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Article Title: Review of epiglottitis in the post *Haemophilus Influenzae* type-b vaccine era

Running Title: Epiglottitis in the post Hib vaccine era

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ABSTRACT

Introduction: To review the demographics, presentation, management, complications and outcomes of acute epiglottitis post *Haemophilus Influenzae* type-b (Hib) vaccine introduction in Australia.

Methods: Retrospective review of acute epiglottitis at four Victorian tertiary centres from 2011 to 2016. Patient characteristics, presentation, investigations, management, complications and outcomes were recorded. Subgroup analysis aiming to identify risk factors for patients requiring acute airway management.

Results: Eighty-seven adult and six paediatric cases were identified. The most frequent clinical findings in adults were sore throat (88.5%), dysphagia (71.3%), odynophagia (57.5%), dysphonia (56.3%) and fever (55.2%). 75.9% required ICU admission. Airway compromise requiring intubation occurred in 27.6%, with 12.5% of these patients undergoing emergency surgical airways. Stridor, hypoxia, shortness of breath, odynophagia, and lymphadenopathy were statistically more frequent amongst cases requiring airway intervention (p<0.05). Cultures revealed mixed results with no aetiological pattern. Hib was never cultured. Amongst paediatric cases fever, tachycardia and stridor were frequently observed and all were admitted to ICU. Two of six required intubation and one underwent surgical intervention. There were no deaths, but one patient suffered a hypoxic brain injury.

Discussion: Modern epiglottitis is not the disease previously encountered by clinicians. With changing demographics and varying organisms, management is adapting to reflect this. Complications are rare, and

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symptomatology at presentation provides aids earlier recognition of patients who may require airway protection.

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INTRODUCTION

Since the widespread introduction of the (Hib) conjugate vaccine in Australia in 1993[1] the clinical presentation and demographics of acute epiglottitis appear to have changed[2-7]. There is however a paucity of recent data on acute epiglottitis in Australia.

Accordingly, we analysed the current presenting symptomatology, acute management and outcomes of epiglottitis in Melbourne, Australia, with the aim to identify specific clinical trends. Moreover, our secondary objective was to identify risk factors for patients requiring acute airway management. Finally, data was also referenced from the Victorian Admitted Episodes Dataset (VAED) for the same period, to identify whether the subgroup of hospitals chosen in this study provided an acceptable representation of the state-wide disease burden. We hypothesized that there would be a limited number of Hib epiglottitis, that most cases would be due to gram-positive organisms, for example *streptococcus*, and that the need for emergency airway management would remain common.

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METHODS

Ethical approval to conduct the multicentre study was granted by the Human Research Ethics Committees at Austin Health, Monash Health, St Vincent's Hospital Melbourne and the Royal Children's Hospital. A retrospective review was performed of health records for all patients with a discharge diagnosis of acute epiglottitis (International Classification of Diseases (ICD)-10 diagnostic code J051) from the aforementioned institutions in Melbourne, Victoria, Australia. The data were collected for a 6-year period between January 2011 and December 2016. As of June 2016 Victoria's population was 6.2 million people, with Melbourne accounting for 4.7 million[8].

Information recorded included: patient demographics, vaccination status if available, past medical history, admission source, presenting signs and symptoms, imaging, laboratory findings and treating speciality unit. In addition, intensive care unit (ICU) admission, intubation type, mechanical ventilation (MV) and ICU hours, operative and medical management, length of stay (LOS), complications and outcomes were also collected.

Acute epiglottitis was defined as inflammation of the epiglottis on direct visualisation or by confirmation with diagnostic abnormalities on imaging. Cases may have also included varying involvement of surrounding supraglottic structures, such as the false cords and epiglottic folds, however epiglottic inflammation was required to fulfil the diagnostic criteria. All patients with the diagnosis of acute epiglottitis were included for data collection. However, patients subsequently not found to fulfil the definition of acute epiglottitis on review of medical records were excluded.

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Managed by the Department of Health and Human Services, the VAED maintains data on all admitted patient episodes of care provided in Victoria. VAED data from all cases of acute epiglottitis from January 2011 to December 2016 was collected with information including: patient demographics (age distribution and sex), admission type and source, treating speciality, LOS, ICU hours and MV hours. In order to assess whether our retrospective review was an accurate representation of all Victorian cases of epiglottitis during our study period, the data collected in our four-hospital retrospective review was compared with the VAED data.

All data was analysed using SAS 5.0.1 software package (SAS Institute Inc., Cary, CA, USA). The mean and range were used for descriptive purposes. A subgroup analysis was performed on the adult population following data collection comparing cases with airway management against those without, to identify associated risk factors. Statistical tests performed included the Chi-squared test. The absolute p-values are presented, with a p-value <0.05 denoting statistical significance. To analyse our collected data compared with VAED data, statistical tests used were the Fisher's exact test or the Chi-square test (if comparing more than two categories), and continuous variables were analysed using the Mann Whitney test, assuming that the variables did not have a Gaussian distribution.

RESULTS

93 patients were identified with acute epiglottitis, of which there were 87 adults and six children. These two groups were analysed separately.

Adult Population

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Demographics and Comorbidities

In the adult population 59 (67.8%) were male, with 56 (64.4%) born in Australia. The mean age at time of admission was 52 years (range 18 to 87). Immunisation status was documented in 18 (20.7%) patient histories. The Charlson Comorbidity Index (CCI), which predicts ten-year mortality, was used to assess level of major medical comorbidities amongst patients. Half of the adult cohort (43 patients) had no medical comorbidities with a CCI score of 0. 7 (8.0%) patients had a CCI score ≥5, indicating severe medical comorbidities. 65 (74.7%) patients were admitted via the emergency department with the remaining 22 (25.3%) patients transferred from other health services.

Clinical Presentation and Diagnosis

The main symptoms and clinical findings are presented in Table 1. The most frequent clinical findings in adults were sore throat (88.5%), dysphagia (71.3%), odynophagia (57.5%), dysphonia, (56.3%) and fever (55.2%). 46.0% of patients experienced subjective shortness of breath (SOB) or tachycardia and one-third of patients presented with stridor (32.2%), with similar numbers for lymphadenopathy and inability to manage upper airway secretions (both 35.6%).

Fibreoptic nasendoscopy was performed and confirmed epiglottitis in 82 (94.3%) patients. For the eight remaining patients for whom nasendoscopy was not performed, epiglottitis was initially diagnosed on imaging. Overall, lateral cervical spine X-ray and computed tomography (CT) of the neck were performed in 20 (23%) and 33 (37.9%) patients respectively. In these cases, lateral cervical spine x-ray was diagnostic for acute epiglottitis in 60% of cases with CT positive in 81.8%. Mean white cell count (WCC) and C-reactive protein (CRP) were 15.7 $x10^9$/L (range 0.3 to 37.3) and 81.5mg/L (range <3 to 374) respectively.

Acute Management and Outcomes

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In total, 66 (75.9%) patients required ICU admission with a mean ICU stay of 64.4 hours (range 4 to 428). The median total in-hospital LOS was 4.0 days (IQR 3.0). 24 patients (27.6%) required airway management. Of those 12 underwent awake fibreoptic intubation, with emergency and semi-elective endotracheal intubations being performed in seven and two patients respectively. Three patients underwent acute surgical tracheostomy following failure of conventional intubating techniques. The mean intubation time was 84.5 hours (range 9 to 254).

All adult patients received intravenous antibiotic therapy. The most common antibiotic regimen used was a combination of ceftriaxone (96.6%) and metronidazole (67.8%). Other common antibiotics recorded included flucloxacillin (19.5%), vancomycin (13.8%) piperacillin-tazobactam (10.3%) and ampicillin (6.9%). All but one patient received at least one dose of intravenous corticosteroid (dexamethasone).

Throat swabs were obtained from 16 patients, with eight (50.0%) of those culturing a range of organisms. *Streptococcus pneumoniae*, *group F Streptococcus*, *group C Streptococcus*, *Aspergillus fumigatus complex* and *Candida glabrata* were cultured in five separate patients. The remaining three patients all cultured a range of unidentified gram positive and negative bacilli and cocci on gram staining. Seven patients were bacteraemic with three patients having positive cultures for *Streptococcus pneumoniae* and the remaining four positive blood cultures growing *Streptococcus pyogenes, Neisseria meningitidis, Klebsiella pneumoniae* and *Corynebacterium* species. Positive throat swabs did not correlate with positive blood cultures.

Two patients developed epiglottic abscesses, treated by incision and drainage. There were no deaths however one patient had a pulseless electrical activity arrest on admission with a downtime of five

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minutes. This patient received cardiopulmonary resuscitation and was acutely tracheotomised but suffered a hypoxic brain injury. All other patients made a full recovery with successful discharge.

Factors Associated with Airway Intervention

Of the parameters presented in Table 2, signs and symptoms of stridor, hypoxia, subjective SOB, odynophagia, and lymphadenopathy at presentation were statistically significantly associated with airway intervention on univariate analysis. This was also the case for major medical comorbidities and an elevated WCC at presentation.

Paediatric Population

Demographics and Comorbidities

Of the six paediatric cases, all were born in Australia and there was a one male and five female patients. The mean age was 5.8 years (range 2 – 16). One patient was immunocompromised due to acute lymphocytic leukaemia (ALL). Only two of six had documented up-to-date immunisation status in their admission paperwork. Half of the patient cohort was admitted via the emergency department versus inter-hospital transfers. The average total inpatient LOS was 8.2 days (range 2 – 20).

Clinical Presentation and Diagnosis

The most common symptoms amongst paediatrics cases are shown in Table 3. Of note, in contrast to adults, children with epiglottitis were more likely to present with fever, tachycardia and stridor (all present in five cases). Four patients experienced sore throat, dysphagia, inability to manage airway secretions or lymphadenopathy. Unlike adults, odynophagia and dysphonia were uncommon, both documented in one case only.

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Unlike adults, all children had a lateral C-spine X-ray, with four of six suggestive of epiglottitis. One patient underwent a CT neck which was diagnostic. Fibreoptic nasendoscopy was performed and was diagnostic in four of six cases. The mean WCC and CRP were 9.7 x 10^9/L (range 1.0 – 13.8) and 79mg/L (range <3 – 227) respectively.

Acute Management and Outcomes

All paediatric patients were admitted to ICU with a mean stay of 73.2 hours (range 15 to 261). Four of six required emergency endotracheal intubation with a mean intubation time of 69.1 hours (range 19.8 to 120).

All paediatric patients were treated with intravenous antibiotics but, unlike adults, there was no consistent choice in antibiotic regime, with the use of broader spectrum antibiotics and antifungals noted. All but one patient received at least one dose of intravenous corticosteroid (dexamethasone).

The single immunocompromised patient with ALL was bacteraemic with *Staphylococcus aureus,* positive on both throat swab and blood cultures. Two other patients had throat swabs which were positive for *Streptococcus pyogenes.* One patient required incision and drainage of an epiglottic abscess but otherwise all patients made a full recovery with successful discharge.

Victorian Admitted Episodes Dataset

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VAED data for the same period as our collected data revealed 243 adult and 16 paediatric cases of acute epiglottitis reported across all Victorian hospitals. Hence, our study captured 35.8% and 37.5% of the total known adult and paediatric cases of epiglottitis for our study period. Tables 4 and 5 show that the data collected largely represented the total cohort for adult and paediatric patients.

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DISCUSSION

Epiglottitis in today's modern medical era remains a potentially life-threatening disease of the airway. The complexities of airway management comprises the most crucial aspect of modern day decision making surrounding acute epiglottitis[5,9]. However, the condition is now a markedly different entity compared with what was previously encountered by otolaryngologists prior to the Hib vaccine. Studies have shown that the incidence of paediatric epiglottitis has significantly decreased in the post-Hib era, shifting the epidemiology towards the adult population[2,3]. However, the nature of this shift is unclear in recent literature with some authors reporting stable incidence when compared to previous studies in the same geographical region[2,5,9] whilst others show an increasing incidence[3,4].

Amongst adults there was male-to-female ratio 2.1:1 in our study which is consistent with previous studies reporting male-to-female ratios between 1.1:1 to 4:1[2,4,9]. Most commonly, our adult patients presented with sore throat, dysphagia, odynophagia and dysphonia, in keeping with previous studies[2,3,5,9].

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Our findings also reinforce that nasendoscopy is gold standard for epiglottitis diagnosis with a 100% diagnostic rate.

The change in clinical adult epiglottitis presents a diagnostic challenge with regards to identifying patients requiring airway protection. Recent literature demonstrates that airway intervention is required in 15% to 32% of patients with epiglottitis[9-13] which was consistent with a 28% airway intervention rate in our study. Whilst there is a lack of consensus regarding which patients require airway management, most authors advocate for a selective approach based on comprehensive evaluation of the individual patient[5,9-13]. On subgroup analysis our study found that stridor, hypoxia, subjective SOB and odynophagia, as well as major medical comorbidities, lymphadenopathy and an elevated WCC on admission were most strongly associated with airway intervention (Table 2). These were all statistically significant. This is in keeping with previous studies, where respiratory distress, stridor and drooling were most strongly associated with airway intervention[5,9,10]. Guardiani et al[5] also found that subjective SOB, rapid symptom onset, tachycardia and tachypnoea were indicative of a more serious clinical course. In contrast to previous evidence, our data identified hypoxia, odynophagia, and lymphadenopathy as clinical markers that are statistically linked to the need for airway intervention.

In our cohort no patients had epiglottitis secondary to a positive Hib culture. There was a broad spectrum of causative organisms identified and these included gram-positive bacteria such as *Streptococcus* and *Corynebacterium* species, gram-negative bacteria such as *Neisseria meningitidis, Klebsiella pneumoniae* and fungal species such as *Aspergillus fumigatus complex* and *Candida glabrata.* These findings may indicate a skin or throat contaminant, but the lack of Hib was notable. Recent literature confirms our findings, showing that the aetiology of epiglottitis amongst adults has shifted towards a

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variety of bacterial, viral and fungal species[2,3]. Of note, no patients in our study had evidence of a positive viral infection. Furthermore, it has been shown that the infective aetiology of adult epiglottitis varies significantly from that of paediatric cases. In our cohort, paediatric cases cultured common gram-positive cocci including *Staphylococcus aureus* and *Streptococcus pyogenes*. This is consistent with previous studies in vaccinated populations whereby streptococcal and staphylococcal infections were dominant[3,6,14].

Antibiotics are fundamental with third generation cephalosporins being the current recommendation for empiric antibiotic therapy in epiglottitis[15]. Nearly all adult patients in our study were treated with ceftriaxone (96.6%) with a large proportion also receiving metronidazole for anaerobic cover. However, no anaerobic organisms were cultured, so the use of this antimicrobial agent may not be of any benefit. The broad spectrum antimicrobial therapy used reflects the lack of consistent causative organisms, in particular Hib[2,3].

Corticosteroid use to reduce airway inflammation is controversial but widespread, and remains firmly in the treatment of epiglottitis[5,9]. Whilst corticosteroids have largely been shown not to decrease the duration of intubation, or length of ICU or overall stay[4,7,9,10,12], it is still common practice for the majority of patients. In our study 98.9% of adult patients and five out of six paediatric cases receiving corticosteroids.

In the paediatric population 66.7% of patients in our study were intubated, however little exists in the literature for comparison. Nonetheless, children are at higher risk of requiring airway protection, as the space within their endolarynx is smaller than adults and they have active lymphoid tissue in the supraglottic region[2].

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Whilst only six paediatric cases were identified in our study, this low incidence is not unexpected and is in keeping with previous studies in the post-Hib era[2,5,9,14]. Compared with adults, paediatric cases had a higher rate of ICU admission and airway intervention, differing symptomatology and an increased average in-hospital LOS compared with adults (8.2 vs 5.0 days). However, due to the very small sample size further analysis was not performed and no comments can be made regarding significance of these findings.

Strengths of this study include the number of patients collected from multiple health services and the subsequent accurate correlation with the state-wide data from the same time period. Specific symptomatology, diagnostic investigations and management approach identified in our data correlated well with previous studies. Moreover, identified risk factors for airway intervention were not only consistent with previous findings but expanded to include elements not previously recognised.

The main limitation of this study was the reliance on clinical documentation. The absence of documented symptomatology or history did not necessarily preclude the patient from presenting with such, and the converse is also true. This is particularly relevant for immunisation histories. Whilst documented immunisation rates were low in adult and paediatric cases, the authors suspect this more likely represents absence of documentation or specific history taking by treating clinicians given that immunisation rates were >90% across Victoria during the study period[16]. Variation between documentation was also evident. Additionally, for patients transferred from other health services, access to the primary data was not available. Hence reliance was placed upon transfer letters and admission documentation. Finally, due to lack of paediatric patients identified, we could not statistically analyse this cohort.

CONCLUSION

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Modern epiglottitis is not the disease previously encountered by otolaryngologists prior to the introduction of the Hib vaccine in 1993. The most common symptomatology in adults include sore throat, dysphagia, odynophagia, dysphonia, and fever. Hib is no longer the dominant causative organism, instead we identified a varying microbiome of causative pathogens reflecting a significant impact of the Hib vaccine. Identifying stridor, subjective SOB, hypoxia, odynophagia and lymphadenopathy at presentation provides aids earlier recognition of patients who may require airway intervention. Complications and mortality remain rare.

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TABLE 1 – Presenting Signs and Symptoms in the Adult Population

Clinical Findings	**Results** **(n=87)**
Sore throat (n (%))	77 (88.5)
Dysphagia (n (%))	62 (71.3)
Odynophagia (n (%))	50 (57.5)
Dysphonia (n (%))	49 (56.3)
Fever (> 37.5°C; n (%))	48 (55.2)
Shortness of Breath (n (%))	40 (46.0)
Tachycardia (n (%))	40 (46.0)
Unable to manage upper airway secretions (n (%))	31 (35.6)
Lymphadenopathy (n (%))	31 (35.6)
Stridor (n (%))	28 (32.2)
Tachypnoea (n (%))	6 (6.9)
Hypotension (n (%))	1 (1.1)

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TABLE 2 - Factors Associated with Airway Intervention

Variable	**Airway Intervention (*n*=24)**	**No Airway Intervention (*n*=63)**	***p*-value**
Stridor (n (%))	17 (70.8)	11 (17.5)	**<0.001**
SOB (n (%))	16 (66.7)	24 (38.1)	**0.017**
Hypoxia (n (%))	11 (45.8)	5 (7.9)	**<0.001**
Dysphagia (n (%))	15 (62.5)	47 (74.6)	0.265
Odynophagia (n (%))	9 (37.5)	41 (65.1)	**0.020**
Dysphonia (n (%))	15 (62.5)	34 (54.0)	0.473
Unable to manage upper airway secretions (n (%))	10 (41.7)	21 (33.3)	0.468
Major medical comorbidities (CCI score)	2.2	1.1	**0.007**
Lymphadenopathy (n (%))	2 (8.3)	29 (46.0)	**0.001**
Febrile (n (%))	16 (66.7)	32 (50.8)	0.183
Tachycardia (HR ≥ 100; n (%))	11 (45.8)	29 (46.0)	0.987
Tachypnoea (RR ≥ 24; n (%))	5 (20.8)	1 (1.6)	0.987
Mean WCC (x10^9/L)	18.1	14.7	**0.039**
Mean ICU LOS (hours)	121.5	21.1	**<0.001**
Average Length of stay (days)	8.3	3.7	**<0.001**

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TABLE 3 – Presenting Signs and Symptoms in the Paediatric Population

Clinical Findings	Results (n=6)
Fever (> 37.5°C; n (%))	5 (83.3)
Tachycardia (n (%))	5 (83.3)
Stridor (n (%))	5 (83.3)
Sore throat (n (%))	4 (66.7)
Dysphagia (n (%))	4 (66.7)
Unable to manage upper airway secretions (n (%))	4 (66.7)
Lymphadenopathy (n (%))	4 (66.7)
Shortness of Breath (n (%))	3 (50.0)
Hypoxic (n (%))	2 (33.3)
Odynophagia (n (%))	1 (16.7)
Dysphonia (n (%))	1 (16.7)
Tachypnoea (n (%))	0 (0)
Hypotension (n (%))	0 (0)

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Table 4 – Comparison of VAED and Collected Data over January 2011 to December 2016 for the Adult Population

Finding	Collected Data (*n*=87)	VAED (*n*=243)	*p*-value
Admission type (n (%))			**<0.001**
Emergency Department	65 (74.7)	220 (90.5)	
Inter-hospital Transfer	22 (25.3)	23 (9.5)	
Age distribution (years (%))			0.38
18 – 39	27 (31.0)	59 (24.3)	
40 – 64	38 (43.7)	125 (51.4)	
65 – 89	22 (25.3)	59 (24.3)	
M : F ratio	2.1:1	2.0:1	1.00
Average Length of stay (days)	5.0	5.8	**0.03**
Mean ICU LOS (mean (range); hours)	64.4 (4 - 428)	75.2 (5 – 471)	0.87
Mean intubation time (mean (range); hours)	84.5 (9 – 254)	90 (2 – 260)	0.57
Anoxic brain injury (n (%))	1 (1.2)	1 (0.4)	0.46
Death (n (%))	0 (0)	1 (0.4)	1.00

Table 5 – Comparison of VAED and Collected Data over January 2011 to December 2016 for the Paediatric Population

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Finding	**Collected Data (*n*=6)**	**VAED (*n*=16)**	***p*-value**
Admission type (n (%))			0.28
Emergency Department	3 (50.0)	13 (81.2)	
Inter-hospital Transfer	3 (50.0)	3 (18.7)	
Age distribution (years (%))			0.84
0 – 4	3 (50.0)	9 (56.3)	
5 – 9	2 (33.3)	3 (18.7)	
10 – 14	0 (0)	1 (6.3)	
15 – 18	1 (16.7)	3 (18.7)	
M : F ratio	1:5	3:5	0.61
Average Length of stay (days)	8.2	16.9	0.41
Mean ICU LOS (mean (range); hours)	73.2 (15 – 261)	105.9 (16 – 374)	0.65
Mean intubation time (mean (range); hours)	69.1 (19.8 – 120)	93.2 (19 – 252)	0.65
Death (n (%))	0 (0)	1 (6.25)	1.00

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