Clinical Review

Evidence behind the WHO guidelines: Hospital Care for Children: What is the Diagnostic Accuracy of Gastric Aspiration for the Diagnosis of Tuberculosis in Children?

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For more information on this project to evaluate the evidence behind the WHO Hospital Care for Children, see J Trop Pediatr 2006; 52:1–2. If you would like suggest a topic or contribute a review, please contact Dr Julian Kelly.
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The World Health Organization has produced guidelines for the management of common illnesses in hospitals with limited resources. This series reviews the scientific evidence behind WHO’s recommendations. The WHO guidelines, and more reviews are available at: http://www.ichrc.org.

The WHO Pocketbook of Hospital Care for Children recommends to try to obtain specimens for microscopic examination of acid-fast bacilli (Ziehl–Neelsen stain) and for culture of tubercle bacilli. Possible specimens include three consecutive early morning fasting gastric aspirates, CSF (if clinically indicated) and pleural fluid and ascites fluid.

This review addresses the question: what is the diagnostic accuracy of gastric aspiration for the diagnosis of tuberculosis in children?

Introduction

A major challenge in the management of suspected paediatric tuberculosis (TB) is confirmation of the diagnosis [1], which is generally made on the basis of history of chronic symptoms, examination findings, tuberculin skin testing, chest radiograph and microscopy and where available, microbiologic culture of relevant samples. [1, 2, 3]

Diagnosis in children is often difficult as TB in this age group is often smear negative and radiology availability and interpretation is limited.

Gastric aspiration or lavage has been an established method for obtaining microbiologic samples in paediatric TB, particularly in the <5 year age group who will not or are unable to expectorate sputum.

It is cheap, simple to perform and requires no special equipment. However, overnight fasting and presentation to a facility early morning is required.

This aim of this review is to determine the diagnostic accuracy of gastric aspiration compared to clinical diagnostic criteria and to other methods of sample collection the diagnosis of tuberculosis in children.

Methodology

Abstracts of all articles located by the search were reviewed. Full-text versions of potentially relevant studies were obtained.

Inclusion criteria:
1. Pulmonary TB in children <15 years
2. Original research (not reviews)
3. Evaluated gastric aspiration (GA) or gastric lavage (GL)
4. Compared GA/GL to clinical criteria or to another diagnostic method
5. English language version

Exclusion criteria:
1. Small sample or subset of population of larger adult study
2. Reported results of GA/GL only as ‘per number samples sent’ and not ‘per number patients tested’

Search strategy
Pubmed’s Haynes Clinical queries [4], Pubmed, EMBASE and the Cochrane Database of Controlled Trials were searched for relevant papers.
Forty-eight studies were identified from a review of abstracts. Further, 15 studies were identified from a review of study citations. Sixty-three articles were reviewed in full. Thirty-two studies were excluded as they did not meet the criteria [5–36], leaving 31 studies included in this review [37–67].

Statistics
Results are expressed as number of children with a positive microscopy or culture result per total number of children tested rather than as a proportion of the number of specimens tested. Where studies did not calculate the statistical significance between the yield of GA/GL and other methods of sample collection, Fisher’s exact test was applied. A meta-analysis of studies comparing the yield of culture of GA/GL to other techniques for sample collection was made using the Mantel–Haenszel random effects model. This method assumes 100% specificity for GA culture.

Results

Description of studies
The 31 included studies had significant variation in study aim and outcomes, geographical location, healthcare setting, sample size, median age of subjects, HIV prevalence, method of sample collection and protocol for lavage or aspiration of gastric contents, method of microscopy and culture and most importantly, case definition of tuberculosis. See Table 1 for details of included studies.

Thirteen studies were from sub-Saharan Africa (eight from South Africa, [39, 42, 47, 50, 53, 54, 57, 60] two from Uganda [63, 67], one from Ethiopia [43], one from Malawi [46] and one from Zimbabwe [55]), four from South America (two from Peru [41, 51], two from Brazil [37, 40]), six from the USA [49, 52, 56, 61, 64, 65], three from India [48, 59, 66], two from France [58, 62], one from Israel [44], one from Spain [45] and one from Yemen [38].

Studies were prospective, apart from one historical case–control study [56] and seven retrospective reviews of case records [44, 49, 55, 58, 61, 62, 65]. Median age varied from 13 months to 7 years. Study sizes varied from 20 to 1732 children. HIV prevalence varied from 0% to 71%, although it was only systematically tested in 11 of the 32 studies [38–43, 46, 47, 49, 51, 55].

The method used to perform the GA or GL differed between studies, with substantial variations in the amount of fluid collected, the number of aspirates or lavages attempted, the enforcement of retaining a recumbent position prior to early morning aspiration and the protocol for standardization and processing of samples.

Definition of pulmonary tuberculosis in children
The definition used to define PPTB in the studies was variable, and the diagnostic accuracy of GA/GL varied according to specificity of definitions used. The studies can be divided into three categories.

The first group had broad, sensitive definitions which required only one symptom or investigation such as a contact history or unexplained weight loss or a positive TST. Seven studies used such criteria, and diagnostic yield from GA/GL was generally low [38, 39, 49, 50, 53, 54, 62]. Microscopy positivity rates ranged from 0% to 5%, median 1% and culture isolation rates from 0% to 13%, median 7%.

The second group used a combination of at least two symptoms or one positive investigation plus one positive investigation such as chronic cough for longer than one month plus a positive TST. Eight studies fell into this category [37, 41, 42, 43, 46, 55, 60, 61]. Microscopy rates ranged from 1% to 13%, median 8% and culture rates from 7% to 75%, median 43%.

The third group included narrow, more specific definition studies. These required at least symptoms and signs of TB or contact history and one positive investigation or two positive investigations such as TST and suggestive CXR changes. Ten studies fell into this group [44, 45, 47, 48, 52, 56, 59, 63–65]. Microscopy rates were 4–21%, median 7% and culture rates 17–50%, median 32%. A subgroup of one study had highly specific criteria requiring three of: contact history, chronic cough, suggestive chest X-ray, positive TST, microscopy positive for AAFB or response to TB treatment and was based in a regional tertiary centre for children referred with suspected TB [63]. These factors partly account for the very high rate of AAFB seen on microscopy of GA at 97% [63].

Six of the studies had vague definitions, such as a ‘clinical diagnosis of TB’, or not described [39, 51, 57, 58, 66, 67]. These studies were included as they compared GA/GL to another diagnostic technique or in the case of one study, inpatient and outpatient GA sampling [40]. The lack of firm diagnostic criteria precluded comparison with other studies.

Comparison between microscopy and culture of GA/GL
Ten studies which adequately described inclusion criteria tested both microscopy and culture of GA/GL [37–39, 42, 43, 47, 48, 55, 59, 62]. In studies of clinically defined cases of paediatric pulmonary tuberculosis where both microscopy and culture of GA/GL was undertaken, the sensitivity of microscopy compared to culture was between 2% and 47%, median 26%.

Age of child
The median age of children in studies varied from 13 months to 7 years. No study systematically
<table>
<thead>
<tr>
<th>Ref. No</th>
<th>Year</th>
<th>Country</th>
<th>Study type</th>
<th>Study objective</th>
<th>Mean or median age (years)</th>
<th>Study size (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>41</td>
<td>2010</td>
<td>Brazil</td>
<td>P</td>
<td>Evaluate use of nebuliser prior to GA/GL</td>
<td>NS</td>
<td>104</td>
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<td>42</td>
<td>2009</td>
<td>Yemen</td>
<td>P</td>
<td>Compare GA, NPA and IS</td>
<td>5</td>
<td>213</td>
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<tr>
<td>43</td>
<td>2009</td>
<td>South Africa</td>
<td>P</td>
<td>Compare IS and GL</td>
<td>1.1</td>
<td>1654</td>
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<td>44</td>
<td>2008</td>
<td>Brazil</td>
<td>P</td>
<td>Compare inpatient and outpatient GA</td>
<td>NS, all &lt;15</td>
<td>53</td>
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<tr>
<td>45</td>
<td>2006</td>
<td>Peru</td>
<td>P</td>
<td>Compare Lowenstein-Jensen and MODS culture methods</td>
<td>4.6</td>
<td>165</td>
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<tr>
<td>46</td>
<td>2005</td>
<td>South Africa</td>
<td>P</td>
<td>Compare GA and IS</td>
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<td>250</td>
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<td>2002</td>
<td>Israel</td>
<td>R</td>
<td>Evaluate the use of bronchoscopy in diagnosis of paediatric TB</td>
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<td>80</td>
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<td>2001</td>
<td>Spain</td>
<td>P</td>
<td>Compare PCR and culture of GA and BAL</td>
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<td>25</td>
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<tr>
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<td>Malawi</td>
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<td>Evaluate the effect of HIV on GA</td>
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<td>102</td>
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<td>51</td>
<td>2000</td>
<td>South Africa</td>
<td>P</td>
<td>Evaluate value of lymph node biopsy or fine-needle aspiration cytology</td>
<td>3.6</td>
<td>45</td>
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<td>52</td>
<td>2000</td>
<td>India</td>
<td>P</td>
<td>Compare GL and BAL</td>
<td>6.2</td>
<td>58</td>
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<tr>
<td>53</td>
<td>1999</td>
<td>USA</td>
<td>R</td>
<td>Evaluate diagnostic criteria, CT thorax and Amplicor PCR</td>
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<td>27</td>
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<td>54</td>
<td>1999</td>
<td>South Africa</td>
<td>P</td>
<td>Assess prevalence of disease in contacts under 5 years of adult patients with MDR-TB</td>
<td>2.3</td>
<td>128</td>
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<td>55</td>
<td>1998</td>
<td>Peru</td>
<td>P</td>
<td>Compare NPA and GA</td>
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<td>24</td>
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<td>56</td>
<td>1998</td>
<td>USA</td>
<td>P</td>
<td>1. Compare outpatient and inpatient GA 2. Evaluate clinical features associated with positive culture</td>
<td>2.8</td>
<td>100</td>
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<td>57</td>
<td>1998</td>
<td>South Africa</td>
<td>P</td>
<td>Evaluate WHO criteria for PPTB</td>
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<td>58</td>
<td>1997</td>
<td>South Africa</td>
<td>P</td>
<td>Screen for TB in household contacts under 5 of sputum positive PTB adults</td>
<td>NS all &lt;5 years</td>
<td>70</td>
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<tr>
<td>59</td>
<td>1997</td>
<td>Zimbabwe</td>
<td>R</td>
<td>1. Descriptive diagnosis of PPTB 2. Effect of HIV infection on diagnosis</td>
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<td>115</td>
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<td>60</td>
<td>1997</td>
<td>USA</td>
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<td>Evaluate standardised GA collection protocol</td>
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<td>21</td>
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<td>1996</td>
<td>South Africa</td>
<td>P</td>
<td>Evaluate use of stool culture</td>
<td>NS</td>
<td>62</td>
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<tr>
<td>62</td>
<td>1995</td>
<td>France</td>
<td>R</td>
<td>Evaluate value of bronchoscopy</td>
<td>4</td>
<td>54</td>
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<tr>
<td>63</td>
<td>1995</td>
<td>India</td>
<td>P</td>
<td>Compare GA and BAL</td>
<td>5.1</td>
<td>50</td>
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<tr>
<td>64</td>
<td>1995</td>
<td>South Africa</td>
<td>P</td>
<td>Evaluate value of clinical features and investigations in diagnosis</td>
<td>2.6</td>
<td>258</td>
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<tr>
<td>65</td>
<td>1994</td>
<td>USA</td>
<td>R</td>
<td>Descriptive study of infants diagnosed with TB</td>
<td>8 months</td>
<td>32</td>
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<tr>
<td>66</td>
<td>1993</td>
<td>France</td>
<td>R</td>
<td>Compare PCR to culture of GA</td>
<td>7</td>
<td>22</td>
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<tr>
<td>67</td>
<td>1992</td>
<td>Uganda</td>
<td>P</td>
<td>Evaluate GA and response to treatment as diagnostic test</td>
<td>NS, all &lt;5 A:210 B:31</td>
<td>60</td>
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<tr>
<td>68</td>
<td>1992</td>
<td>USA</td>
<td>P</td>
<td>Compare GA and BAL</td>
<td>2</td>
<td>20</td>
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<tr>
<td>69</td>
<td>1989</td>
<td>USA</td>
<td>R</td>
<td>Descriptive study, epidemiology and clinical features</td>
<td>2</td>
<td>58</td>
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<tr>
<td>70</td>
<td>1971</td>
<td>India</td>
<td>P</td>
<td>Compare GL, LS and lung puncture</td>
<td>5</td>
<td>30</td>
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<tr>
<td>71</td>
<td>1968</td>
<td>Uganda</td>
<td>P</td>
<td>Compare GA and LS</td>
<td>NS, all &lt;6</td>
<td>60</td>
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</tbody>
</table>

P, prospective; R, retrospective; MODS, microscopic observation drug susceptibility; BAL, bronchoalveolar lavage; NS, not stated; PPTB, paediatric pulmonary tuberculosis.
assessed the relationship between age of the child and microscopy or culture yield from GA/GL.

**Inpatient versus outpatient**

Three studies assessed the effect of inpatient versus outpatient GA/GL [40, 43, 52]. All three studies found that the yield for microscopy was less than from culture. There was no significant difference between inpatients or outpatients. Culture rates ranged from 37% to 74% for outpatients and 46% to 50% for inpatients (p-value not significant).

**Prior nebulization with hypertonic saline**

One study from two large public hospitals in Vitoria, Brazil [37] tested the effect of nebulization with 3% hypertonic saline prior to gastric lavage. A total of 104 children with an intermediate sensitivity definition of: chronic cough plus one of: contact history, unexplained weight loss, positive TST or suggestive chest X-ray, were randomized 2:1 to normal GL or with prior nebulization. Prior nebulization had a slightly higher yield on both microscopy 4/36 (11%) versus 4/68 (6%), p = 0.44 and culture 9/36 (25%) versus 14/68 (21%), p = 0.62 of lavage fluid.

**Comparison with bronchoalveolar lavage**

Five studies compared bronchoalveolar lavage with GL/GA [44, 48, 58, 59, 64]. A study from Chandigarh, Northern India [48] performed both investigations on 58 children, with suggestive chest X-ray changes, and either a positive TST or a contact history. There was no statistically significant difference between BAL and GL/GA, although when both were done isolation rates rose from 17–21% to 34%.

A study from Madras, India [59] studied 55 children, with symptoms and signs suggestive of TB with CXR changes not responding to antibiotics after three weeks. Culture of GL was shown to be superior to culture of BAL [16/50 (32%) versus 6/50 (12%), p < 0.001].

A small prospective study from New York City, USA [64] of 20 children, required chest X-ray changes and either a contact history or positive TST and showed a statistically significant difference in culture rate between BAL and GA/GL at 2/20 (5%) versus 10/20 (50%), p = 0.014.

Two retrospective studies found no statistically significant difference for BAL and had serious limitations relating to study design, selection bias and sample size. While two of the three above prospective studies showed that GA/GL had significantly higher culture yield than BAL, there was no significant difference when they were analysed using the Mantel–Haenszel random effects model. The combined risk ratio of a positive culture of BAL compared to GA/GL was 0.50 (95% CI 0.18–1.39), p = 0.18.

**Comparison with induced sputum**

Three studies compared induced sputum (IS) to GA [38, 39, 42]. A study from a national TB centre in Yemen [38] compared nasopharyngeal aspirate (NPA), expectorated sputum (ES), GA and IS on 213 children, and had broad screening criteria for inclusion with any of: history of PTB contact, children not returning to health after measles or whooping cough, unexplained weight loss, the presence of cough or wheeze not responding to antibiotics or suggestive chest X-ray changes. GA, IS and expectorated sputum were carried out for three consecutive days. Each child did not necessarily have consecutive testing with all four tests and different proportions of children received each test so the methodological quality and comparative power of the study was weakened. The study reported that three sets of induced sputum 13/82 (16%) had a higher isolation rate than three sets of GA 19/203 (9%), p = 0.15 but the difference was not statistically significant.

A large community-based study from South Africa [39] compared IS to GA in 1654 children presenting with 1869 case episodes. Screening criteria for suspected TB from a community surveillance programme was used: unexplained cough, weight loss, failure to thrive, unexplained fever or contact history with adult with PTB. Results of individual tests were compared to total cumulative yield from all tests, which was 191 of the 1869 case episode (10%). The researchers found no statistical difference between the yield of a single sample of IS, 73/191 [38% (95% CI 31–45)] versus a single sample of GL 80/191 [42% (95% CI 35–49)] or two combined samples of each: IS 106/191 [yield 55% (95% CI 48–62)], GL 126/191 [66% (95% CI 59–73)].

A study of 250 children from two general paediatric wards in South African public hospitals [42] compared IS and GL in 250 children. The criteria were: chronic cough for one month and one of: unexplained weight loss, failure to thrive, positive TST or suggestive CXR changes. In this study, one IS was equivalent to three GL samples. The odds ratio between one IS and one GL for a positive culture was 5.2 (95% CI 2.0–17.3, p = 0.0003) and for three IS samples to three GL samples the odds ratio was 2.8 (1.2–7.2, p = 0.018.

**Comparison with nasopharyngeal aspiration**

Three studies compared NPA to GA [38, 41, 51]. The study by Al-Aghbari et al. [38] from Yemen, described above, demonstrated NPA was equivalent to GA. There was no statistical difference between culture of one sample of NPA (all that was taken in the trial) and three samples of GA (14/200, 7% versus 19/203, 9%, Fisher’s exact test, p = 0.47).

In a study from the National Children Hospital in Lima, Peru [41], NPA appeared to be less sensitive
then GA by culture 8/165 (5%) versus 15/165 (9%) but $p = 0.2$.

A small study from a national referral hospital in Peru [51] compared NPA and GA in 24 children. There were no defined diagnostic criteria for TB. GA was shown to be equivalent to NPA although there was a trend towards superiority of GA, yield on culture, NPA 19/64 (29.7%), GA 24/64 (37.5%) $p = 0.45$. Again the study was underpowered to detect any clinically significant difference.

Comparison with lymph node biopsy or fine needle aspiration cytology

A study from a tertiary centre in Durban, South Africa [47] evaluated lymph node sampling on 45 children presenting with over 1 month of persistent lung disease and generalized lymphadenopathy. Narrow, specific clinical inclusion criteria for TB were used. All patients underwent lymph node biopsy and 39 (87%) patients, trucut needle biopsy and fine needle aspiration cytology (FNAC) performed. The histological diagnosis of TB from lymph nodes was made in 16 of 45 cases (36%) compared to histological diagnosis of TB from lymph node biopsy performed. The 39 (87%) patients, trucut needle biopsy and fine needle aspiration cytology was 80% cheaper than a lymph node biopsy.

Comparison with laryngeal swab

Three included studies compared GA to the use of a laryngeal swab (LS) [46, 66, 67].

A descriptive prospective study from a national referral hospital in Blantyre, Malawi looked at the effect of HIV on the diagnosis of suspected PTB [46]. Enrolled children had chronic cough with either persistent fever or unexplained weight loss and a cough not responding to antibiotics. The first 60 children (of 110 in total) enrolled underwent a LS and either sputum or GA. GA was performed in 42 of the 60 patients. The yield of GA for combined microscopy and culture was 3/42 (7%) and for LS 4/60 (7%), $p = 1.00$. There was no additional yield for LS compared to GA or expectorated sputum.

A small study from a hospital in Udaipur, India from 1971 [66] compared LS and GL in 30 children ‘suspected of TB’. Diagnostic or inclusion criteria were not described. LS was equivalent to GL in smear (20 versus 13%, $p = 0.73$) and in culture positivity rates (13 versus 10%, $p = 1.00$).

A study from Uganda from 1968 [67] compared LS and GL in 60 children of unspecified ages. Diagnostic criteria were not set and the sample included children with abdominal, spinal and TB meningitis. LS was shown to be superior to GA, 38/60 (63%) versus 17/60 (28%), $p < 0.0002$.

For the two earlier studies, lack of diagnostic criteria and small sample sizes provide insufficient evidence for the use of LS compared to GA and preclude meta-analysis.

Comparison with stool culture

Two studies compared GA to stool culture [41, 57]. The study from Lima, Peru [41] described above, compared stool culture to GA. Stool was found to have a significantly lower yield on culture, 3/165 (2%) versus 15/165 (9%) for gastric aspirate culture, $p = 0.006$.

A study from South Africa had a primary objective of assessing the use of stool culture [57]. They enrolled 62 children and did not give the inclusion criteria other than that they were ‘suspected of TB’. They determined that stool culture was significantly inferior to culture of GA, 3/62 (5%) versus 20/62 (32%), $p = 0.001$.

Multiple samples

Two studies described the use of multiple samples to improve the overall yield. The study from Yemen by Al-Aghbari et al. [38], described above, tested four methods: expectorated sputum, IS, NPA and GA. The highest overall yield (13.6%) was given by culturing samples from multiple methods (NPA, ES, IS, GA) over several days. As noted above, investigations were not applied consecutively to each child and variable proportions of children were tested, ranging from induced sputum in 44% of children to nasopharyngeal aspirate in 92%.

For microscopy, individual sampling methods from one day gave a maximum yield of 10/213 children (5%) for NPA and GA, while a combination of all four methods gave a yield of 14/213 (6.5%), which was equivalent to three days of testing of any one sample method (yield 5–7%). Using all four methods for three days increased the yield further to 18/213 (8.5%) [38].

For culture, single investigations on only one day gave a maximum yield of 18/213 (8.5%) for GA, while using multiple methods on one day gave the maximum yield at 29/213 (13.6%) and no additional yield was obtained from three consecutive days of using all four methods.

The large community study from South Africa by Hatherhill et al. [39], described above, found that using both GL and IS on two consecutive days gave the highest yield from culture (10% isolation rate), but the second highest yield was gained from one IS and one GL on the same day (67% of yield from 2×IS and 2×GL), which was equivalent to two consecutive GLs but superior to two consecutive ISs.

Discussion

The most important finding for low income countries is that multiple specimens taken on one day, including GA, NPA and IS have a higher yield than...
successive samples from any one site. This can reduce the need for hospitalization and cut overall costs.

This review showed that the sensitivity of GA/GL compared to a range of clinical diagnostic criteria ranged from 0% to 21% (median 7%) for microscopy and from 0% to 75% (median 20%) for culture. The sensitivity of microscopy and culture respectively of GA/GL using a broad, screening definition was 0% to 5% (median 1%) and 0% to 13% (median 7%), using an intermediate sensitivity case definition was 1–13% (median 8%) and 7–75% (median 43%) and using a narrow specific definition was 4–21% (median 7%) and 17–50% (median 32%).

An important source of heterogeneity between studies was the definition on clinical or radiological grounds for tuberculosis, against which the GA or GL was compared. The lack of an accepted research definition of tuberculosis has led to the present variation in this review and has prevented a meaningful aggregate calculation of diagnostic accuracy.

IS represents a promising alternative to gastric aspiration, showing no significant difference from GA from three well conducted trials [37, 38, 42]. IS involves using of a nebuliser to deliver salbutamol then hypertonic saline. The child then receives chest physiotherapy and either self-expectorates in older children or suction of the nasopharynx is performed [3]. A major advantage of IS is the ability to perform sampling rapidly in the outpatient clinic without the need for hospitalization. The disadvantages of IS are important and include the need for ward ventilation, face masks for staff protection, nebulizers, monitoring and the cost of sterilization and equipment which will preclude its use in some resource limited settings.

Using hypertonic saline nebulization to increase the yield of GA/GL is promising and the technique requires further prospective, randomized and adequately powered investigation.

GA was shown to be superior to two other sampling methods in this review. BAL and GA/GL were not significantly different in culture yield from three prospective studies [48, 59, 64]. As a more expensive and invasive test which requires facilities for supportive ventilation, BAL is not recommended as a diagnostic test for suspected PTB in children.

Implications for practice

- For GA/GL microscopy was positive in 0–21% (median 7%) and culture was positive in 0–75% (median 20%) of children with clinical diagnoses of likely TB, with isolation rates depending on the clinical criteria used to define TB.
- Gastric aspiration remains a useful diagnostic technique, especially in the inpatient setting.
- IS is a promising, less invasive technique with possible equivalence to GA.

Taking specimens using multiple methods (e.g. GA/GL, IS) on 1 day is a cost-effective and promising method of making an outpatient diagnosis of TB.

Conclusion

References


