Evidence-Based Series 21-3-9-EDUCATION AND INFORMATION 2013

The Role of IMRT in Skin Cancers

A. Sun, R.B. Rumble, P. Warde, and members of the IMRT Indications Expert Panel

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO), and the Radiation Treatment Program, CCO

Report Date: October 29, 2010

An assessment conducted in November 2013 put Evidence-based Series (EBS) 21-3-9 in the Education and Information section. This means that the recommendations will no longer be maintained but may still be useful for academic or other information purposes. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol).

EBS 21-3-9 is comprised of 3 sections and is available on the CCO website (http://www.cancercare.on.ca)

PEBC Cancer Screening page at: http://www.cancercare.on.ca/toolbox/qualityguidelines/clin-program/radther/

Section 1: Guideline Recommendations
Section 2: Evidentiary Base
Section 3: EBS Development Methods and External Review Process

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Phone: 905-527-4322, ext. 42822 Fax: 905-526-6775   E-mail: ccopgi@mcmaster.ca

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Evidence-Based Series 21-3-9: Section 1

The Role of IMRT in Skin Cancers: Guideline Recommendations

A. Sun, R.B. Rumble, P. Warde, and members of the IMRT Indications Expert Panel

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)
and the Radiation Treatment Program, CCO

Report Date: October 29, 2010

QUESTION

In the treatment of skin cancer, is there a benefit in local control, adverse events, or quality of life associated with IMRT compared with 2D external beam radiation therapy (EBRT)?

Outcomes of interest included local control, overall survival, acute and chronic adverse effects, and quality of life.

TARGET POPULATION

The target population is comprised of all adult patients with large, locally advanced skin cancers (both melanomas and non-melanomas) for whom treatment with radiation is being considered. The target population excludes patients suitable for local treatment with simple radiation techniques (e.g., orthovoltage) or simple, wide, local excision with surgery.

INTENDED USERS

This guideline is targeted for radiation oncologists, physicists, dosimetrists, patients, and others involved in the treatment of skin cancers where treatment with IMRT is being considered. Administrators may find the report of value when considering the benefits of IMRT over other methods of radiation delivery.

BACKGROUND

IMRT is a newer method of delivering radiation to target structures that differs from traditional methods. The basis of IMRT is the use of intensity-modulated beams that can provide two or more intensity levels for any single beam direction and any single source position (1). Through this mechanism, IMRT treatment plans are able to generate concave dose distributions and dose gradients with narrower margins than those allowed using traditional methods (1,2). This fact makes IMRT especially suitable for treating complex...
treatment volumes and avoiding close proximity organs at risk (OAR) that may be dose limiting (1). As a consequence, IMRT may theoretically provide benefits in terms of increased tumour control through escalated dose and reduced normal tissue complications through OAR sparing. It must be noted that as total radiation dose delivered via IMRT would be the same as the total radiation dose given via any other method of radiation therapy, no difference in disease-related outcomes would be expected. The main benefit expected with IMRT is a reduction in adverse event rates, especially those associated with radiation damage to nearby OARs.

Given the potential dosimetric advantages of IMRT and the commercial availability of IMRT-enabled treatment planning systems and linear accelerators, IMRT has been introduced clinically for a number of disease sites, including head and neck cancer and prostate cancer. This evidence-based series reviews the published experience with IMRT in the treatment of skin cancer to quantify the potential benefits of this new technology and make recommendations for radiation treatment programs considering adopting this technique.

RECOMMENDATIONS AND EVIDENCE

| Insufficient evidence was obtained in this systematic review; therefore, it is not possible to propose recommendations informed by evidence. |

| Evidence: |
| No evidence meeting the inclusion criteria was obtained. |

Qualifying Statement

Despite the lack of comparative evidence in this disease site, there remain compelling reasons why IMRT might be offered to patients as an alternative to the standard treatment of 2D EBRT. In other settings, IMRT has a demonstrated ability to avoid OARs sparing patients significant short- and long-term morbidity. Also, IMRT can improve target coverage in a difficult volume to treat, which may translate into an increase in local control with or without the ability to safely increase the maximum tumour dose. For these reasons, IMRT should be considered for the treatment of large, locally advanced skin cancers, as IMRT is better able to target tumours while avoiding nearby OARs, reducing adverse effects compared with 2-D EBRT. In addition, IMRT may allow for the ability to safely deliver radical radiation doses to selected large, locally advanced skin cancers that would otherwise not be treatable to radical doses using conventional EBRT techniques. In this case, IMRT may be considered a viable treatment option, as it is ethical to recommend a treatment with little known harm over one with greater expected harm prior to scientific proof of the difference in harm being established.

FUTURE RESEARCH

Ideally future research should focus on studies with a large sample size and long-term follow-up that provide data on local control rates, acute and late toxicities, and quality of life; however, this is a challenge in a disease site as diverse as skin cancer.

RELATED GUIDELINES

Funding
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REFERENCES


The Role of IMRT in Skin Cancers: Evidentiary Base

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Given the potential dosimetric advantages of IMRT and the commercial availability of IMRT-enabled treatment planning systems and linear accelerators, IMRT has been introduced clinically for a number of disease sites, including head and neck cancer and prostate cancer. This evidence-based series reviews the published experience with IMRT in the treatment of
skin cancer to quantify the potential benefits of this new technology and to make recommendations for radiation treatment programs considering adopting this technique.

INTRODUCTION

Skin cancers, including melanomas and non-melanomas, are a diverse group of malignancies in terms of where they present anatomically—they can essentially present on any sun-exposed area of the skin, although not exclusively. Due to this fact, a variety of OARs must be considered, depending on the anatomical site of the lesion. One of the most common sites of presentation is in the head and neck region. In this region, some of the OARs to consider are the eyes, brain, and salivary glands. Often, advanced skin cancers of the head and neck region are treated very similarly to other cancers of the head and neck and, therefore, pose very similar issues (other cancers of the head and neck are discussed in a separate report [see EBS21-3-3: The Role of IMRT in Head & Neck Cancer (in development)]). The other issue in advanced skin cancers is the need to cover the clinical target volume adequately with a homogeneous dose distribution while avoiding OARs. This issue often relates to the nature of the surface area that the skin covers, with its many undulations, curvatures, and invaginations creating very complex treatment volumes. A good example of this is a large lesion affecting the scalp that extends around the curvature of the head and involves the ear (invaginations) and the nose (undulations), and is close to the eye. Therefore, skin cancers can very easily create complex treatment volumes in close proximity to a variety of important OARs, which cannot be adequately treated with the standard treatment of conventional 2D EBRT (3).

With the advent of IMRT, some of these issues may be overcome. To evaluate the efficacy of IMRT compared to conventional 2D EBRT, a systematic review of the literature is warranted.

METHODS

The evidence-based series (EBS) guidelines developed by Cancer Care Ontario’s Program in Evidence-Based Care (PEBC) use the methods of the Practice Guidelines Development Cycle (4). For this project, the core methodology used to develop the evidentiary base was the systematic review. Evidence was selected and reviewed by one member of the IMRT Indications Expert Panel (see Appendix 1 for Panel membership) and by one methodologist.

The systematic review is a convenient and up-to-date source of the best available evidence on the role of IMRT in skin cancers. The body of evidence in this review is primarily comprised of published reports of comparative studies between IMRT and 2D EBRT. That evidence forms the basis of the recommendations developed by the IMRT Indications Expert Panel and will be published when completed. The systematic review and companion recommendations are intended to promote evidence-based practice in Ontario, Canada. The PEBC and the Radiation Treatment Program (RTP) are supported by the Ontario Ministry of Health and Long-Term Care through Cancer Care Ontario. All work produced by the PEBC is editorially independent from its funding source.

Literature Search Strategy

The MEDLINE and Embase databases were searched for evidence on skin cancer and IMRT on June 15, 2009 (see Appendix 2). In both databases, keywords for “skin cancer” were combined with keywords for “intensity-modulated radiotherapy” and the following terms were excluded: “brachytherapy” “proton therapy”, “biological markers”, “gene therapy”, “children”, “childhood cancer”, “pediatric cancer”, “quality assurance”, “treatment plan comparison”, “aperture optimization”, independent dose calculation”, “EPID dosimetry”, and
'set up errors”. Results were limited to those published in English from the year 2000 to the current date in 2009.

A search for clinical practice guidelines (CPG), systematic reviews (SR), and health technology assessments (HTA) was also performed. A search of the National Guidelines Clearinghouse (located at: http://www.guideline.gov) was performed on March 9, 2009. Additionally, a search of the MEDLINE and Embase databases was performed on March 25, 2009, using keywords for IMRT in combination with terms for all disease sites, limited to review articles published after 2000. Finally, the Scottish Collegiate Guidelines Network (SIGN) (located at: http://www.sign.ac.uk), the National Institute for Health & Clinical Evidence (NICE) (located at: http://www.nice.org.uk), and the Agency for Healthcare Research & Quality (AHRQ) (located at: http://www.ahrq.gov) were searched on March 25, 2009, using keywords for “IMRT”, and “radiation” in combination with disease-site-specific terms.

Study Selection Criteria

Inclusion Criteria

All evidence must include comparative data on IMRT versus 2D EBRT in the treatment of skin cancer, must report on at least one of the outcomes of interest (local control, overall survival, acute and chronic adverse effects, or quality of life), and must be one of the following publication types:

- CPGs, SRs, HTAs
- Randomized phase II or phase III trials
- Dose escalation studies, toxicity reports, Quality-of-life (QOL) reports, case-series, and retrospective studies
- Published in English
- Published in the year 2000 to current date

Exclusion Criteria

- Published in a language other than English
- Do not provide comparative data
- Published prior to the year 2000

Synthesizing the Evidence

No statistical analyses were planned in this systematic review, although this would be considered if data allow.

RESULTS

Literature Search Results

The MEDLINE and Embase search returned 13 and 18 potential articles, respectively. After removing ineligible articles based on title and abstract review, one was ordered for full-text review, but on examination this single paper did not meet the inclusion criteria. No evidence was found in this systematic review, and recommendations were drafted based on expert opinion.

Ongoing Trials

The U.S. National Institutes of Health online directory of clinical trials (located at http://www.clinicaltrial.gov) was searched on October 15, 2009, for listings of relevant studies. No studies were found investigating the use of IMRT in the treatment of skin cancers.
DISCUSSION

Although IMRT is especially suited for treating complex treatment volumes, while avoiding close proximity OARs encountered in advanced skin cancer, and may theoretically provide benefits in terms of increased tumour control through the escalated dose and reduced normal tissue complications through OAR sparing, no evidence was obtained in this systematic review that met the inclusion criteria.

Only dosimetric case reports have been published comparing IMRT with conventional radiotherapy techniques such as 3DCRT with photons and/or electrons or high dynamic range imaging (HDR) brachytherapy. Wojcicka et al (5) compared photon/electron 3DCRT, IMRT, and HDR brachytherapy plans for total scalp irradiation. The authors concluded that IMRT provided the best target-dose homogeneity and coverage, and delivered clinically acceptable doses to normal structures. Bedford et al (3) compared static electron, electron arc therapy, and photon IMRT for extensive scalp lesions. These authors concluded that photon IMRT resulted in the improved homogeneity of dose to the planning target volume (PTV) but with a moderate increase in dose to the brain.

However, advanced skin cancers located in the head and neck often behave similarly and are managed similarly to other advanced head and neck cancers. They share issues such as xerostomia and QOL, blindness, and osteoradionecrosis. Therefore, all of the recommendations and key evidence cited for the use of IMRT for advanced head and neck cancers would equally apply to advanced skin cancers located in the head and neck (see EBS21-3-3: The Role of IMRT in Head & Neck Cancer [in development]).

CONCLUSIONS

As no comparative evidence was obtained in this systematic review, it is not possible to propose any evidence-based recommendations in the use of IMRT for skin cancer. Despite the lack of comparative evidence in this disease site, there remain compelling reasons why IMRT might be offered to patients as an alternative to the standard treatment of 2D EBRT. In other settings, IMRT has a demonstrated ability to avoid OARs, sparing patients significant short- and long-term morbidity. In addition, IMRT can improve target coverage in a difficult volume to treat, which may translate into an increase in local control with or without the ability to safely increase the maximum tumour dose.

CONFLICT OF INTEREST

None declared.

ACKNOWLEDGEMENTS

The IMRT Indications Expert Panel would like to thank Dr. Alexander Sun and Mr. R. Bryan Rumble for taking the lead in drafting this systematic review.
Funding
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REFERENCES


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**Expert Panel**

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<thead>
<tr>
<th>Name</th>
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<tbody>
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<td>Dr. Michael Sharpe</td>
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**Working Group**

<table>
<thead>
<tr>
<th>Name</th>
<th>Role and Organization</th>
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<tbody>
<tr>
<td>Dr. Alexander Sun</td>
<td>Radiation Oncologist, Princess Margaret Hospital</td>
</tr>
<tr>
<td></td>
<td>Assistant Professor, Department of Radiation Oncology, University of Toronto</td>
</tr>
</tbody>
</table>
Appendix 2. Literature search strategies.

Database: Ovid MEDLINE(R) <1996 to June Week 1 2009> Search Strategy:

1 skin cancer.mp. or exp Skin Neoplasms/ (36761)
2 exp Radiotherapy, Intensity-Modulated/ or imrt.mp. (2678)
3 brachytherapy.mp. or exp Brachytherapy/ (8646)
4 protons.mp. or exp Protons/ (15654)
5 biological markers.mp. or exp Biological Markers/ (316505)
6 gene therapy.mp. or exp Gene Therapy/ (33518)
7 children.mp. or exp Child/ (542180)
8 pediatric cancer.mp. (677)
10 exp Quality Assurance, Health Care/ or quality assurance.mp. (139579)
11 treatment plan comparison.mp. (5)
12 aperture optimization.mp. (30)
13 independent dose calculation.mp. (13)
14 EPID dosimetry.mp. (14)
15 set up errors.mp. (88)
16 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 (1023906)
17 1 and 2 (14)
18 1 and 16 (7160)
19 17 not 18 (13)
20 limit 19 to (English language and humans and yr="2000 - 2009") (13)
21 from 20 keep 1-13 (13)

Database: EMBASE <1996 to 2009 Week 24>

1 skin cancer.mp. or exp Skin Cancer/ (35246)
2 imrt.mp. or exp Intensity Modulated Radiation Therapy/ (3476)
3 brachytherapy.mp. or exp Brachytherapy/ (11022)
4 proton therapy.mp. or exp Proton Therapy/ (718)
5 biological marker.mp. or exp Biological Marker/ (33165)
6 gene therapy.mp. or exp Gene Therapy/ (35195)
7 Child/ or child.mp. or children.mp. (467955)
8 exp Childhood Cancer/ or pediatric cancer.mp. (10099)
9 quality assurance.mp. or exp Quality Control/ (112673)
10 treatment plan comparison.mp. (5)
11 aperture optimization.mp. (31)
12 independent dose calculation.mp. (12)
13 EPID dosimetry.mp. (15)
14 set up error.mp. (60)
15 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 (652139)
16 1 and 2 (30)
17 1 and 15 (2829)
18 16 not 17 (19)
19 limit 18 to (human and English language and yr="2000 - 2009") (18)
20 from 19 keep 1-18 (18)
Evidence-Based Series 21-3-9: Section 3

The Role of IMRT in Skin Cancers: EBS Development Methods and External Review Process

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THE PROGRAM IN EVIDENCE-BASED CARE

The Program in Evidence-Based Care (PEBC) is an initiative of the Ontario provincial cancer system, Cancer Care Ontario (CCO) (1). The PEBC mandate is to improve the lives of Ontarians affected by cancer, through the development, dissemination, implementation and evaluation of evidence-based products designed to facilitate clinical, planning and policy decisions about cancer care.

The PEBC supports a network of disease-specific panels, termed Disease Site Groups (DSGs) and Guideline Development Groups (GDGs), as well as other groups or panels called together for a specific topic, all mandated to develop the PEBC products. These panels are comprised of clinicians and other health care providers, as well as decision makers, methodologists, and community representatives from across the province.

The PEBC is well known for producing evidence-based guidelines, known as Evidence-Based Series (EBS) reports, using the methods of the Practice Guidelines Development Cycle (1,2). The EBS report consists of an evidentiary base (typically a systematic review), an interpretation of and consensus agreement on that evidence by our Groups or Panels, the resulting recommendations, and an external review by Ontario clinicians and other stakeholders in the province for whom the topic is relevant. The PEBC has a formal standardized process to ensure the currency of each document, through the periodic review and evaluation of the scientific literature and, where appropriate, the integration of that literature with the original guideline information.
The Evidence-Based Series
Each EBS is comprised of three sections:

- **Section 1: Guideline Recommendations.** Contains the clinical recommendations derived from a systematic review of the clinical and scientific literature and its interpretation by the Group or Panel involved, and a formalized external review in Ontario by review participants.
- **Section 2: Evidentiary Base.** Presents the comprehensive evidentiary/systematic review of the clinical and scientific research on the topic, and the conclusions reached by the Group or Panel.
- **Section 3: EBS Development Methods and External Review Process.** Summarizes the evidence-based series development process and the results of the formal external review of the draft version of Section 1: Guideline Recommendations and Section 2: Evidentiary Base.

DEVELOPMENT OF THIS EVIDENCE-BASED SERIES
Development and Internal Review
This EBS was developed by the IMRT Indications Expert Panel of the CCO PEBC and RTP. The series is a convenient and up-to-date source of the best available evidence on the role of IMRT in central nervous system cancer, developed through review of the evidentiary base, evidence synthesis, and input from external review participants in Ontario.

IMRT Expert Panel Conference
On December 3, 2009, the IMRT skin cancer guideline was presented to members of the IMRT Expert Panel (N=24), and feedback was obtained on the quality and comprehensiveness of the evidence and the recommendations. The results are as follows:

| Are you responsible for the care of patients for whom this draft report is relevant? |
|---------------------------------|--------|--------|--------|--------|--------|--------|
| Response | Yes | No | Unsure | TOTALS | Missing |
| n | 12 | 11 | 0 | 23 | 1 |
| % | 52.2 | 47.8 | 0 | 100 | 4.2 |

| Rate the overall quality of the guideline report. |
|---------------------------------|--------|--------|--------|---------|--------|--------|
| Response | 1.Lowest | 2. | 3. | 4. | 5.Highest | TOTALS | Missing |
| n | 0 | 6 | 15 | 1 | 2 | 24 | 0 |
| % | 0 | 25 | 62.5 | 4.2 | 8.3 | 100 | 0 |

| I would make use of this guideline in my professional decisions. |
|---------------------------------|--------|--------|--------|--------|--------|--------|
| Response | 1.Strongly disagree | 2. | 3. | 4. | 5.Strongly agree | TOTALS | Missing |
| n | 3 | 5 | 11 | 1 | 1 | 21 | 3 |
| % | 14.3 | 23.8 | 52.4 | 4.8 | 4.8 | 100 | 12.5 |

| I would recommend this guideline for use in practice. |
|---------------------------------|--------|--------|--------|--------|--------|--------|
| Response | 1.Strongly disagree | 2. | 3. | 4. | 5.Strongly agree | TOTALS | Missing |
| n | 3 | 6 | 11 | 2 | 2 | 24 | 0 |
| % | 12.5 | 25 | 45.8 | 8.3 | 8.3 | 99.9 | 0 |
RECOMMENDATIONS

1. No evidence meeting the inclusion criteria was obtained in this systematic review; therefore, it is not possible to propose evidence-based recommendations.

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Additionally, the following feedback was also obtained (summarized to only include main points that were addressed in subsequent drafts):

What are the barriers to the implementation of this guideline report?

- The Target Population needs to be changed to locally advanced skin cancer

Comments Recommendation One:

- Guideline should clarify that skin cancers of certain anatomical sites (e.g. Head & Neck) may benefit from IMRT by extrapolation of benefit noted with IMRT for other cancers at that site.

Other Comments:

- None that were responded to.

Report Approval Panel

Following presentation of this EBS draft report for Expert Panel review, the report was submitted to the PEBC Report Approval Panel (RAP) for review on May 25, 2010. The RAP is comprised of two members, including an oncologist, with expertise in clinical and methodological issues.

No issues were raised by the RAP, and the document was considered approved as of June 25, 2010.

External Review: Professional Consultation

On September 20, 2010, the RAP-approved document was distributed to clinicians practicing within the Province of Ontario as part of a Profession Consultation review process. A total of 126 clinicians were invited to participate, and a total of five submitted responses (4% response rate). The results are as follows:

1. Rate the overall quality of the guideline report

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<td>2</td>
<td>2</td>
<td>0</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
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<td>0</td>
<td>40</td>
<td>40</td>
<td>0</td>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

2. I would make use of this guideline in my professional decisions

<table>
<thead>
<tr>
<th>Response</th>
<th>1.Strongly disagree</th>
<th>2.</th>
<th>3.</th>
<th>4.</th>
<th>5.Strongly agree</th>
<th>TOTALS</th>
<th>Missing</th>
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</thead>
<tbody>
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<td>1</td>
<td>2</td>
<td>1</td>
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<td>20</td>
<td>0</td>
<td>40</td>
<td>20</td>
<td>100</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

3. I would recommend this guideline for use in practice

<table>
<thead>
<tr>
<th>Response</th>
<th>1.Strongly disagree</th>
<th>2.</th>
<th>3.</th>
<th>4.</th>
<th>5.Strongly agree</th>
<th>TOTALS</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1</td>
<td>3</td>
<td>0</td>
<td>5</td>
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</table>
4. What are the barriers or enablers to the implementation of this guideline report?
   None submitted.

5. Additional comments.
   None submitted.

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REFERENCES
