

Single centre experience of Hydrocortisone Granules (Alkindi) in children under 6 years of age with Adrenal Insufficiency

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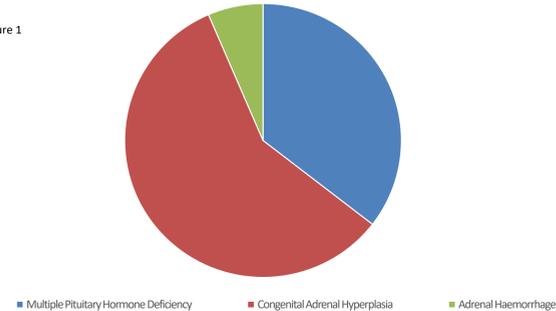
INTRODUCTION

Children with Adrenal insufficiency (AI) are usually managed with glucocorticoid replacement as hydrocortisone. Treatment options in younger patients include administering an aliquot of 10mg hydrocortisone tablets dissolved in water.⁽¹⁾ However, this is time consuming and may be inaccurate.⁽²⁾ We describe our experience of using Alkindi (www.diurnal.co.uk), the first hydrocortisone preparation licensed for children with AI

METHOD

Thirty-one patients with Adrenal insufficiency (AI) (24M, 7F) under 6 years of age in our service were identified over a 30 month period. 18 were diagnosed with congenital adrenal hyperplasia, 11 combined pituitary hormone deficiency and 2 neonatal adrenal haemorrhage. 22 patients were on hydrocortisone preparations already and 9 new patients were started on Alkindi at the time of diagnosis. Data on growth, episodes of stress dosing and adrenal crisis were documented at clinic visits and a questionnaire captured caregivers experience with their current regimen, with stress-dose information focused around the last 6-months.

Figure 1



CONCLUSIONS

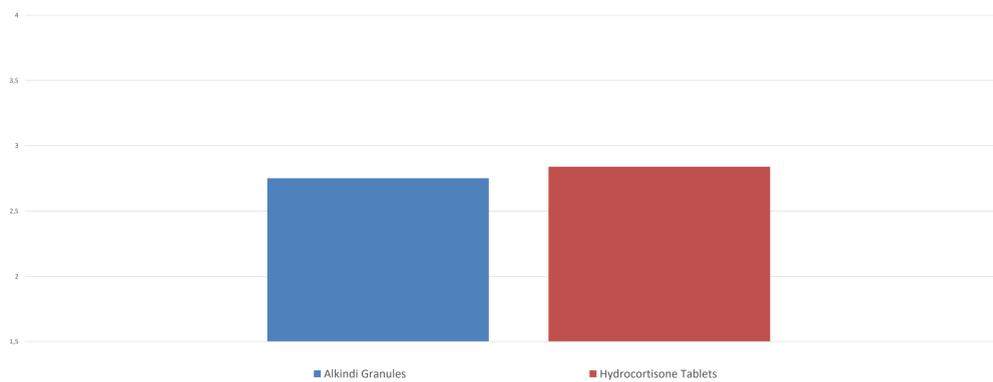
This is the largest single centre report of Alkindi administration over the longest time-period. All newly treated patients remained on Alkindi, although 25% of families who transitioned to Alkindi opted to return to dissolving tablets. There was high patient satisfaction irrespective of the underlying preparation, with no safety issues highlighted and in particular no adrenal crises. Growth parameters were encouraging, with no evidence of toxicity based on height SDS scores.

RESULTS

- The 9 newly-diagnosed patients started directly onto Alkindi all remain on this preparation. 20 of the 22 patients on hydrocortisone 'tablet solution' were switched to Alkindi- 15 (75%) remain on Alkindi 23-30 months later, tolerating and preferring this treatment; 5 (25%) did not tolerate Alkindi and returned to dissolving tablets
- In the most recent 6-months, stress dosing varied from 0-4 occasions, with an average of 2.8 episodes per patient per year and with no significant difference between preparations.
- No patient was admitted with an adrenal crisis.

Figure 2

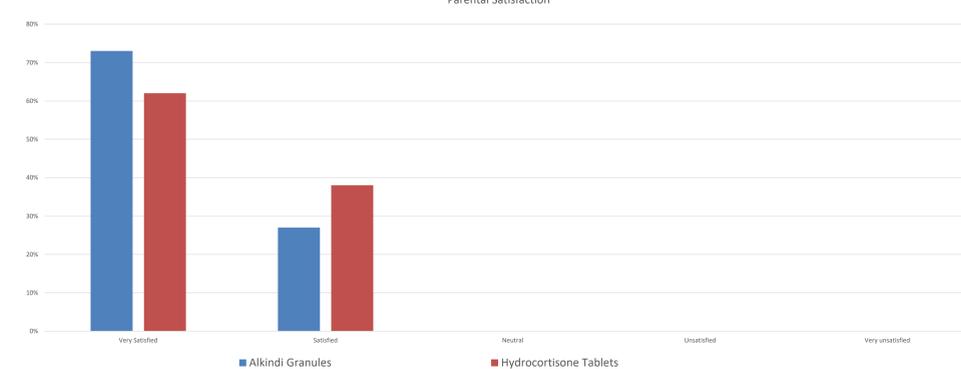
Average Episodes of Stress Dosing in months



- E-mail questionnaires were sent to 27 patients and 23 responded. All were satisfied (38% HC; 27% Alkindi) or very satisfied (62% HC; 73% Alkindi) with their current hydrocortisone preparation.

Figure 3

Parental Satisfaction



REFERENCES

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- Watson C, Webb E, Kerr S, Davies J, Stirling H, Batchelor H. How close is the dose? Manipulation of 10mg hydrocortisone tablets to provide appropriate doses to children. *Internal Journal of Pharmaceutics*. 2018;545(1-2):57-63

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- For patients on Alkindi (n=15), the height SDS moved closer to the population average after 18 months on Alkindi (mean height SDS pre-treatment -0.42; 18 months post-treatment 0.05).
- The heights of 12/14 patients were closer to the mid-parental target standard deviation score (SDS) (0.15).
- For those starting Alkindi at diagnosis (n=9), height SDS also moved closer to the population average (mean height SDS pre-treatment -1.53; 1-year post-treatment -0.06) and mid-parental height SDS (0.58).

Figure 4

Mean height SDS data over time for each patient group

	Parent height SDS (SD)	12 month prior SDS (SD)	Baseline SDS (SD)	6 month SDS (SD)	1 year SDS (SD)	18 month SDS (SD)
Hydrocortisone	-0.17 (0.86)	-	-0.99 (1.44)	-	-0.52 (0.91)	-
Alkindi from diagnosis	0.58 (0.77)	-	-1.53 (1.68)	-0.30 (1.45)	-0.06 (1.18)	-
Switched to Alkindi	0.15 (0.66)	-0.57 (1.19)	-0.42 (1.17)	-0.38 (1.26)	-0.20 (1.21)	0.05 (1.30)

Figure 5

