

BMJ Open High-risk basal cell carcinoma excision in primary care: a retrospective observational study of compliance with NICE guidance

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ABSTRACT

Objectives To assess compliance with 2010 National Institute for Health and Care Excellence (NICE) guidance on cancer services relating to the management of basal cell carcinomas (BCC) in the community, where except in specific circumstances it is recommended that only low-risk BCCs should be excised routinely.

Design and setting A retrospective observational study of the histopathology reports of BCC excisions received from primary care in two district general hospitals in the South of England. One hundred consecutive BCC excisions were analysed from each hospital.

Outcome measures The numbers of high-risk BCCs excised in primary care according to histological subtype, anatomical site and age and if these excisions were compliant with NICE 2010 guidance. Completeness of excision and mention of BCC on histology request were secondary outcomes.

Results Histologically high-risk subtypes were present in 32% (64/200) of BCCs excised in the community. Only 17/64 were excised by general practitioners (GPs) who were accredited to do so. Non-compliance regarding anatomical site occurred in 16% of samples; only one was non-compliant regarding patient age. There was a high overall rate of complete excision (94.5%) with variation in presence of the term BCC on histology request forms.

Conclusions NICE 2010 guidance relating to BCC excision in primary care was not followed in a considerable number of cases. Compliance with NICE 2010 guidance depends on the ability to recognise high-risk BCCs clinically and manage appropriately. It also shows that despite close supervision by secondary care, there are still failures of compliance. GP training in identification of subtypes of BCC might be improved, as well as an increase in numbers of GPs accredited to carry out high-risk BCC excisions. Difficulty in diagnosing high-risk histological subtypes of BCC preoperatively should be considered in any future revision of NICE guidance.

INTRODUCTION

Basal cell carcinoma (BCC) is the most common type of cancer in the UK, and although it rarely metastasises, inadequate treatment or late diagnosis can result in the BCC invading important anatomical

Strengths and limitations of this study

- The introduction of model 2 practitioner status means that the conclusions of previous studies on primary care adherence to National Institute for Health and Care Excellence (NICE) guidance are less relevant now, and there is relatively little published on high-risk basal cell carcinomas (BCC) excision according to the categories of general practitioner (GP) that are appropriate to carry out the surgery.
- Presence or absence of high-risk features of BCCs is a binary measure and therefore simplifies data analysis.
- Two hundred BCCs represented a sufficient sample size to demonstrate a large percentage discrepancy in compliance with guidance between the two groups, and the short time frame limited the opportunity for changes in potentially confounding variables.
- It was not the aim to comment on overall diagnostic accuracy of GPs so no information was obtained relating to other lesions that had been referred directly for excision to be done within secondary care and were subsequently diagnosed histologically as BCCs or lesions that were excised as possible BCCs but were revealed to be other skin cancers on histology.
- It was assumed that any high-risk histological subtype excisions performed in the area with a model 2 GP were approved for excision by a multidisciplinary team member, consistent with NICE guidance; this process means that model 2 GPs will have a different case mix with more high-risk BCCs that could affect secondary outcome measures.

structures, making them difficult to treat or resulting in the lesion becoming advanced or inoperable.¹

The 2010 National Institute for Health and Care Excellence (NICE) guidance primarily addresses the excision of low-risk BCCs in the community. It has been shown² that patients are generally more satisfied if their procedure can be performed in primary care because of convenience.

However, NICE 2010 also addressed the importance of high-risk BCCs being treated appropriately. 'High risk' BCCs include those of a high-risk histological subtype, those in difficult anatomical sites including the face and lower leg, in young patients under 24 years of age and those which have previously been incompletely excised or are recurrent. In a study of 1039 consecutive BCC excisions in secondary care,³ only 38.4% were low risk histologically (nodular or superficial), and all the remaining BCCs had high-risk features such as micronodular, infiltrative or morphoeic subtypes.

The NICE guidance aims to provide the best care for patients with BCCs whether these are excised in primary or secondary care. This guidance is based on best available evidence from observational studies, a randomised controlled trial and expert opinion including from primary care, patients and carers. To quote from the guidance: 'the retrospective studies, although flawed, do indicate a consistent trend of current practices and outcomes in favour of specialist care in this setting'. As a general practitioner (GP) who is part of a direct enhanced service or local enhanced service, an enhanced services GP (ESGP) is eligible to excise low-risk BCCs below the clavicle if less than 1 cm in diameter and not in the pretibial region. If a GP with a special interest (GPwSI; which since 2015 is included under the new term GP with extended role) sees a lesion that is a possible BCC but is unable to confirm this clinically as a low-risk lesion, then they are expected to refer the case to the local specialist multidisciplinary team (MDT). If it is pre-diagnosed by the local specialist MDT, a model 2 practitioner can excise a high-risk BCC.

Prior to classification as a high-risk or low-risk subtype, clinicians must first have suspected the lesion to be a BCC. In a study in the Grampian region,⁴ the accuracy of clinical diagnosis of BCC based on 1087 histology reports was 67.1% for the GPs, 82.1% for the dermatologists and 83.3% for plastic surgeons. GPs were more likely to state 'no diagnosis' than secondary care specialists.

In a self-reported study from volunteer GPs doing local anaesthetic skin lesion excisions,⁵ 6138 procedures were analysed, of which 926 were confirmed as malignancies, including 722 BCCs. Model 2 GPs and GPwSIs had statistically significantly higher rates of complete excision than ESGPs. Only 37% of model 2 GPs took written consent. In a review of 1743 BCCs excised over a 32-month period by GPs,⁶ only 3% were considered to be 'low risk' according to NICE 2010 criteria. The authors concluded that low-risk BCCs are of low prevalence, which therefore leads to difficulties for GPs to maintain competencies. NICE guidance includes clinical governance recommendations. However, in a small study whereby questionnaires were sent out to 13 GPs with a special interest in dermatology or skin surgery, only eight replies were received, and it was confirmed that none of them were following the Department of Health guidelines for MDT attendance and annual appraisal.⁷

Other studies have reported on the variability of suitability for case selection for primary care treatment. Two audits in 2008 and 2009 from Liverpool⁸ reported that in 2008, out of 117 BCCs excised in primary care, 46% were high risk (clinically and/or histologically), and in 2009, out of 251 BCC excisions in primary care, 35% were high risk. In a further study of skin cancer excisions in primary care prior to the 2010 NICE guidance⁹ reporting on the treatment of 71 lesions, there were 50 excisions and 21 other procedures. Of these 71, 64 were reported as high risk, 27 were at high-risk sites and 37 of 44 lesions at low-risk sites were actually high-risk histologically. Of the 71 skin cancers, 24 (34%) required further excision. Further evidence of high-risk BCC excisions in primary care was reported in a 2010 study in Lothian, Fife and Tayside,¹⁰ where GPs excised 380 skin cancers in 1 year compared with 385 excised by dermatologists in 1 month and 179 by plastic surgeons also in 1 month. There were high-risk features (recurrent BCC, infiltrative BCC or located on the head and neck regions) in 63% of the BCCs excised by GPs.

Compliance with NICE 2010 guidance is compromised by the difficulties recognising and diagnosing BCC, and the clinical recognition of the morphological subtypes. The aim of this study is to assess compliance with NICE 2010 guidance and also the reasons for non-compliance and how it could be improved.

METHODS

The outcome of 200 BCC excisions carried out in primary care received at the histopathology laboratories of two district general hospitals in the South of England was studied.

Using the same start date, a total of 100 consecutive cases of lesion excisions confirmed on histology as BCC from each hospital were analysed according to the NICE criteria and also the category of GP performing the surgery.

Full pathology reports were studied by two independent researchers (SJC and RH) who were blinded to operator's identity and category. Re-excisions, shaves, punch biopsies and other diagnostic samples were excluded as were all secondary care excisions. Presence or absence of each of the high-risk criteria was recorded for every excision. Where required, clarifications were provided by the pathology department. The category of each operator whose excisions were studied was revealed by the pathology department at the end of data collection. Operators were categorised as GPs, GPwSI or model 2 practitioners so that appropriateness of different BCC risk group according to type of GP could be assessed.

Data were collected from 4 September 2014, giving time for the update guidance from NICE in 2010 to be included in the practice of both areas.

'High-risk' BCCs are defined by the NICE 2010 guidance including those with high-risk histological subtypes, those at specific anatomical sites (including face and pretibial region) and in patients under 24 years of age.

Table 1 Results of BCC excisions and compliance with NICE 2010

| | High-risk histology | Fail histology criterion | Fail site criterion | Fail age criterion | Total BCCs |
|----------------------|---------------------|--------------------------|---------------------|--------------------|------------|
| Area 1 | | | | | |
| GP | 2 | 2 | 1 | 0 | 14 |
| Model 2 practitioner | 17 | 0 | 15 | 0 | 86 |
| Total | 19 | 2 | 16 | 0 | 100 |
| Area 2 | | | | | |
| GP | 26 | 26 | 15 | 0 | 54 |
| GPwSI | 19 | 19 | 0 | 1 | 46 |
| Total | 45 | 45 | 15 | 1 | 100 |
| Area 1 and 2 | | | | | |
| Total | 64 | 47 | 31 | 1 | 200 |

BCC, basal cell carcinoma; GP, general practitioner; GPwSI, GP with a special interest; NICE, National Institute for Health and Care Excellence.

As secondary outcomes, completeness of BCC excision was assessed and whether the possibility of BCC as a clinical diagnosis was included on the histology request form.

Patient involvement

Consideration of patient preference for excision in primary care was key factor in study conception, balanced against the need for effective and safe procedures. Patients were not directly involved in the design or conduct of the study.

RESULTS

Out of the total of 200 BCC excisions shown in [table 1](#), histologically high-risk subtypes were present in 32% (64/200). For the lesions received from the area associated with a model 2 practitioner (area 1), there were 19 excisions of high-risk histological subtype BCCs, but 17 of those were carried out by the model 2 practitioner, which is in line with guidance. In the area with GPwSI and GPs exclusively (area 2), there were 45 BCCs with high-risk histological features, none of which were excised by a model 2 practitioner. Across both areas, there were 47 incidents of non-compliance on the histological subtype criterion (23.5%).

There was non-compliance in 31 excisions on the anatomical site criterion (15.5%). There was non-compliance in one case on the grounds of the age of the patient (0.5%). Some excisions were non-compliant on more than one criterion.

Secondary outcome measures are shown in [table 2](#). The overall completeness of excision rate was 189 out of 200 (94.5%) with GPs across both areas achieving 92.65%, GPwSIs achieving 95.65% and model 2 achieving 95.4%. The terms 'basal cell carcinoma' or 'BCC' were not on the request forms accompanying 28 specimens. Model 2

Table 2 Secondary outcome measures

| | Incomplete excision | Not stated as 'BCC' on request form | Total BCCs |
|----------------------|---------------------|-------------------------------------|------------|
| Area 1 | | | |
| GP | 3 | 5 | 14 |
| Model 2 practitioner | 4 | 3 | 86 |
| Total | 7 | 8 | 100 |
| Area 2 | | | |
| GP | 2 | 14 | 54 |
| GPwSI | 2 | 5 | 46 |
| Total | 4 | 20 | 100 |
| Area 1 and 2 | | | |
| Total | 11 | 28 | 200 |

BCC, basal cell carcinoma; GP, general practitioner; GPwSI, GP with a special interest.

practitioners were most likely to mention BCC on their request form (96.6%), followed by GPwSI (88.2%) then GPs (72.1%).

DISCUSSION

Principle findings

The principle finding of this study is low compliance with NICE 2010 guidance, particularly regarding high-risk histological subtypes of BCC and anatomical site of the lesion ([table 1](#)). Histologically high-risk BCCs have an increased risk of incomplete removal. A study examining the association between histological pattern and adequacy of excision³ showed that completeness of excision was worse for high-risk micronodular, infiltrative and mixed types of BCC. From a study of 16 066 BCC excisions,¹¹ it was concluded that, for a non-morpheiform type of BCC of less than 2 cm in diameter, a 3 mm margin is sufficient to obtain a 95% cure rate. The importance of an involved margin was also shown in this study, which was a review of 89 articles published on the subject and confirmed that a positive pathological margin would lead to an average recurrence rate of 27%. A BCC of 2 cm diameter requires a surgical margin of at least 13 mm for relative certainty of removal of the tumour in 95% of cases.¹² Surgical margins of this width create large defects closure of which may be challenging in a primary care setting.

Various studies have reported on inadequacy of completeness of excision of BCCs in primary care. In a review of 366 BCC excisions in Aberdeen,¹³ those excised by GPs had a 34.1% incomplete excision rate. In a review from the Netherlands in 2009¹⁴ of 1898 pathological specimens of skin tumours excised by GPs, 35% were incomplete and 65.4% were incomplete from the face and neck region. A study of 2586 BCC excisions in 1717 patients¹⁵ quoted a recurrence rate of incompletely excised BCCs at 5-year follow-up of 30%–41%. Of 184 incompletely excised BCCs, 62 were re-excised and 39 of these showed residual tumour so complete excision is essential and is

therefore of importance as an outcome measure. The majority of publications report a high incomplete excision rate in primary care, but in a review of 124 BCC excisions in primary care,¹⁶ there was an incomplete excision rate of only 1.6%. In the present study, the incomplete excision rate was also low at only 5.5%.

Model 2 practitioners and GPwSI performed better in secondary outcome measures compared with GPs, which may reflect their increased training and experience in the field or closer supervision from secondary care.

The strength of this study is that the NICE guidance is clear on subtypes of BCC that are considered 'high risk' and also which anatomical sites and age of patient represent high-risk cases. These binary parameters make it relatively easy to assess compliance.

A further strength of this study is that there is relatively little published on high-risk BCC excision according to the new categories of GP that can carry out the surgery. The introduction of model 2 practitioner status means that the conclusions of previous studies on adherence to NICE guidance are of less relevance.

A potential weakness of this study is the sample size. The main requirement for the samples was that they were consistent across the two geographically similar areas. By using the same start date for sampling, the only difference was the category of operators. The study was designed to be able to show a difference between the two areas, and by avoiding a long data collection period, changes in staffing structure or training and other confounding variables could also be minimised. The sample size and findings were comparable with those in the literature, suggesting generalisability and a clear pattern emerged within the data.

The present study confirmed a high complete excision rate by all of the GPs involved, but no information was obtained about any suboptimal healing or complications that could lead to scarring or less than satisfactory cosmetic results. Delayed healing or scarring is of particular relevance to the higher risk sites such as the face and pretibial region. There was also no information on BCCs that were referred into secondary care for treatment and whether those were originally diagnosed correctly clinically as BCCs.

Explanation and implications

Some high-risk features are easy to ascertain once aware of the guidance, such as age of patient and anatomical site, but it can be difficult to differentiate clinically between histological subtypes, and a significant proportion of BCCs are of mixed subtype that include high-risk morphology. Further training in primary care in the recognition of subtypes of BCC, possibly assisted by more widespread use of dermoscopy, could improve compliance with regard to recognition of histological subtype. Greater numbers of these operations carried out by model 2 practitioners with a link to the local specialist MDTs would also improve compliance with NICE 2010 guidance. The authors believe that these suggestions for

improving compliance will be relevant to any other units with similar outcomes and that these results are likely to be representative of the UK as a whole in terms of variations in adherence to guidance.

NICE guidance should put patients at the forefront and also make the most of opportunities to deliver care in the most convenient location for them; the present study has demonstrated a high complete excision rate for BCCs treated in primary care. However, several other studies have shown that the recognition of BCC was poor, and there were high incomplete excision rates that can lead to poor patient outcomes. NICE guidance is specifically intended to improve the outcomes for people with skin tumours. In its patient perspective section, the 2010 NICE guidance reports that patients want their BCC to be accurately diagnosed and treated effectively first time, with minimal risk of recurrence and the best cosmetic result possible by adequately trained professionals who have met prescribed standards.

There is the potential to increase the numbers of model 2 practitioners as a bridge between primary and secondary care for skin cancer surgery. Murchie *et al*⁴ also comment on the scope for improving training for GPwSIs. To quote from the 2010 NICE guidance: 'only doctors and nurses who have received locally approved training and who are active members of a skin cancer MDT should carry out surgery for skin cancers'. Increased provision in both primary and secondary care is likely to be necessary to give the best outcomes for people with skin tumours.

Future research in this area could involve a comparison of the performance in terms of diagnosis of skin cancers by GP with extended roles and model 2 practitioners compared with secondary care; a larger study could examine GP referrals that were subsequently confirmed as being BCCs and what was stated in the referral letter. Accuracy of clinical diagnosis of pigmented lesions referred for excision would be of interest and also consideration of squamous cell carcinoma excisions inadvertently carried out in primary care because they did not look clinically suspicious.

In conclusion, this study of the management of BCCs in adjacent areas in the South of England demonstrated that compliance with NICE 2010 BCC excision guidance could be improved with further GP education, closer involvement with the local skin MDTs and a more straightforward progression to accreditation as model 2 practitioner status. Consideration might be given to revising the NICE guidance taking into account the difficulty of diagnosing high-risk histological subtypes of BCC preoperatively, which makes compliance with this parameter difficult. Although operating on a high-risk site or younger aged patient is avoidable, operating on a high-risk histological BCC is not. A revision of NICE guidance to allow for this could help to negate any perceived criticism of GPs who excise skin lesions in primary care, which is more convenient for patients and also reduces the pressure on secondary care.

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