The development and validation of a decision aid to facilitate patient choice of surgery versus radiotherapy for high-risk basal cell carcinoma

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Abstract

Basal Cell Carcinomas (BCCs) are increasingly common. For high risk BCCs, there are several treatment options, with similar efficacies. Current best practice is for a patient centred approach in deciding upon treatment modality. At present, there are few resources for clinicians to give to patients to assist their choice. This reduces patient autonomy and increases the burden on clinicians within clinic. Patient decision aids (PDAs) have been shown to increase patient autonomy and facilitate shared decision making. Currently, there is no published PDA designed to facilitate the decision between surgical management or radiotherapy in high risk BCCs.

Here, we propose a novel decision aid designed along the International Patient Decision Aid Standards to fill this clinical need and evaluate its acceptance by both patients and clinicians. We describe the challenges faced at initial alpha and subsequent beta testing and go on to validate our PDA with both the Decisional Conflict Scale (DCS) and the 9-item Shared Decision Making Questionnaire (SDMQ9). We encourage other units to modify the PDA for their own use and include an example.
High-risk Basal Cell Carcinoma (BCC) as defined by recent British Association of Dermatologists (BAD) guidelines, is based on various features such as site of tumour, clinical border, histological subtype and level of invasion.\textsuperscript{1} Whilst surgical options, namely primary excision or Mohs micrographic surgery, are preferentially recommended in guidelines, in practice, radiotherapy is frequently a treatment option offered to patients 60 years or older and as suggested by BAD guidelines, this may be given where patients express a preference for radiotherapy over surgery.\textsuperscript{1} Whilst the 2021 guidelines note increased recurrence rates (with one trial noting a 10-fold increase in recurrence rates\textsuperscript{2}) the guidelines note the acceptance of radiotherapy as a treatment modality across a number of international guidelines\textsuperscript{1}. Indeed, a 2018 systematic review suggested that at 3.5%, the recurrence rate with radiotherapy was comparable to the standard of primary excision or Moh’s microsurgery, both 3.8%\textsuperscript{3}. A range of specialists may be involved in treatment discussions, including plastic surgeons and oncologists, and patients are often given a sizeable amount of information at a single consultation, including the diagnosis and treatment options, as well as potential risks.

As shared decision making becomes the gold standard for clinicians, patient decision aids (PDAs) have been adopted across the clinical spectrum. These are evidenced to increase knowledge of a condition and its treatment modalities and encourage patients to consider the advantages and disadvantages of various treatment options.\textsuperscript{4} The most updated Cochrane Review found evidence indicating positive effects, when decision aids were used either within or in preparation for the consultation.\textsuperscript{4}

We identified a clinical need for improved information dissemination for patients diagnosed with BCC, facing the decision between surgery, namely primary excision, and radiotherapy. Thus, between May-August 2021 we developed a novel PDA following the principles set out
by the International Patient Decision Aid Standards\textsuperscript{5}. The study was classified as service evaluation, and therefore ethical approval was not required. A literature search was conducted to provide accurate evidence-based data for the PDA.

Alpha testing was undertaken with feedback from clinicians and patients. Subsequently in beta testing, we validated this decision aid using two validated outcome measures, the 9-item Shared Decision Making Questionnaire (SDMQ9) and the Decisional Conflict Scale (DCS).\textsuperscript{6-7} We also assessed the overall benefit of the PDA using a patient satisfaction questionnaire to compare pre- and post-implementation experiences, based on negative-framing of questions (Supplementary Material). Responses were graded on a Likert scale and examples of questions included were: ‘I feel I was overwhelmed with the information I was given today’, ‘I don’t feel I have a clear understanding of the risks and benefits of each treatment’ and ‘I felt rushed to make a decision today’. Average response scores were calculated with 95\% confidence intervals (CI) and following Jarque-Bera test to confirm normality, the student’s t test was used to compare pre- and post-decision aid scores.

After an initial draft of the PDA was created, alpha testing prompted several modifications including the addition of questions ‘how many hospital visits are needed?’ and ‘where is it done?’, as well as a QR link to the British Association of Dermatologists BCC patient information leaflet. Complexity of language was also discussed. The average reading age of the UK public has been estimated at less than 12 years.\textsuperscript{8} Accordingly, we adapted the text to simplify its language and we estimated a final readability age between 8 and 12 years old, based on widely-available readability calculators: Flesch Reading Ease Score, Gunning Fog, Flesch-Kinkaid Grade Level, Automated readability index and Coleman-Liau Index.
The final version of the PDA (Figure 1, available for free distribution and modification) was then developed and distributed to 18 consecutive patients referred to a combined clinic, at clinic attendance, for consideration of surgery vs. radiotherapy for BCC, together with the patient satisfaction questionnaire and example photographs to demonstrate post-surgery and post-radiotherapy outcomes. We also distributed the patient satisfaction questionnaire to 18 consecutive patients, who were similarly referred to the combined clinic, prior to PDA development. Patients under the age of 60, deemed eligible for Mohs surgery, with recurrent BCCs, or with BCCs on limbs, were not offered radiotherapy, as per BAD guidelines.¹

Post-implementation, we found the mean DCS response across the beta testing cohort of 14 complete responses was 1.70/5 (95% CI 1.60, 1.79) – between ‘strongly agree’ and ‘agree’ that the PDA aided deciding on a treatment. We received 17 responses for the SDMQ9, with mean of 4.93/5 (95% CI 4.71, 5.15), between somewhat agree and strongly agree (tending towards the latter) that the PDA facilitated shared decision making. The patient satisfaction questionnaire was completed by 17 patients who received the PDA, with mean response of 1.62/5 (95% CI 1.51, 1.74), between disagree and strongly disagree that there was excessive/inadequate information or that they felt rushed. This represented a modest mean improvement of 0.75 points (p<0.001) versus pre-PDA implementation, where scores had a mean value of 2.38/5 (95% CI 2.20, 2.56).

A large volume of information is given to patients diagnosed with BCC, including prognosis, treatment options and potential benefits/risks of each treatment modality. A PDA given in advance of a multidisciplinary combined clinic, usually when giving the histopathology result, allows a patient time to review the options and discuss with family and/or friends. This decision aid has been developed and validated to facilitate the choice of primary excision vs
radiotherapy and we encourage its use in outpatient settings, where both options are available and equitable. In general, we encourage use of PDAs to enhance patient-centred care and facilitate shared decision making.

References


Figure Legend

Figure 1. Decision aid, primary excision vs. radiotherapy
**How should I treat my Basal Cell Carcinoma?**

A Basal Cell Carcinoma (also called a 'BCC') is a type of skin cancer (tumour). BCCs are often a result of sun damage and grow slowly over a few years.

Sometimes people will get more than one BCC as they get older. It **doesn’t spread** to other parts of your body like some cancers, but can cause damage to local areas. Sometimes this damages nerves and blood vessels and so we strongly advise treating it. In your case, we recommend using either surgery or a special x-ray treatment called radiotherapy, to do this. This guide, together with a discussion with the doctors in clinic, should help you decide between the two.

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**Surgery (primary excision)**

- An injection is given to make the area numb. The BCC and an area of surrounding skin is cut out. It is then stitched together (sutured).
- Sometimes skin is taken from a different part of the body to allow us to join the skin together – this is called a graft. Sometimes we have to move skin from a nearby area to allow us to join the skin together – this is called a flap.
- What does the treatment involve?
- Is it painful?
- The injection to numb the area does sting but you shouldn’t feel any pain after that. You may still feel some pulling.
- No.

- The surgery usually takes 30 minutes to 1 hour.
- How long does it take?
- Yes – the surgery is done with local anaesthetic.
- Will I be awake?
- (insert) Hospital.
- Where is it done?
- Yes - we do not use any anaesthetic.
- Two visits: one for the procedure and one to check the healing after surgery.
- How many hospital visits are needed?
- Approximately 92-97%.
- How successful is it?

**Radiotherapy**

- You may need a mask to be made to protect normal skin from the treatment. The treatment takes place inside an x-ray machine and you will need to lie still for 15-20 minutes. The treatment is repeated over 5-10 days.
- Each session lasts 15-20 minutes
- Yes - we do not use any anaesthetic.
- (insert) Hospital.
- One initial visit for planning and then one visit per day for 5-10 days for the treatment
- Approximately 91-96%.

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You will have a scar with some stitches in - the doctor will suggest the shape of the scar. The stitches may need to be taken out, usually between 5 and 14 days, depending on the site. Grafts take longer to heal and may need dressings over a few weeks.

The main risks with surgery are bleeding and infection. If a graft is used, sometimes the graft can fail and break down.

The skin that has been cut out is looked at under a microscope to make sure there is no tumour left. This is a very good test, but not 100% accurate.

The circle-shaped area will look red at first, but will fade to become a white colour. Over time, you may see blood vessels in this area.

Rarely, dry scaly skin or irritation of the skin can occur. Very rarely, the skin in the treated area can break down.

No special test is done. We look at the treated area after treatment is finished to make sure it looks clear.