FLAIR Study: Clinical effectiveness of anti-inflammatory reliever therapies (AIR) for asthma control – A non-inferiority study

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Abstract #629

Background and Aims

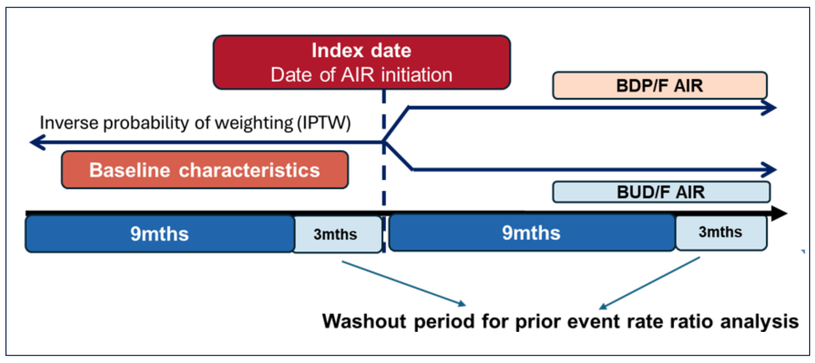
- Irrespective of asthma severity, all patients living with asthma still face ongoing chronic inflammation of the lower respiratory tract and risk of severe exacerbations.[1]
- International and national guidelines now recommend inhaled corticosteroid (ICS)-formoterol as anti-inflammatory reliever (AIR) therapy, for people with newly diagnosed asthma or on SABA monotherapy, to improve asthma control and reduce the risk of exacerbations[2,3]
- Budesonide-formoterol (BUD-F) is the only combination licensed for AIR therapy in UK, however beclometasone-formoterol (BDP-F) is widely prescribed within the ICS-formoterol marketplace[4] which results in the potential for significant off-label use.
- Here we evaluate the clinical effectiveness of AIR for asthma control in UK clinical practice.

Methods

- FLAIR is a retrospective observational real-world evidence cohort study, using the Optimum Patient Care Research Database, UK [July 2012 - April 2025].
- Objective was to evaluate non-inferiority of Fostair (beclometasone-formoterol; BDP-F) compared to Symbicort (budesonide-formoterol; BUD-F) when prescribed in adult asthma patients in an AIR approach, comparing 12 months baseline with 12 months outcome data (**Figure 1**).
- Inverse probability treatment weighting, and prior event rate ratio methods used to control for baseline confounding. Non-inferiority of achieving asthma control used logistic regression (odds ratios [OR], bootstrapped confidence intervals [95% CI]; pre-specified non-inferiority margin of 20% [OR=0.8]).

Non-parametric and weighted regression methods were used to investigate ICS use, persistence, and healthcare utilisation.

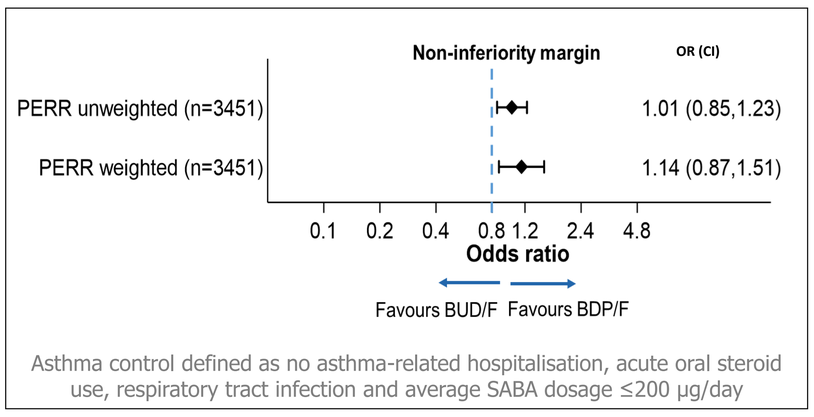
Figure 1: FLAIR Study Design



Results

- Of 8,750 adults with asthma, 1,630 (18.6%) were initiated onto BDP-F AIR, and 7,120 (81.4%) onto BUD-F AIR.
- Asthma patients initiated onto BDP-F were more severe than those initiated onto BUD-F; prescribed higher level therapies and more SABA inhalers, experienced more exacerbations with lower level of asthma control in the 12 months prior to initiation. Patient baseline demographic data and characteristics are shown in **Table 1**.
- Increase in asthma control in both groups after initiating AIR therapy; trend towards greater increase in BDP-F group compared to BUD-F (24.1% vs 21.4%).
- BDP-F AIR was found to be non-inferior to BUD-F AIR for achieving asthma control: OR=1.14 (0.87,1.51) (**Figure 2**).

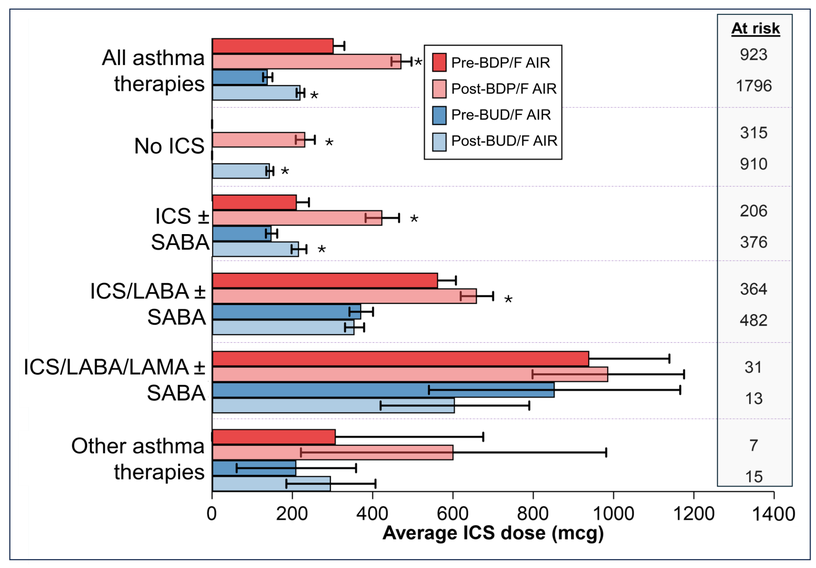
Figure 2: Asthma Control



Asthma control defined as no asthma-related hospitalisation, acute oral steroid use, respiratory tract infection and average SABA dosage ≤200 µg/day

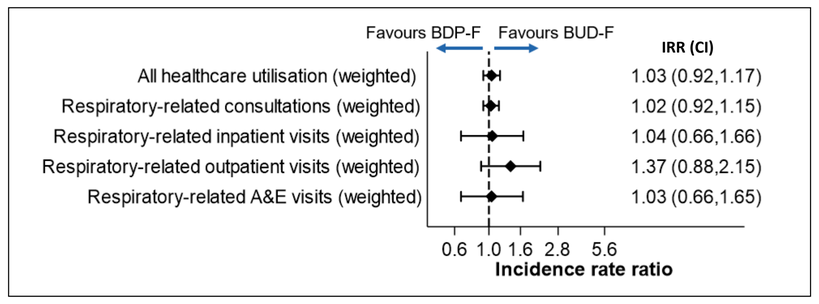
- Average (mean) ICS dosage increased for both groups from baseline (p<0.001; **Figure 3**)
  - Mean increase in ICS dose primarily associated with step-up in ICS-naïve or ICS ± SABA patients

Figure 3: Average (mean) ICS dose according to background therapy



- No significant difference in treatment persistence between BDP-F and BUD-F (p=0.36).
  - Approximately 10% of people in each group switched therapy during follow-up (9.5% [n=353/3708.1 person-years] in BUD-F group compared to 10.4% [n=124/1188.4 person-years] in BDP-F group).
- Time to switching was similar in the BDP-F vs BUD-F groups (HR=1.11 [0.85,1.46]; p=0.44).
- Healthcare utilisation (asthma-related primary care consultations and hospitalisations) was also similar in both groups (IRR=1.03 [0.92,1.17]; p=0.51) (**Figure 4**).

Figure 4: Healthcare Utilisation



Summary and Conclusion

- BDP-F AIR is non-inferior to BUD-F AIR for asthma control.
- Both arms showed increases in ICS dose, similar healthcare utilisation patterns, and low switching rates.

Table 1: Baseline patient demographics and characteristics

Selected Baseline Characteristics		Total AIR population (N=8,750)	BDP-F (N=1,630)	BUD-F (N=7,120)	Standard Mean
Age (Years)	Mean (SD)	46.5 (16.9)	47.6 (17.0)	46.3 (16.8)	0.079
Gender	Male, N (%)	3,752 (42.9%)	647 (39.7%)	3,105 (43.6%)	0.080
	Female, N (%)	4,998 (57.1%)	983 (60.3%)	4,015 (56.4%)	0.080
Ethnicity	White, N (%)	6,663 (92.5%)	1,238 (91.3%)	5,425 (92.8%)	0.006
Number of SABA inhalers	Mean (SD)	1.5 (2.2%)	1.8 (2.7%)	1.4 (2.1%)	0.235
Asthma Exacerbations in 12 months prior to study	None, N (%)	7,440 (85%)	1,289 (79.1%)	6,161 (86.4%)	0.194
	1, N (%)	1,024 (11.7%)	250 (15.3%)	774 (10.9%)	0.133
	2, N (%)	193 (2.2%)	51 (3.1%)	142 (2%)	0.072
	3, N (%)	61 (0.7%)	23 (1.4%)	38 (0.5%)	0.089
	4+, N (%)	32 (0.4%)	17 (1.0%)	15 (0.2%)	0.106
Asthma Control (RCP-3)	Controlled	2,013 (61.7%)	314 (51.3%)	1,699 (64.1%)	0.134
	Poorly controlled	1,251 (38.3%)	298 (48.7%)	953 (35.9%)	0.112
Asthma control (research database derived)	Controlled	3,553	479 (29.4%)	3,074 (43.2%)	0.290
	Poorly controlled	5,197	1,151 (70.6%)	4,046 (56.8%)	0.290

References

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4. Chiesi. Data on file.

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