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Title:

Bell's palsy in children: Current treatment patterns in Australia and New Zealand. A PREDICT study

Date:

2017-04-01

Citation:

Babl, F. E., Gardiner, K. K., Kochar, A., Wilson, C. L., George, S. A., Zhang, M., Furyk, J., Thosar, D., Cheek, J. A., Krieser, D., Rao, A. S., Borland, M. L., Cheng, N., Phillips, N. T., Sinn, K. K., Neutze, J. M. & Dalziel, S. R. (2017). Bell's palsy in children: Current treatment patterns in Australia and New Zealand. A PREDICT study. *Journal of Paediatrics and Child Health*, 53 (4), pp.339-342. <https://doi.org/10.1111/jpc.13463>.

Persistent Link:

<https://hdl.handle.net/11343/292429>

**Title: Bell's palsy in children: Current treatment patterns in Australia and New Zealand. A PREDICT study**

**Type of manuscript: Original Article**

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: [10.1111/jpc.13463](https://doi.org/10.1111/jpc.13463)

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**Version:** Revision 1 V1

**Date** 28.9.2016

**Word Count:** (2500 max)

**Key words:** Bell's palsy, facial palsy, child, prednisolone

**ABSTRACT (250)**

**Background:** The aetiology and clinical course of Bell's palsy may be different in paediatric and adult patients. There is no randomised placebo controlled trial (RCT) to show effectiveness of prednisolone for Bell's palsy in children.

**Objective:** To assess current practice in paediatric Bell's palsy in Australia and New Zealand Emergency Departments (ED) and determine the feasibility of conducting a multicentre RCT within the Paediatric Research in Emergency Departments International Collaborative (PREDICT).

**Methods:** A retrospective analysis of ED medical records of children less than 18 years diagnosed with Bell's palsy between January 1, 2012 and December 31, 2013 was performed. Potential participants were identified from ED information systems using Bell's palsy related search terms. Repeat presentations during the same illness were excluded but relapses were not. Data on presentation, diagnosis and management were entered into an online data base (REDCap).

**Results:** 323 presentations were included from 14 PREDICT sites. Mean age at presentation was 9.0 (SD 5.0) years with 184 (57.0%) females. Most (238, 73.7%) presented to ED within 72 hours of symptoms, 168 (52.0%) had seen a doctor prior. In ED, 218 (67.5%) were treated with steroids. Prednisolone was usually prescribed for 9 days at around 1 mg/kg/day, with tapering in 35.7%.

**Conclusion:** Treatment of Bell's palsy in children presenting to Australasian EDs is varied. Prednisolone is commonly used in Australasian EDs, despite lack of high-level paediatric evidence. The study findings confirm the feasibility of an RCT of prednisolone for Bell's palsy in children.

## Key Points

### What is already known on this topic

- In adults high level evidence indicates that steroids improve recovery rates.
- In children there is no placebo controlled evidence to support steroid use.
- Current use rate and regimens for steroid use in Australia and New Zealand are not known.

### What this paper adds

- In this study 71.2% of the sample were treated with steroids, by GPs and/or after a visit to the ED, which is higher than reported in the past.
- Usual treatment regimen is prednisolone at 1 mg/kg for 7-10 days.
- The data support the feasibility of and provide the baseline for a multicentre randomised controlled trial to assess the efficacy of prednisolone in Bell's palsy.

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## Introduction

Bell's palsy denotes a unilateral peripheral facial nerve palsy with rapid onset.<sup>1</sup> While Bell's palsy is by definition idiopathic, similar to other demyelinating conditions it is likely that the aetiology and course of adult and childhood Bell's palsy differ.<sup>2-5</sup> Childhood Bell's palsy appears to recover earlier and the overall recovery rate has been reported up to 100%, which is higher than in adults.<sup>6-11</sup>

In adults high level evidence indicates significant improvements in the proportion who reached complete recovery when Bell's palsy was treated with steroids compared with placebo.<sup>12-14</sup> Similar high level evidence is not available in children as shown in two systematic reviews of the use of steroids to treat Bell's palsy in children.<sup>8,15</sup> A small unblinded randomised trial of methylprednisolone use in children without a placebo group indicated that all children recovered regardless of group assignment, **though earlier with steroids.**<sup>7</sup>

While recommendations for steroid use in adults are clear, evidence reviews and clinical practice guidelines call for definitive trials in children on the utility of steroid use.<sup>8,15,16,17</sup> The lack of recommendations for or against steroid use in children has led to variable physician practice.<sup>6,8,9,11</sup> Royal Children's Hospital, Melbourne, guidelines, for example, state that "the role in treatment of Bell's palsy in children is unclear, however, steroids appear to benefit adults, particularly if given within 72 hours of onset and if complete palsy is present. Prednisolone (1 mg/kg/day PO daily for 10 days) may be considered for children with Bell's palsy presenting within 72 hours of onset<sup>18</sup> and a recent study from this centre indicated that 36% of Bell's palsy patients received prednisolone.<sup>6</sup>

We set out to assess the current management of paediatric Bell's palsy more broadly in Australian and New Zealand Emergency Departments (ED). This will provide important background information for conducting a multicentre RCT of prednisolone for Bell's palsy in children.

## Methods

This was a multicentre retrospective cohort study based on an analysis of medical records of patients less than 18 years of age diagnosed with Bell's palsy between January

2012 and December 2013. The study was conducted at 14 PREDICT sites in Australia and New Zealand<sup>19</sup> and approved by the ethics committees at all participating sites.

Using ICD 10 codes for discharge diagnosis and key word searches of the triage notes in the ED Hospital Administrative Software Solutions (HASS) database or equivalent, we identified all patients presenting with Bell's Palsy and selected neurological problems. We used the following search terms: Bell's Palsy (G51.0); Disorder of the facial nerve, unspecified (G51.9); Cranial nerve disorder (G52.0 - G52.9); Disorder of tri-geminal nerve, unspecified (G50.9); Disorder of the optic nerve, unclassified (H47.0); Third, Fourth or Sixth nerve palsy (H49.0 – H49.2); Disorders of the acoustic nerve (H93.3); Cerebro vascular accident/stroke (I61.9, I63.0-I63.9, I64.0); Peripheral neuropathy (G62.9); Disorders of the autonomic nervous system, (G90.0, G90.9, G99.0, G99.1, G60.9). Inpatient records of patients with a discharge diagnosis of Bell's Palsy over the period were also checked in case of missed diagnosis of Bell's Palsy in the ED or, incorrect coding of the condition in the ED.

We reviewed medical records thus identified and excluded patients other than idiopathic peripheral facial palsy or Bell's palsy (such as facial nerve palsy related to ear infections, local trauma and other defined causes). We also excluded repeat presentations during the same illness but not relapses. A piloted, standardised Clinical Report Form was used to collect information on patient demographics, details of facial palsy, including prior health care contacts and prehospital management, Australasian Triage Scale (ATS) category<sup>20</sup> and management whilst in the ED, consultations, investigations and follow up arrangements.

Data were directly entered into a web-based REDCap<sup>21</sup> data base and were analysed using Stata 13 (Statacorp, College Station, Texas, USA).

Data were descriptively analysed using mean and standard deviation (SD) and median and interquartile range (IQR) as appropriate.

## Results

Over the 2 year study period our search strategy identified 555 possible cases of facial palsy. Of these 192 were excluded with a diagnosis other than Bell's palsy, 39 were excluded as repeat presentations during the same episode and one patient was older than 18 years of age (**Figure 1**). The study group therefore consisted of 323 Bell's palsy presentations over a 2 year period with a mean age of 9 years (SD 5.0) and 184 (57%) being female. Twenty-five

patients had past presentations for separate episodes of Bell's palsy. Half had been seen by a GP or at another ED previously and most were triaged to ATS category 4 (55.4%) and presented within less than 72 hours (73.7%) (Table 1).

ED treatment practices are outlined in Table 2 with 218 (67.5%) treated with steroids as part of ED management (whilst in the ED or prescribed at discharge from ED), and 230 (71.2%) receiving steroids either via a prior visit to the GP and or following the ED visit. Overall 211 of 323 (65.3%) had presented to the ED within 72 hours of onset and were untreated with steroids, the likely window for a study into steroid use.

Most usually prednisolone was prescribed at a dose of 1 mg/kg, at a mean starting dose of 1.1mg/kg/day, with 35.7% prescribed tapering of the dose. Few patients (n=33, 10.2%) received antiviral treatment. A minority of presentations (n=74, 23.0%) underwent further investigations with few undergoing neuroimaging or blood testing. Consultation with other specialties whilst in the ED occurred for half the presentations (n=164, 50.5%) with a broad range of specialties, mainly neurology (n=108, 33.4%) and ear-nose-throat (ENT) (n=36, 11.2%). Follow up of some kind was scheduled for 285 (88.2%) presentations with a broad range of clinicians including general practitioners, neurology, ENT and ED follow up.

## Discussion

The key findings of this multicentre study are that in paediatric EDs in Australia and New Zealand two thirds of children with Bell's palsy are being treated with steroids, mostly in the form of prednisolone at a dose of 1 mg/kg. Steroid use in this study is twice as high than what has been reported from one of the Australian participating centres in the past.<sup>6</sup> It is likely that high level adult evidence supporting steroid use<sup>22,12,16</sup> has influenced practice in children, despite the lack of paediatric placebo controlled evidence and the concern that both aetiology and natural outcome differ from adults. Dosing regimens are in line with adult use<sup>12,22</sup> and are listed as a management option at one of the participating hospital's Clinical Practice Guidelines.<sup>18</sup>

Antiviral agent use was low at less than 10%, again in line with adult evidence of lack of efficacy.<sup>12,22</sup> Few patients underwent blood testing to rule out illnesses such as leukaemia and Bell's palsy was generally diagnosed without using neuroimaging.

There are a number of important findings for the set-up of an RCT investigating prednisolone use in children within the PREDICT network. Prednisolone dose of 1 mg/kg for 10 days as part of a placebo controlled study design will likely be an acceptable regimen for many PREDICT clinicians. A large number of patients first saw a GP prior to coming to ED, with some treated with steroids prior to arrival. For an RCT it may be important to inform local GPs about the study to encourage early referral and if possible, create a short-cut pathway for study assessment for referred patients.

### ***Limitations***

While study sites included both tertiary children's hospitals and mixed hospitals, PREDICT sites are based on paediatric EDs which are actively involved in research. Therefore results may not be generalizable outside the PREDICT network at mixed EDs. The retrospective nature of case ascertainment may underestimate the true incidence of Bell's palsy at the participating hospitals. In addition, ED presentations reflect local referral patterns in general practice. While we followed guidelines for high quality chart reviews<sup>23</sup>, retrospective data have inherent limitations and data abstractors were not blinded to the purpose of the study.

### ***Conclusions***

Steroid use for Bell's palsy is widespread in patients presenting to Australasian EDs despite insufficient evidence of effectiveness. The study findings hold important lessons for the RCT on prednisolone for Bell's palsy in children now under way.

### **FUNDING**

The study was funded in part by grants from the National Health and Medical Research Council (Centre of Research Excellence grant GNT1058560), Canberra, Australia; the Murdoch Children's Research Institute, Melbourne, Australia, and the Victorian Government's Operational Infrastructure Support program. FEB's time was part funded by a grant from the Royal Children's Hospital Foundation, Melbourne, Victoria, Australia. SRD's time was part funded by the Health Research Council of New Zealand (HRC13/556).

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**Table 1** Demographic and clinical characteristics of study participants

<b>Gender</b>	Female (%)	184 (57.0%)
<b>Age (years)</b>	Mean (SD)	8.99 (5.0)
<b>Triage category on arrival</b>	2	9 (2.8%)
	3	131 (40.6%)
	4	179 (55.4%)
	5	4 (1.2%)
<b>Side of Palsy</b>	Left	149 (46.1%)
	Right	168 (52.0%)
	Bilateral	2 (0.6%)
	Data not available	4 (1.3%)
<b>Prior medical care</b>	GP	139 (43.0%)
	ED elsewhere	26 (8.1%)
	Other	3 (1.0%)
<b>Prior treatment by GP</b>	Any steroid	30 (9.3%)
<b>Past history of Bell's Palsy</b>	Previous Bell's	25 (7.7%)
<b>Time to presentation</b>	<24 h	124 (38.4%)
	24-47 h	66 (20.4%)
	48-72 h	48 (14.9%)
	>72 h	81 (25.1%)
	Not recorded	4 (1.2%)

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GP general practitioner

ED emergency department

SD standard deviation

**Table 2** Management in the emergency department (ED)

<b>Steroids</b>	Treatment with any steroid whilst in ED or prescribed at discharge	218/323 (67.5%)
<b>Type of steroid given in ED</b>	Prednisolone	81/89 (91.0%)
	Prednisone	6/89 (6.7%)
	Dexamethasone	2/89 (2.3%)
<b>Steroid prescription for discharge</b>	Prednisolone	202/213 (94.8%)
	Prednisone	11/213 (5.2%)
	Tapered discharge dose	76/213 (35.7%)
<b>Prednisolone dosage in ED</b>	Mean mg/kg/day (+/- SD)	1.1 (+/- 0.43)
<b>Days of treatment with prednisolone</b>	Mean days (+/- SD)	8.8 (+/- 4.8)
<b>Antivirals</b>	Treatment with any antiviral	33/323 (10.2%)
	Acyclovir	24/33 (73.7%)
	Valaciclovir	6/33 (18.1%)
	Famciclovir	1/33 (3.0%)
	Data not available	1/33 (3.7%)
<b>Days of treatment Acyclovir</b>	Mean (+/- SD)	5.95 (+/- 1.89)
<b>Specialty involvement (phone consult or review)</b>	Any speciality consulted	164/323 (50.5%)
	Neurology	108/323 (33.4%)
	Neurosurgery	2/323 (0.6%)
	Ear-nose-throat	36/323 (11.2%)
	Ophthalmology	14/323 (4.3%)
	General Medicine	26/323 (8.1%)
	Other	6/323 (1.9%)
	Data not available	4/323 (1.2%)
<b>Investigations</b>	Any tests conducted	74/323 (23.0%)
	Full blood count	51/323 (15.8%)
	Erythrocyte sedimentation rate	9/323 (2.8%)
	C reactive protein	20/323 (2.8%)
	Head computed tomography	11/323 (3.4%)
	Head magnetic resonance imaging	14/323 (4.3%)
	Lumbar puncture	1/323 (0.3%)
	Other	34/323 (10.5%)
<b>Follow-up arranged</b>	Any arranged follow-up documented	285/323 (88.2%)
	General practitioner	101/323 (31.3%)
	Neurology	63/323 (19.5%)

Neurosurgery	1/323 (19.5%)
Ear-nose-throat	39/323 (12.1%)
Ophthalmology	21/323 (6.5%)
ED follow-up	54/323 (16.7%)
General paediatrics	41/323 (12.1%)
Audiology	1/323 (0.3%)
Physiotherapy	3/323 (0.9%)
Other	3/323 (2.5%)

**Reason for follow-up**

Further investigation	8/285 (2.8%)
Review of symptoms	248/285 (87.0%)
Uncertainty regarding diagnosis	9/285 (3.2%)
Eye review	16/285 (5.6%)
Radiological abnormalities	2/285 (0.7%)
Other	21/285 (7.4%)
Data not available	16/285 (5.6%)

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ED emergency department

SD standard deviation

Figure 1

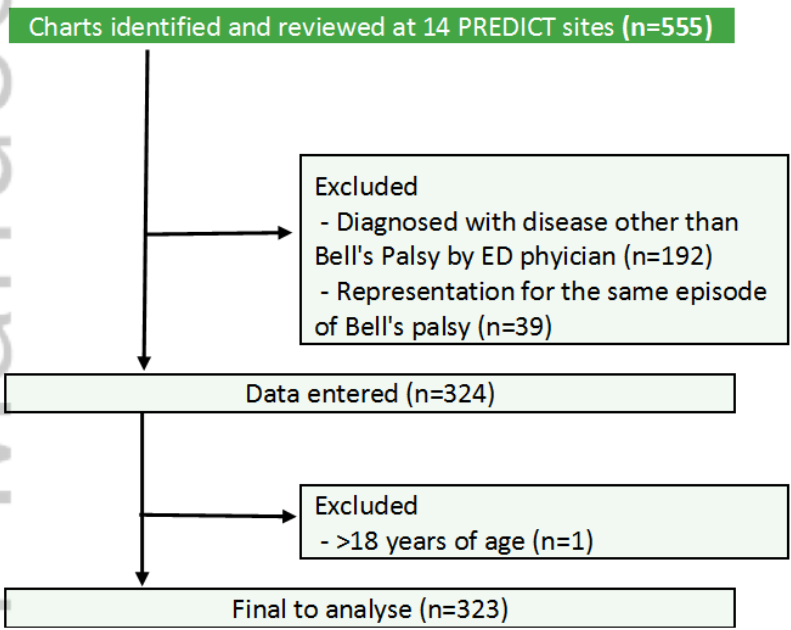


Figure 1.tif