Evaluating red flag criteria for surveillance of ear diseases

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Abstract:

The red flag criteria designed by the FDA and the AAO were proposed to provide surveillance of medically treatable ear diseases in individuals seeking hearing aids. However, the ability of these red flags to effectively screen patients has not been well-established. Using a pool of 307 patients from the Mayo Clinic Florida with a disproportionate prevalence of ear disease (75%), we evaluated the sensitivity and specificity of both sets of red flag criteria. Blinded neurotologist opinion was used as the gold standard for the presence or absence of an ear disease, and data for each of the red flags were pulled retrospectively from examinations performed by audiologists. The conservative nature of the AAO red flag criteria resulted in relatively high sensitivity and very low specificity, with many patients being flagged for referral unnecessarily. The FDA red flag criteria were less sensitive than the AAO's, but were substantially more specific. As the prevalence of these diseases is thought to be quite low in the hearing aid-seeking population (~5%), the high rate of referrals due to false positives would lead to substantial unnecessary costs. Possible solutions that provide adequate surveillance while reducing the rate of false positive referrals will be discussed.

Acknowledgements

Funding for this work was provided by NIH/NIDCD grant DC013115 and the Knowles Hearing Center at Northwestern University.

Introduction

- On rare occasions, hearing loss may be caused by disease (e.g. vestibular schwannoma) rather than age- or noise-related changes
- Untreated diseases have potentially significant deleterious effects at the individual- and healthcare system-levels
- Current Food and Drug Administration (FDA) policy does not provide for surveillance of diseases that may cause hearing loss
- We have recently developed the Consumer Ear Disease Risk Assessment questionnaire (CEDRA) for the purposes of low-cost disease surveillance for individuals seeking treatement for hearing difficulty.

- **Red flag symptoms defined by the FDA and proposed by the American Academy of Otolaryngology (AAO) do not have published test performance estimates. Here we compare the test performance of the two sets of red flags along with the newly created CEDRA.**

Methods

Chart histories from participants in the Consumer Ear Disease Risk Assessment (CEDRA) validation[3]

Participants

- 307 patients from the Audiology or Otorhinolaryngology Departments at Mayo Clinic Florida
- 40-80 years of age (mean 62.9)
- 147 females

Coding

- Two independent coders
  - Hand-coding by an experienced audiologist (DZ)
  - Automated coding from examination data (NK)
  - 95% agreement on first pass
  - Disagreements only from interpretation of red flags (see figures 4, 5)
- Gold standard diagnosis by neurotologist for presence/absence of 104 targeted ear diseases[3]
- Additional criterion for includsion: all data collected ±90 days for a given individual (Ð in figures 4, 5)

References

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Results

FDA red flags

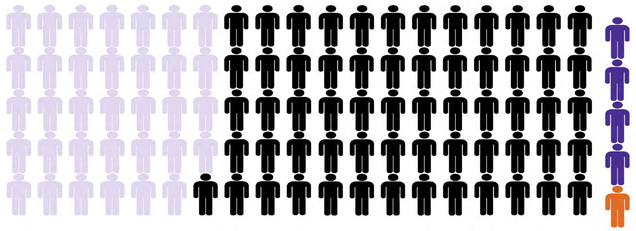

Figure 1. Average FDA results in one-hundred hearing aid seeking individuals: 88% sensitive, 69% specific. Cumulative prevalence of 104 targeted ear diseases is estimated at 5%.

AAO red flags

Figure 2. Average AAO results in one-hundred hearing aid seeking individuals: 96% sensitive, 14% specific. Cumulative prevalence set at 5%.

CEDRA questionnaire

Figure 3. Average CEDRA questionnaire results in one-hundred hearing aid seeking individuals: 92% sensitive, 58% specific. Cumulative prevalence set at 5%.

FDA red flags:

1. Visible congenital or traumatic deformity of the ear
2. History of active drainage from the ear within the previous 90 days
3. History of sudden or rapidly progressive hearing loss within the previous 90 days
4. Acute or chronic dizziness
5. Unilateral hearing loss of sudden or recent onset within the previous 90 days
6. Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz
   ‡ *at all three frequencies?*
   Ħ *average of all three frequencies?*
7. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal
8. Pain or discomfort in the ear
   Ħ *pain, discomfort, otalgia?*
   Ø *fullness, pain, discomfort, otalgia?*

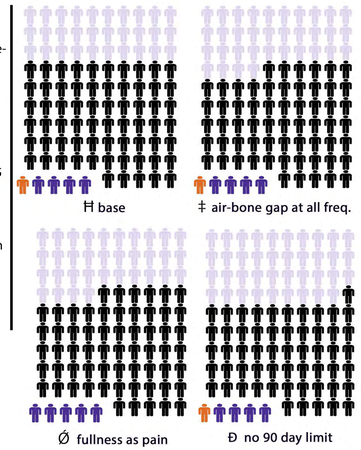

Figure 4. FDA test performance depends on red flag interpretation. Sensitivity: 85-92%. Specificity: 64-73%.

AAO red flags:

1. Hearing loss with a positive history of ear infections, noise exposure, familial hearing loss, TB, syphilis, HIV, Meniere's disease, autoimmune disorder, ototoxic medication use, otosclerosis, von Recklinghausen's neurofibromatosis, Paget's disease of bone, ear or head trauma related to onset.
   ŧ *hearing loss as PTA>20 dB HL?*
   Ħ *hearing loss at two, consecutive frequencies >20 dB HL?*
2. History of pain, active drainage, or bleeding from an ear.
   Ħ *pain as pain, otalgia*
   Ø *pain as fullness, pain, otalgia*
3. Sudden onset or rapidly progressive hearing loss.
4. Acute, chronic, or recurrent episodes of dizziness.
5. Evidence of congenital or traumatic deformity of the ear.
6. Visualization of blood, pus, cerumen plug, foreign body, or other material in the ear canal.
7. An unexplained conductive hearing loss or abnormal tympanogram.
8. Unilateral or asymmetric hearing loss (a difference of greater than 15 dB Pure Tone Average between ears); or bilateral hearing loss > 30 dB.
9. Unilateral or pulsatile tinnitus.
10. Unilateral or asymmetrically poor speech discrimination scores (a difference of greater than 15% between ears); or bilateral speech discrimination scores <80%.

Figure 5. AAO test performance depends on red flag interpretation. Sensitivity: 93-98%. Specificity: 7-22%.

Discussion

- AAO red flags were very sensitive to disease, but provided many false referrals
- FDA red flags were fairly sensitive and reasonably specific
- Both red flag sets require audiological evaluation
- Consumer-based screening (CEDRA) may provide reasonable surveillance without additional barriers to access
- A full examination of the red flags in a more typical patient population is currently underway.