involving irrigation with diluted acetic acid, was conducted under ethical approval from the Ethics Committee of the Angolan Ministry of Health.

Materials and methods

Study design and setting

We conducted a prospective observational study in the Otorhinolaryngology Service of Hospital Josina Machel–Maria Pia, a tertiary-level national referral hospital in Luanda, Angola. The patients were observed between August 2024 and August 2026. Participants were evaluated at baseline, with planned reassessment on days 5 and 10 after starting treatment; the actual timing of visits could vary marginally for logistical reasons. Additional later observations were used when explicitly documented in the clinical record.

Participants

The study included 100 consenting patients diagnosed with chronic suppurative otitis media. The protocol specified inclusion of patients with otorrhoea lasting more than three weeks and a visible tympanic membrane perforation diagnosed using a video otoscope. Active HIV infection, tuberculosis, malaria, and meningitis were exclusion criteria.

Bellows pipette and treatment procedure

At the initial visit, an otolaryngology clinician used the bellows pipette to aspirate visible purulent material from the external auditory canal. The ear was then irrigated with 2% acetic acid or vinegar diluted to a concentration of 2%.The first pipette was used for suction and the next clean one for irrigation. Patients and caregivers were instructed on the procedure and were asked to continue at home with aspiration followed by irrigation twice daily for one to two weeks while discharge persisted. Patients were given six pipettes at the instructional visit. (Ear Clean® bellow pipette, ReiBeck Innovation AB, Sweden) .

The bellow pipette has a soft plastic nozzle, a depth-limiting flange. Insertion of approximately 10 mm into the ear canal is possible. Of the pipettes given to the patients, some were only for aspirating the ear discharge and others for irrigating with the vinegar solution

Outcome definitions

The primary clinical outcome was complete resolution of otorrhoea at the patient level, defined as no otorrhoea in any affected ear at the final recorded assessment. A persistent tympanic membrane perforation was not classified as treatment failure if otorrhoea had resolved. In patients with bilateral disease, complete resolution required both affected ears to be free of otorrhoea. Persistent otorrhoea was defined as continued discharge with no affected ear documented as dry. A mixed bilateral outcome denoted one dry ear and persistent discharge in the contralateral ear. Patients without an interpretable final outcome were classified as not assessable.
Secondary descriptive outcomes included day-5 and day-10 otoscopic findings, usability problems reported during pipette use, microbiological findings when available, and exploratory comparisons between patients with complete resolution and those with persistent otorrhoea.

Microbiology

Ear-discharge specimens were collected in a subset of participants. Culture and antimicrobial susceptibility testing were not available for all patients, in part because microbiological sampling and laboratory processing were constrained by limited laboratory capacity in Angola. Because the microbiological data were incomplete and included contaminated, frozen, and non-evaluable specimens, microbiology was treated as descriptive and exploratory rather than as a prespecified efficacy endpoint.

Statistical analysis

Descriptive statistics were used to summarize demographic, clinical, microbiological, usability, and outcome data. Continuous variables are presented using means and medians with interquartile ranges where available; categorical variables are reported as

counts and percentages with denominators reflecting available observations. For the exploratory comparison of complete resolution (n=82) versus persistent otorrhoea (n=8), continuous variables were compared using the Mann–Whitney U test and categorical variables using Fisher's exact test. Two-sided $p<0.05$ was used as a conventional threshold, without adjustment for multiple testing. Because this comparison was exploratory and the persistent-otorrhoea group was small, p-values should be interpreted as hypothesis-generating.

Ethics

The National Institute for Health Research in Angola approved the study (No. 035/CEMS/2025). Written informed consent was obtained from the patients or their caregivers, and confidentiality was maintained in accordance with the Declaration of Helsinki.

Results

Participant characteristics

The cohort comprised 100 patients aged 1–63 years (mean 16.2 years; median 11 years; interquartile range 7.0–22.3 years). Sixty-six patients were younger than 18 years. Fifty-six patients were male and 44 female. Ninety-nine patients were living in Luanda Province and one in Icolo e Bengo. Otorrhoea had lasted more than one year in 60 of 98 patients (61.2%), and 85 of 98 patients (86.7%) had received previous medical treatment.

Table 1. Baseline characteristics of the study population.

Characteristic	Result
Enrolled patients	100
Age, mean; median (IQR), years	16.2; 11 (7.0–22.3)
Age range, years	1–63
Age <18 years	66/100 (66.0%)
Male sex	56/100 (56.0%)
Female sex	44/100 (44.0%)

Otorrhoea duration >1 year	60/98 (61.2%)
Previous medical treatment	85/98 (86.7%)
Bilateral disease at baseline	38/100 (38.0%)
Unilateral disease at baseline	62/100 (62.0%)

Baseline otoscopic findings

All participants had otorrhoea in at least one ear at baseline. Bilateral disease was recorded in 38 patients. Among 199 ear-level observations assessable at baseline, 138 (69.3%) had otorrhoea and 125 (62.8%) had a tympanic membrane perforation. Of 131 ears with classifiable discharge volume, 73 (55.7%) had profuse, 34 (26.0%) moderate, and 24 (18.3%) scant otorrhoea. Two patients had signs of cholesteatoma, one had signs of mastoiditis, three had an external auditory canal polyp, one a postauricular abscess, and one cervical lymphadenopathy.

Clinical course and final outcome

At day 5, 15 of 94 patients with classifiable observations (16.0%) were free of otorrhoea; 79 remained with persistent or mixed otorrhoea. At day 10, 62 of 90 patients with classifiable observations (68.9%) were free of otorrhoea, while 27 had persistent or mixed otorrhoea and one observation could not be reliably classified. Some patients achieved resolution of otorrhoea at later follow-up visits, including day 15.

At the final recorded assessment, complete resolution of otorrhoea in all affected ears was documented in 82 of 100 enrolled patients (82.0%). Nine patients were not assessable: seven did not return for follow-up, one did not undergo irrigation because of a large ear-canal polyp, and one lacked a definitive final outcome. Among the 91 patients with an assessable final outcome, 82 (90.1%) had complete resolution, eight (8.8%) had persistent otorrhoea, and one (1.1%) had a mixed bilateral outcome.

Table 2. Short-term clinical course and final patient-level outcome.

Outcome	**n/N (%)**
Free of otorrhoea at day 5	15/94 (16.0%)
Free of otorrhoea at day 10	62/90 (68.9%)

Complete resolution at final assessment, all enrolled	82/100 (82.0%)
Complete resolution among evaluable patients	82/91 (90.1%)
Persistent otorrhoea among evaluable patients	8/91 (8.8%)
Mixed bilateral outcome among evaluable patients	1/91 (1.1%)
Not assessable	9/100 (9.0%)

Usability and safety observations

Usability data were available for 94 patients, of whom 85 (90.4%) had no recorded problems and nine (9.6%) had one recorded issue. The reported problems comprised technical difficulty or limited cooperation in four cases, non-adherence in one, inability to irrigate because of a large external auditory canal polyp in one, mild pain during irrigation in one, vertigo leading to discontinuation in one, and fever with ear pain treated with antibiotics in one. One patient with persistent otorrhoea subsequently developed left-sided otomastoiditis requiring hospital admission; was discharged improved and continues under follow-up

Microbiological findings

Microbiological information was recorded for 52 patients, but only 33 had a definitive culture result. Twenty-nine of these 33 cultures (87.9%) showed bacterial growth. *Pseudomonas* species, including *P. aeruginosa* (n=6), were the most frequently identified organisms (n=6), followed by *Staphylococcus* species (n=5), *Enterobacter* species (n=3), *Citrobacter* species (n=3), with smaller numbers of other Gram-negative and Gram-positive organisms. Antimicrobial susceptibility information was available for 28 of 29 positive cultures. At least one listed antibiotic resistance was recorded in 23 of the 29 positive cultures (79.3%).

Exploratory predictors of persistent otorrhoea

The binary exploratory analysis compared 82 patients with complete resolution with eight patients who had persistent otorrhoea; the mixed outcome and non-assessable patients were excluded. All eight patients with persistent otorrhoea had a history of discharge lasting more than one year, compared with 46 of 80 patients with complete resolution and usable duration data (100% versus 57.5%; Fisher's exact test p=0.021). No statistically significant differences were observed for age, sex, age at first episode of otorrhoea, bilateral disease, baseline abundance of otorrhoea, tympanic membrane perforation, identification of a bacterial organism, or reported problems during pipette use.

Table 3. Exploratory comparison of complete resolution versus persistent otorrhoea.

Variable	**Complete resolution (n=82)**	**Persistent otorrhoea (n=8)**	**p value**
Age, median (IQR), years	12 (7–25)	9.5 (6–11)	0.207
Female sex	40/82 (48.8%)	2/8 (25.0%)	0.276
Otorrhoea duration >1 year	46/80 (57.5%)	8/8 (100%)	0.021
Age at first otorrhoea, median (IQR), years	8 (3–20), n=77	4 (3–6.5), n=7	0.187
Bilateral otorrhoea at baseline	30/82 (36.6%)	3/8 (37.5%)	1.000
Profuse otorrhoea at baseline	38/82 (46.3%)	6/8 (75.0%)	0.153

Recorded tympanic membrane perforation	78/82 (95.1%)	8/8 (100%)	1.000
Bacterial organism identified	23/82 (28.0%)	4/8 (50.0%)	0.234
Recorded problem during pipette use	6/82 (7.3%)	2/8 (25.0%)	0.148

IQR, interquartile range. Denominators reflect available non-missing data. Continuous variables were compared with Mann–Whitney U tests and categorical variables with Fisher's exact tests. The analyses were exploratory and were not adjusted for multiple comparisons.

Discussion

In this prospective observational cohort of 100 patients with CSOM in Luanda, 82% of all enrolled patients and 90.1% of patients with an assessable final outcome achieved complete resolution of otorrhoea during short-term follow-up after aspiration and irrigation with a manually operated bellows pipette and 2% acetic acid or diluted vinegar. The proportion of patients documented as dry increased between day 5 and day 10, and some additional patients achieved resolution of otorrhoea by day 15. These findings support the feasibility of the approach in a setting where repeated access to specialist treatment may be difficult.

The findings are consistent with earlier work suggesting that repeated aural cleaning combined with acidic irrigation can control chronic ear discharge [8,9]. This study had no randomized or concurrent comparison group, and therefore should not be presented as demonstrating superiority over dry mopping, topical antibiotics, or other standard-care approaches. However, the findings suggest that bellows pipette aspiration followed by topical 2 % acetic acid may be feasible and potentially effective strategy for reducing chronic otorrhoea in resource-limited, low socioeconomic settings. A clinically important feature of this approach is that it does not require electricity. This could have relevance for primary care and community-level management in settings where suction equipment and specialist personnel are scarce. Furthermore, the ease of

performance may be advantageous where specialized personnel are limited. The high proportion of participants with a previous history of medical treatment suggests that the cohort included many patients with longstanding or recurrent disease rather than exclusively first episodes. Nevertheless, implementation outside a supervised study would require standardized training, clear contraindications and reliable preparation of the irrigating solution.

The exploratory analysis suggested that a history of otorrhoea for more than one year may be associated with persistent discharge. All eight patients with persistent otorrhoea had disease lasting more than one year compared with 57.5% of patients with complete resolution. Longer-standing disease may plausibly reflect more complex middle-ear pathology, biofilm formation, chronic mucosal change, or other factors that reduce the likelihood of rapid resolution [10,12].

Microbiological data showed a diverse bacterial spectrum, including *Pseudomonas* and *Staphylococcus* species, broadly consistent with prior Angolan studies [5,6]. Resistance to at least one reported antibiotic was common among positive cultures with susceptibility results. These microbiological observations provide contextual support for interest in non-antibiotic local approaches, but the present study was not designed to estimate resistance prevalence or to compare antimicrobial strategies.

Nine of 94 patients with available usability information had a recorded deviation. Most were related to technique, cooperation, adherence, or anatomical constraints. Pain, vertigo, fever, and otalgia were also recorded. These events underline the importance of standardized safety monitoring in future studies. One patient required admission for otomastoiditis; the available records do not establish a causal relationship to treatment.

Because formal audiometric data were not recorded, the study cannot assess hearing outcomes or exclude ototoxic effects. This is an important limitation when acidic irrigation is used in ears with tympanic membrane perforation. However, none of the patients selfreported hearing loss during or after treatment.

The preliminary results suggest that the approach may be practical and beneficial in a setting where access to specialist ear care is limited. The appropriate next step is therefore a phased project led by the hospital’s ENT clinicians, who would train local

healthcare staff, define which patients can be treated, arrange specialist referral when needed, and monitor outcomes and adverse events.

Strengths and limitations

The principal strengths are the prospective clinical setting, inclusion of 100 patients in a resource-constrained environment, repeated follow-up observations, a low drop out rate, and the use of patient-level final outcome adjudication that distinguished persistent tympanic membrane perforation from persistent discharge. The study also provides practical information on home or caregiver use of a simple non-electric cleaning device. The limitations are that microbiological sampling was incomplete. Audiometry and standardized hearing outcomes were absent. The data do not clarify whether the six observations with otorrhoea but no recorded tympanic membrane perforation represented unconfirmed perforation, an alternative source of discharge, or incomplete documentation.

Conclusions

In this prospective cohort from Luanda, aspiration of ear discharge using a manually operated bellows pipette, followed by irrigation with 2% acetic acid or diluted vinegar, was feasible and was associated with complete short-term resolution of otorrhoea in 82 of 100 enrolled patients (82%) and in 82 of 91 patients with an assessable final outcome (90.1%). The clinical experience gained from 100 patients with chronic suppurative otitis media (CSOM) treated at Hospital Josina Machel provides a strong rationale for the next step: a carefully supervised implementation study in selected primary healthcare units in underserved areas of Luanda.

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Author contributions

[TO BE COMPLETED using the CRediT taxonomy. Suggested categories to allocate among authors: Conceptualization; Methodology; Investigation; Data curation; Formal analysis; Supervision; Project administration; Writing – original draft; Writing – review & editing.]

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Competing interests

ÅR is a co-founder and Chief Executive Officer of ReiBeck Innovation AB, the manufacturer of EarClean, the device used in this study. ReiBeck Innovation AB holds rights relating to the production and marketing of EarClean within the European Union. Palmira Kuatoko and all other authors declare that they have no competing interests.

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FIGURE 1

