

# A 5- versus 3-day course of oral corticosteroids for children with asthma exacerbations who are not hospitalised: a randomised controlled trial

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**E**xacerbation of childhood asthma is one of the most common acute presentations to general practices and emergency departments (EDs). Most of these children are not hospitalised, but asthma exacerbations are associated with significant cost<sup>1</sup> and both acute and prolonged morbidity.<sup>2,3</sup>

The main treatments are bronchodilators and systemic corticosteroids. While corticosteroids have been shown to be effective,<sup>4-7</sup> there is a lack of consensus regarding the dose, length and route of administration.<sup>5</sup> There is considerable variation regarding length of administration among published guidelines<sup>8-10</sup> and systematic reviews,<sup>4-6</sup> varying from 1–3 days to 3–10 days.<sup>6</sup> Australian guidelines recommend oral corticosteroids (prednisolone, 1 mg/kg, up to 60 mg daily) for up to 5 days,<sup>8</sup> while United States guidelines recommend 1–2 mg/kg/day (in two doses) for 3–10 days.<sup>9</sup>

However, few studies have compared the dose and length of corticosteroid administration.<sup>5,11</sup> While a longer course of oral corticosteroids might improve short-term symptoms of asthma and quality of life (QOL), adverse events seen in children after short courses of corticosteroids include behavioural changes, hallucinations, fungal infections, increased appetite and adrenal insufficiency.<sup>12,13</sup> Thus, it is desirable to keep courses of oral corticosteroids as short as possible while retaining efficacy.

We conducted a double-blind, multi-centre randomised controlled trial with concealed allocation to compare the efficacy of a 5-day course versus a 3-day course of oral prednisolone in reducing the 2-week morbidity of acute asthma exacerbations in children.

## METHODS

Participants were children aged 2–15 years who presented during ordinary hours (07:30–17:00) to the EDs of three Queensland hospitals (Royal Children's Hospital [Brisbane, Qld], Mater Hospital [Brisbane, Qld] or Gympie Hospital [Gympie, Qld]) with an acute exacerbation of asthma

## ABSTRACT

**Objective:** To determine whether a 5-day course of oral prednisolone is superior to a 3-day course in reducing the 2-week morbidity of children with asthma exacerbations who are not hospitalised.

**Design, setting and participants:** Double-blind randomised controlled trial of asthma outcomes following a 5-day course of oral prednisolone (1 mg/kg) compared with a 3-day course of prednisolone plus placebo for 2 days. Participants were children aged 2–15 years who presented to the emergency departments of three Queensland hospitals between March 2004 and February 2007 with an acute exacerbation of asthma, but were not hospitalised. Sample size was defined a priori for a study power of 90%.

**Main outcome measures:** Difference in proportion of children who were symptom-free at Day 7, as measured by intention-to-treat (ITT) and per-protocol analysis; quality of life (QOL) on Days 7 and 14.

**Results:** 201 children were enrolled, and there was an 82% completion rate. There was no difference between groups in the proportion of children who were symptom-free (observed difference, 0.04 [95% CI, –0.09 to 0.18] by ITT analysis; 0.04 [95% CI, –0.17 to 0.09] by per-protocol analysis). There was also no difference between groups in QOL ( $P=0.42$ ). The difference between groups for the primary outcome was within the equivalence range calculated post priori.

**Conclusion:** A 5-day course of oral prednisolone confers no advantage over a 3-day course for children with asthma exacerbations who are not hospitalised.

**Trial registration:** Australian Clinical Trials Registry ACTRN012605000305628.

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between March 2004 and February 2007 (however, the start date was different for each hospital: Royal Children's Hospital: March 2004; Mater Hospital: December 2004; Gympie Hospital: July 2006), but were not hospitalised.

Asthma was defined as recurrent (>2) episodes of wheeze and/or dyspnoea with a clinical response (decreased respiratory rate and work of breathing) to salbutamol. Asthma exacerbation was defined as acute deterioration of asthma control requiring treatment with more than a single dose (>600 µg via metered dose inhaler and spacer or >2.5 mg nebulised) of salbutamol in an hour.

Exclusion criteria were: underlying respiratory disease (eg, bronchiectasis); cerebral palsy or severe neurodevelopmental abnormality; immunodeficiency; previous enrolment in the study; being on maintenance oral corticosteroids; having received >1 dose of oral corticosteroids before presentation; and very severe asthma (status asth-

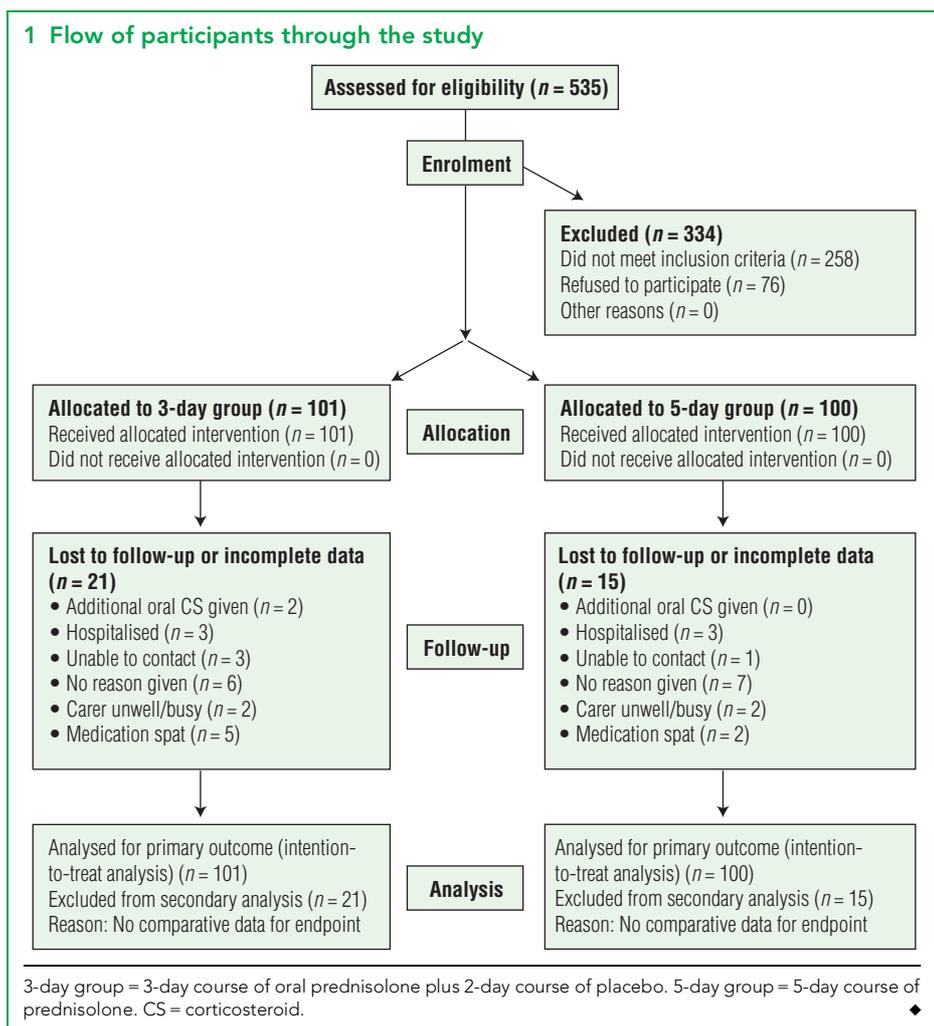
maticus; requiring hospitalisation, continuous nebulisation, and/or intravenous salbutamol).

The study was approved by the human ethics committees of all three institutions. The trial was registered with the Australian Clinical Trials Registry (ACTRN012605000305628).

## Study protocol

Before discharge from the ED, eligible children and their parents or carers were approached by a study nurse not involved in the child's acute treatment. Written informed consent was obtained from a parent or carer. Children were randomised within strata of age (<6 or 6–15 years) and site of enrolment.

On recruitment, children were allocated to the next treatment regimen on a list (randomised by permuted block design at a remote site). A sticker obscured the



next treatment group and was only removed after enrolment (concealed treatment allocation).

Children received either oral prednisolone (1 mg/kg to a maximum of 50 mg/day; Redipred, Aspen Pharmacare, Sydney, NSW) for 5 days ("5-day group") or prednisolone for 3 days, followed by a placebo (a liquid with a similar taste, also manufactured by Aspen Pharmacare) for 2 days ("3-day group").

The trial medications were stored in identical bottles and labelled A and B. The study team (other than the pharmacist, who was not involved in data collection), children and parents were blinded to the trial medication. The code was revealed only after the study and statistical analysis were completed.

### Data collection

At recruitment, a clinical history and examination were undertaken and documented on a standardised data collection sheet. Questions specific to asthma (eg, number of

exacerbations in previous 12 months, routine medications) were asked. Severity of acute asthma on presentation was categorised according to the Asthma Severity Scale (ASS) (0–3 = mild;  $\geq 4$  = moderate).<sup>14</sup> Scores on the five-point Australasian Triage Scale (1 = immediately life-threatening; 3 = potentially life-threatening; 5 = less urgent) were also recorded.<sup>15</sup>

Baseline and weekly Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) scores<sup>16</sup> and validated daily diary scores for asthma<sup>17</sup> and cough<sup>18</sup> were recorded. The asthma score was the average of four questions.<sup>17</sup> Follow-up phone calls occurred 24–48 hours after enrolment and at Days 7, 14, 21 and 28, where PACQLQ scores and adverse events were specifically recorded.

### Outcomes

The endpoint was admission into any hospital or Day 28, whichever occurred first. However, as a significant number of parents found it too difficult to complete diaries for

28 days, we analysed data up to Day 14. Symptoms refer to asthma-specific symptoms as recorded in the diary cards.

The primary outcome was the proportion of children without asthma symptoms, as scored on the validated diary cards on Day 7. Children were considered still symptomatic if their average asthma score for the day was  $\geq 0.2$ .

The main secondary outcomes were PACQLQ scores on Days 7 and 14. Other outcomes were: average asthma scores as scored on asthma<sup>17</sup> and cough<sup>18</sup> diary cards on Days 5, 10 and 14; recurrence of exacerbation; and unscheduled re-presentation to a health facility. In accordance with Australian guidelines,<sup>8</sup> we did not use peak flow as an outcome measure.

### Statistical analysis

The sample size required was calculated a priori from previous data.<sup>19</sup> Assuming a dropout rate of 20%, 180 children (90 per group) were required for a reduction in proportion from 60% to 30% of children known to be symptomatic on Day 7 when given a longer course of oral corticosteroids. We recalculated the sample size for the primary outcomes after the first 30 children were enrolled, and the sample size increased to 200 for the same power. For the PACQLQ outcome, 168 children were required for a power of 90% at a 5% significance level, for a minimally important mean difference of 0.5 in PACQLQ scores.<sup>20</sup>

Data were examined for type of distribution using normality plots. We used unpaired Student's *t* test for two-group comparisons of normally distributed data, the Kruskal–Wallis test for non-normal data and Pearson's  $\chi^2$  test for categorical variables. Linear regression was used to examine effect of asthma severity (ASS)<sup>14</sup> on presentation on Day 7 symptom scores and PACQLQ scores. A two-tailed  $P < 0.05$  was considered significant. Data were initially analysed using intention-to-treat (ITT) analysis, followed by per-protocol analysis.

SPSS, version 13.0 (SPSS Inc, Chicago, Ill, USA) was used for all statistical calculations except for mean difference between groups for PACQLQ scores and asthma diary scores, for which Confidence Interval Analysis (Gardner M, BMJ, London, UK) was used.

## RESULTS

There were 201 children enrolled in the study: 175 (87%) at Royal Children's Hospital, 17 (9%) at Mater Hospital and nine (5%)

at Gympie Hospital; 36 did not complete the study (Box 1). Baseline characteristics were similar for patients in both groups and for those who completed and did not complete the study (Box 2). The reasons for dropping out for 21 children from the 3-day group and 15 from the 5-day group ( $P = 0.36$ ) were also similar (Box 1).

There were five recorded adverse events, with no significant difference between groups. In the 3-day group, two parents reported that their child had behavioural disturbance (cranky and irritable) and one had a rash, while two children in the 5-day

group had behavioural disturbance (angry and aggressive).

Sixty-six children (3-day group, 31; 5-day group, 35) were symptom-free by Day 7. ITT analysis showed no significant difference between groups (observed difference, 0.04 [95% CI, -0.09 to 0.18]). Per-protocol analysis showed no significant difference between groups on Day 7 (observed difference, 0.04 [95% CI, -0.17 to 0.09]) or on Day 4 (0.004 [95% CI, -0.13 to 0.14]).

PACQLQ scores were obtained for 165 children (82%). The median PACQLQ score on Day 7 in the 3-day group (5.9; interquar-

tile range [IQR], 1.6) was similar to that of the 5-day group (5.9; IQR, 1.2) ( $P = 0.42$ ). The mean difference between groups in PACQLQ on Day 7 was 0.18 (95% CI, -0.16 to 0.51); on Day 14 it was 0.17 (95% CI, -0.08 to 0.44).

There was no significant difference between groups in any other secondary outcome, with  $P$  values ranging from 0.17 to 0.91 (Box 3). The difference between groups in Day 5 asthma score was 0.02 (95% CI, -0.36 to 0.40). Between Days 4 and 14, only one child (from the 3-day group) was hospitalised, and 13 received additional prednisolone (eight children from the 3-day group; five from the 5-day group). However, the difference between groups was not significant ( $P = 0.40$ ).

When we categorised children according to ASS score at presentation, there was also no difference between groups in any of the outcomes (data not shown,  $P$  values from 0.15 to 0.80). Using linear regression, Day 7 symptom score was not influenced by ASS category or PACQLQ scores on Day 7 or 14 ( $P = 0.50, 0.80, \text{ and } 0.66$ , respectively).

DISCUSSION

In this multicentre randomised placebo-controlled trial of children presenting to EDs (but not hospitalised) for an acute asthma exacerbation, we found that asthma morbidity (defined by proportion of children who were symptom-free at Day 7, and QOL) was similar whether a 5- or 3-day course of prednisolone was given. Two weeks later, there was no difference in symptoms or QOL between the groups.

2 Baseline characteristics of the children, by trial group and completion of study

	3-day group (n = 101)	5-day group (n = 100)	$P^*$	Complete† (n = 165)	Incomplete (n = 36)	$P^\ddagger$
Age in years	4.8 (2.8)	4.7 (3.1)	0.64	4.6 (2.9)	4.1 (3.2)	0.42
Sex (F : M)	40 : 61	40 : 60	0.95	67 : 98	13 : 23	0.38
ETS exposure, no. (%)	34 (34%)	37 (37%)	0.77	57 (35%)	14 (39%)	0.70
Asthma Severity Scale <sup>14</sup>	4.6 (1.8)	4.5 (1.8)	0.92	5.0 (2.0)	4.5 (1.8)	0.14
Australasian Triage Scale <sup>15</sup>	2.8 (0.6)	2.9 (0.6)	0.37	2.8 (0.5)	2.9 (0.6)	0.77
PACQLQ <sup>16</sup>	5.0 (1.0)	5.1 (1.0)	0.99	5.0 (1.1)	5.1 (0.8)	0.92
Inhaled CS, no. (%)	25 (25%)	22 (22%)	0.77	39 (24%)	8 (22%)	0.43
Regular medications, no. (%)	34 (34%)	31 (31%)	0.69	54 (33%)	11 (31%)	0.80
Days unwell	2.5 (1.8)	2.7 (2.4)	0.95	2.7 (2.2)	2.1 (1.2)	0.15
No. of oral CS courses in previous 12 months	1.5 (1.7)	1.4 (1.9)	0.42	1.5 (1.8)	1.3 (1.6)	0.42

Data are mean (SD) unless otherwise stated.

3-day group = 3-day course of oral prednisolone plus 2-day course of placebo. 5-day group = 5-day course of prednisolone. ETS = environmental tobacco smoke, defined as presence of any smoker in the household.

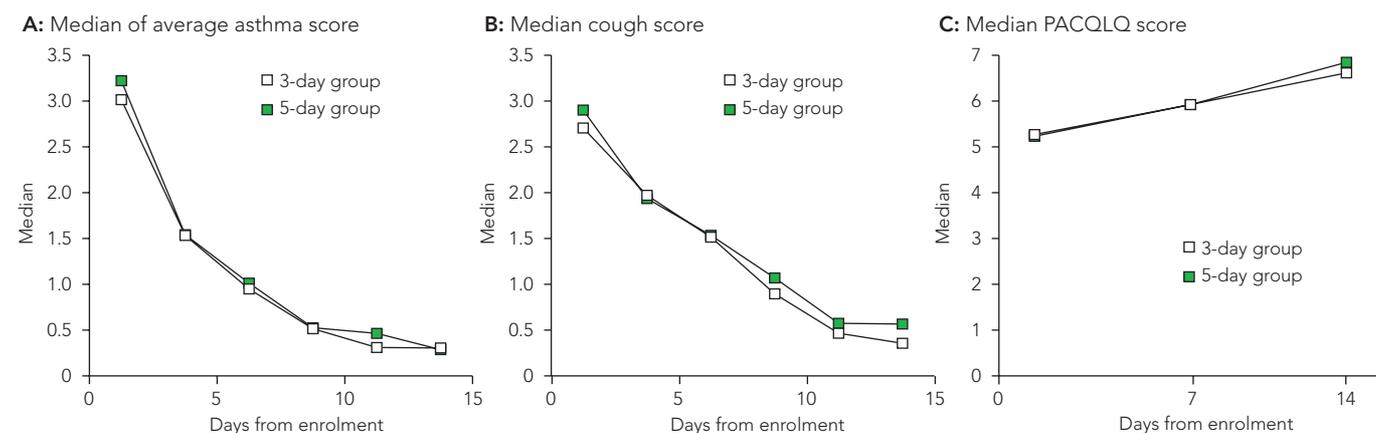
PACQLQ = Paediatric Asthma Caregiver's Quality of Life Questionnaire. CS = corticosteroid. Regular medications = child on regular maintenance medications for asthma.

\* Comparison of children randomly allocated to receive either 3 or 5 days of prednisolone.

† Complete = children who completed study (ie, secondary outcomes available).

‡ Comparison of children who completed and did not complete trial.

3 Median scores of asthma-related morbidity in children who received a 5-day or a 3-day course of oral prednisolone



3-day group = 3-day course of oral prednisolone plus 2-day course of placebo. 5-day group = 5-day course of prednisolone. PACQLQ = Paediatric Asthma Caregiver's Quality of Life Questionnaire.<sup>16</sup>

Our results are similar to those of smaller single-centre studies, which found that a shorter duration of systemic corticosteroids was as effective as a longer course.<sup>21,22</sup> In one study of young children (mean age, 36–37 months), the short-term morbidity (at Day 5) of 15 children who received a single dose of intramuscular dexamethasone was similar to that of 17 who received oral prednisolone for 5 days.<sup>21</sup> However, some of these children may not have had asthma.<sup>21</sup> In a study of 117 children aged 2–6 years, outcomes on Day 5 were similar in those given a single dose of oral dexamethasone and those given prednisolone twice daily for 5 days.<sup>22</sup> Dexamethasone is thought to be effective for up to 72 hours,<sup>22</sup> which amounts to a similar length of effect to 3 days of prednisolone. We used prednisolone rather than dexamethasone, as the latter is only available in hospitals and our findings would be relevant to children presenting to general practitioners with acute asthma not severe enough to require hospitalisation. However, these studies were arguably underpowered and did not examine the effect beyond the first 3–5 days.

Our study was larger and longer, and included symptom diaries and QOL measures. The importance of QOL for children with asthma has been previously highlighted,<sup>23</sup> and outcomes beyond the period of corticosteroid administration are important, as studies have shown that morbidity beyond the immediate asthma exacerbation period is greater than expected.<sup>3</sup> Our study thus adds important high-level evidence to the literature.

The dose of oral corticosteroids we used was similar to current guidelines, but lower than that used in previous studies.<sup>21,22</sup> It was chosen based on current practice and evidence of adverse events when 2 mg/kg/day was used.<sup>13</sup> Further, a systematic review found only two trials that assessed clinical responses to different doses of systemic corticosteroids; neither found a therapeutic advantage of higher doses.<sup>11</sup>

Our study must be interpreted in consideration of its limitations. Although an inadequate sample size may have contributed to our finding of no difference between a 5-day and 3-day course, we believe this is unlikely, as the power of our study was 90%. It would have been ideal to define a non-inferiority or equivalence margin a priori on the basis of a minimally important effect or historical controls. Our study was designed as a superiority trial, and we did not define a non-inferiority margin a priori. Nevertheless, for

the primary outcome measure, the chosen symptom score cut-off of 0.20 (ie, chosen minimally important difference), the study shows equivalence (the upper 95% confidence limit of the difference between groups in our study was 0.18).

There was also no significant difference between groups when per-protocol analysis was performed (as opposed to ITT analysis). The small difference between groups in PACQLQ scores on Days 7 and 14 (0.18 and 0.17) was less than the established minimally important mean difference of 0.50 in PACQLQ scores.<sup>20</sup> However, the upper 95% confidence limit for Day 7 PACQLQ scores (0.51) is just larger than the minimum clinically important difference, so equivalence was not shown for this outcome. The upper 95% confidence limit for PACQLQ on Day 14 was 0.44, demonstrating equivalence. Also, the difference between groups in the Day 5 asthma diary score of 0.02 is well within the non-inferiority margin of expected change in the diary score<sup>17</sup> based on historical controls. Post-priori calculation showed that a study size of 201 patients is sufficient to be 87% sure that the upper 95% confidence limit for the difference between the two treatment groups is <20% for symptom score on Day 4. For PACQLQ scores on Day 7, 160 children provided 99% surety that the upper 95% confidence limit for the difference between the two groups was <0.50.

Although our study was a multicentre study, the different size of the hospitals and starting dates resulted in unequal distribution of the children enrolled. Another limitation of our study was the deviation from protocol. We had intended to include data to Day 28, as we had done in our previous study,<sup>19</sup> but as many parents found this too difficult, our data were limited to 14 days. Nevertheless, given the negative results and the short duration of action of prednisolone, it is likely that data beyond 14 days would not have altered our findings.

Our findings are limited to children who did not require hospitalisation. We chose this criterion as this is a more common problem than hospitalisation and hence more relevant to the community.

Our study was unique in using patient-oriented outcomes, which are arguably as important as objective measures<sup>23</sup> — especially in young children, in whom objective respiratory measures are limited. We also examined data beyond the immediate exacerbation period.

We conclude that a 5-day course of oral prednisolone confers no additional advantage over a 3-day course for children with an acute asthma exacerbation that does not require hospitalisation. Although we saw few adverse events in our study, more significant adverse events following short courses of oral corticosteroids may occur.<sup>12,13</sup> Shortening courses of oral corticosteroids to the minimum effective length would limit the exposure of children to unnecessary medications and reduce costs.

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## COMPETING INTERESTS

None identified.

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