Compliance with isotretinoin national guidelines – where are we 2 years since the last audit?

A national clinical re-audit by the British Association of Dermatologists (BAD) based on audit standards derived from BAD clinical guidelines on the safe introduction and continued use of isotretinoin in acne in the UK.

1. Background and introduction
Clinical audits are important in their role to ascertain and consequently improve the quality of care for patients. The BAD has clinical audit support as one of its key objectives in provision of data on quality standards in British dermatology.

2. Aims and purpose
The main objective of this re-audit was to determine any improvements in clinical practice amongst dermatologists in the UK, as measured against BAD/national standards, compared with the first isotretinoin audit in 2012. A secondary objective was to undertake an appropriate benchmarking exercise to ascertain geographic variations in complying with those standards.

3. Methodology
Survey Monkey was used as a convenient platform for online data entry, with no patient-identifiable data requested. As well as the 2012 BAD audit questions, several additional questions were added; one to ascertain in which settings were patients seen and the others were general questions to ascertain the level of complaints or litigation cases due to pregnancy or mood changes.

The invitation to participate was circulated to the BAD membership (n=1226 as of 5th Dec 2013) by email, with weekly reminders circulated during the 8½-week data collection period. Based on previous feedback from the membership with regard to the need for national audits to be both quick and easy, members were requested to enter relevant data for the last three consecutive patients (including at least one male and one female) who had completed treatment with isotretinoin for acne vulgaris within the last 6 months. An audit proforma spreadsheet was also circulated to facilitate initial data entry offline, for smoother online entry at a later stage; it was envisaged that this would be helpful in cases where a medical secretary or student would enter an entire department’s audit data. The spreadsheet was also intended for audit departments who would wish to extend the audit locally with a greater total number of patients.

4. Results
4.1 Responses
A total of 338 respondents provided data from 1013 patients; this represented a 27.6% response rate, which is the second highest of all recent BAD audit surveys. All aborted entries, where the respondent had subsequently made a second complete submission, were excluded. The one member with confirmed duplicate responses was contacted directly and the correct entry was confirmed. Seven unidentifiable responses with a total of 21 patients were excluded from the benchmarking exercise, reducing the sample size to a

Questions based on BAD audit standards

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1. Was the patient seen in a monitoring clinic* for patients on systemic treatment? (*any clinic specifically for monitoring patients receiving systemic therapies)</td>
</tr>
<tr>
<td>Q2. Did female patients of childbearing potential receiving isotretinoin sign the ‘acknowledgement of PPP information’ form indicating that they received appropriate information?</td>
</tr>
<tr>
<td>Q3. Did all patients have serum lipids checked prior to starting treatment and at least once during treatment?</td>
</tr>
<tr>
<td>Q4. Did female patients in the pregnancy prevention programme have pregnancy tests before treatment and at monthly intervals through treatment?</td>
</tr>
<tr>
<td>Q5. Did female patients in the pregnancy prevention programme have a pregnancy test 5 weeks after completing treatment?</td>
</tr>
<tr>
<td>Q6. Did the patient become pregnant during or within 5 weeks of completing treatment?</td>
</tr>
<tr>
<td>Q7. Was there documentation of mental health and/or mood state for all patients on isotretinoin, both at the assessment for treatment and on follow-up?</td>
</tr>
<tr>
<td>Q8. Have you (clinician with patient responsibility) had any patients within the past 12 months who have become pregnant whilst on isotretinoin or within 5 weeks of completing treatment (other than those whose information have already been entered in this audit)?</td>
</tr>
<tr>
<td>Q9. If yes to Q8, has this led to any complaints or litigation?</td>
</tr>
<tr>
<td>Q10. Have you (clinician with patient responsibility) had any patients within the past 12 months who have become depressed or developed clinically relevant mood changes whilst on isotretinoin or within 5 weeks of completing treatment?</td>
</tr>
<tr>
<td>Q11. If yes to Q10, has this led to any complaints or litigation?</td>
</tr>
</tbody>
</table>

Table 1. Audit questions
Q1. Have you (clinician with patient responsibility) had any patients within the past 12 months who have become depressed or
Q2. Have you (clinician with patient responsibility) had any patients within the past 12 months who have become pregnant whilst on
treatment and on follow-up?
Q3. Did all patients have serum lipids checked prior to starting treatment and at least once during treatment?
Q4. Did the patient become pregnant during or within 5 weeks of completing treatment?
Q5. Did female patients of childbearing potential receiving isotretinoin sign the 'acknowledgement of PPP information' form
through treatment?
Q6. Was there documentation of mental health and/or mood state for all patients on isotretinoin, both at the assessment for
Did female patients in the pregnancy prevention programme have a pregnancy test 5 weeks after completing treatment?
Q8. Have you (clinician with patient responsibility) had any patients within the past 12 months who have become pregnant whilst on
isotretinoin or within 5 weeks of completing treatment (other than those whose information have already been entered in this audit)?
Q9. Have you (clinician with patient responsibility) had any patients within the past 12 months who have become depressed or
within the past 12 months who have become depressed or

Additional questions

If yes to Q8, has this led to any complaints or litigation?

Figure 1. Breakdown of the 338 participants by region

Figure 2. Responses for type of consultant-involved clinics in which the patients were seen

Figure 3. Boxplots showing the distributional mean percentage of “Yes” responses to having recorded acknowledgement of PPP information for each female patient, per hospital, in each region

KEY: In all boxplots, the national mean is denoted by the horizontal red line; regional sample medians are denoted by red dots; absolute figures for each region are indicated at the bottom of each boxplot; the lower or upper quartiles are denoted by ‘whiskers’; outliers are denoted by blue coloured dots. High median values indicate widespread alignment with the appropriate standards; small interquartile ranges indicate little variation in practice.
the remaining 456 female patients who were in the PPP, 54.2% had had a pregnancy test 5 weeks after completing treatment, 32.5% had not had a pregnancy test and in 12.9% of cases it wasn’t known [blank entries = 0.4%].

There is some variation across the country when the data are broken down by region, as well as variations within each region (see Figure 5) and between different types of clinic (see Figure 6).

d. Pregnancy during treatment

Three pregnancies occurred during treatment or within 5 weeks of completion. One had an abortion and continued with treatment. [NB: The other two pregnancies are from the same respondent.]

e. Serum lipids checking

Overall, 93.4% of patients had their serum lipids checked prior to starting treatment and at least once during treatment [blank entries = 0.2%].

There is very little variation across the country when the data are broken down by region (see Figure 7) or by type of clinic, with monitoring clinics at 94.0%, nurse-led monitoring 96.8% and non-monitoring 91.6%, with widespread compliance and very little variation in practice.

f. Documentation of mental health/mood state

The majority of patients (82.1%) had documentation of mental health and/or mood state whilst on isotretinoin, both at the assessment for treatment and on follow-ups [blank entries = 1.6%].

There is some variation across the country when the data are broken down by region (see Figure 8), and between different types of clinic, with monitoring clinics at 83.1%, nurse-led monitoring 88.0% and non-monitoring 79.1%.

4.4 Additional questions

These questions are not linked to each set of three patients whose data had been entered and therefore involve some degree of recall bias.

There had been no complaints or litigations in relation to the 14 responders who reported that their patients had become pregnant whilst on isotretinoin or within 5 weeks of completing treatment in the previous year.

The majority of respondents (68.0%) had not had any patients within the previous year who have become depressed or developed clinically relevant mood changes whilst on isotretinoin or within 5 weeks of completing treatment [blank entries = 1.5%]. Of the 30.5% of respondents who did, 64.1% reported one patient, 13.6% two and 7.7% more than two; in 14.6% of the responses, the number of patients involved was not stated. There was one suicide reported that occurred a few months after completing treatment which had led to a complaint; the inquest into the death returned an open verdict. In addition, there were three attempted suicides, one of which was too recent to know if there would be any subsequent complaint.

5. Discussion

It is noted that any findings for regions with low response rates and associated interpretations need to be treated with caution.

5.1 Responses

This audit had a response rate of 27.6% which is an increase of 52.9% on the 2012 audit response rate (18.7%). We would welcome feedback from members on how the BAD could facilitate participation in future national audits.
5.2 BAD standards

With an increased sample size, i.e. 1013 vs. 663, the results from this audit show a continuing improvement in the areas identified in the 2012 audit as requiring better compliance. Adherence to the standard to check serum lipids was up by 2.9% on the 2012 audit (93.4% vs. 90.5%) and documentation of mood was up by 8.0% (82.1% vs. 74.1%).

There was also a slight improvement in recording whether a female patient who was in the PPP had had a pregnancy test 5 weeks after treatment: ‘yes’ was up by 3.7% (54.2% vs. 50.5%), ‘no’ down by 2.3% (32.5% vs. 34.8%) and ‘not known’ down by 1.9% (12.9% vs. 14.8%).

In other areas where there was widespread compliance in the 2012 audit, there has been little change in performance. In the 2012 audit, 91.4% of female patients in the PPP signed the consent form and 8.4% did not, compared with 91.6% and 6.8% for this year’s audit. While pregnancy testing of female patients before and at monthly intervals throughout treatment has decreased slightly (93.3% vs. 93.7%), there were no ‘don’t know’ responses this time (three in 2012). [NB: 2012 audit ignored blank entries].

There were three pregnancies recorded during treatment or within 5 weeks of completion, compared to one in 2012. Looking at compliance by type of clinic, there was higher compliance in both types of monitoring clinic for pregnancy testing of female patients before and at monthly intervals throughout treatment compared to non-monitoring clinics, i.e. 98.8% [monitoring (m)] and 98.1% [nurse-led monitoring (n)] vs. 88.5% [non-monitoring (o)]. Nurse-led monitoring clinics were much more efficient at ensuring female patients who were on the PPP had a pregnancy test 5 weeks after completing treatment [73.2% (n) vs. 46.3% (m) and 43.9% (o)]. Female patients seen in non-monitoring clinics were more likely not to have had a pregnancy test [44.9% (o) vs. 34.1% (m) and 14.6% (n)], and non-nurse-led monitoring clinics were more likely not to know if their female patients had had a pregnancy test at 5 weeks [19.5% (m) vs. 12.5% (n) and 11.2% (o)].

Nurse-led monitoring clinics were also more likely to have checked serum lipids prior to starting and during treatment [96.8% (n) vs. 94.0% (m) and 91.6% (o)] and with the documentation of mental health and/or mood state both at the assessment for treatment and on follow-up [88.0% (n) vs. 83.1% (m) and 79.1% (o)].

6. Conclusions

This re-audit has been a useful exercise in ascertaining the improvement in compliance with BAD audit standards for isotretinoin over 2011-2013. There is currently good compliance nationally with standards relating to serum lipid checking, acknowledgement of PPP in female patients and pregnancy testing of these patients during treatment. The greatest improvement was with documentation of mood, which increased by 8%; however, there is still further scope for improvement in this area when the performance is broken down by individual regions. There is also further scope for improvement in recording pregnancy tests 5 weeks after completing treatment for female patients in the PPP.

Overall, compliance with the audit standards was the highest in cases where patients were seen in nurse-led monitoring clinics where consultants tend to be in charge of prescribing.

7. Action Points

1. Another re-audit is recommended after 5 years (2018) to ascertain any improvement.

2. Introduction of an isotretinoin initiation and follow-up proforma to help record data to improve patient care, recording:
   a. Mental health/mood state
   b. 5 week post isotretinoin treatment pregnancy test results

3. A number of improvements to the audit process have also been noted.

Please email Andrew Brain at clinicalaudit@bad.org.uk if you have any comments and suggestions or if you participated in the audit and would like to obtain the collective data for your hospital.

References

