CONE BEAM CT FOR DENTAL AND MAXILLOFACIAL RADIOLOGY: THE DEVELOPMENT OF EUROPEAN EVIDENCE-BASED GUIDELINES*

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Abstract

Cone Beam CT (CBCT) is an emerging technology in dental practice. The primary care location of dental radiology, evidence of problems with quality control, the numbers of dental X ray examinations carried out on children and the radiation doses associated with CBCT all led to concerns about the use of CBCT in the absence of guidelines on the radiation protection aspects. As a part of the 7th Euratom Framework project SEDENTEXCT (2008-11), there was an objective to develop evidence-based guidelines on dental CBCT, including justification, referral criteria and optimization. A multidisciplinary panel was assembled which formulated a literature search strategy, performed critical appraisal and undertook guideline development. This included a systematic review of diagnostic accuracy of dental CBCT. Collaboration with stakeholders was used to derive consensus guideline statements where there was insufficient evidence. 67 guideline statements were included in a final document which also contains a quality control manual. In 2012 the guidelines were published by the European Commission as "Radiation Protection 172: Cone Beam CT for Dental and Maxillofacial Radiology. Evidence-based Guidelines". The work has already influenced several national guidelines in Europe and it is anticipated that it will act as a significant set of standards in the years ahead.

1. INTRODUCTION

It has been estimated that dentists perform approximately one fifth of all X ray examinations [1] but in some countries this proportion is much greater. Unlike many types of medical X ray imaging, dental radiography is often carried out in children and young people, reflecting the incidence of dental caries (decay) and orthodontic treatment. Furthermore, dental radiology is largely performed in a private practice situation, away from easy access to medical physics support to help with optimization. Over many years, X ray based dental imaging was limited in its scope to simple radiographic techniques. In recent years, however, cone beam CT (CBCT) equipment for dentists began to be manufactured, largely in response to a need for cross-sectional imaging for implant dentistry. Nonetheless, CBCT, also known as Digital Volumetric Tomography (DVT) is an attractive method for many dental applications. CBCT is, however, associated with a greater radiation dose than is the case with traditional dental radiographic methods.

European Guidelines on Radiation Protection for Dental Radiology were produced in 2004 [2] covering all relevant aspects of justification, optimization and referral criteria for conventional dental X ray imaging techniques, but these guidelines did not cover CBCT in any way. The concern held by many was that CBCT, carrying higher radiation doses than conventional dental methods, would be used inappropriately, without optimization of exposures and with poor quality control procedures. In order to address these concerns, in 2007, a European consortium of six Universities and an industrial partner were successful in obtaining funding under the 7th Euratom Framework Programme to perform the project SEDENTEXCT (Safety and Efficacy of a New and Emerging Dental X ray modality). A central objective of the project was to develop evidence-based guidelines on use of CBCT in dentistry, including referral criteria, quality assurance guidelines and optimization strategies.

2. METHODS

The SEDENTEXCT project commenced on January 1st 2008 and ended on 30th June 2011 (details available at the project website www.sedentexct.eu). The guideline development process fell

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into two phases, performed between January 2008 and February 2011. The work plan was to develop "provisional" guidelines by early in 2008 and to revise these, taking into account the growing scientific literature and the results of other work packages within the project, to produce "definitive" guidelines at the end of the project. Early in 2008, however, it became apparent that there was an urgent need to provide some basic guidance because of concerns over inappropriate use. These concerns were voiced by the European Academy of DentoMaxilloFacial Radiology (EADMFR). In view of the mutual aims of EADMFR and SEDENTEXCT, a decision was taken to collaborate in the development of a set of "Basic Principles" for the use of dental CBCT, based upon existing standards.

2.1 Basic principles for use of dental CBCT

The detailed methodology followed in the preparation of these guidelines is fully described elsewhere [3]. Briefly, a Guideline Development Panel (GDP) was formed to develop a set of draft statements using fundamental international principles, EC Directives [4, 5] and previous Guidelines [2] statements, covering justification, optimization and training of dental CBCT users. These statements were revised after an open debate of attendees at the 11th EADMFR Congress on 28th June 2008. A modified Delphi procedure was then used to present the revised statements to the EADMFR membership utilizing an online survey in October/November 2008. Consensus of EADMFR members, indicated by high level of agreement for all statements, was achieved without a need for further rounds of the Delphi process.

2.2 Provisional guideline development

The methods used were those outlined by SIGN [6] where appropriate. A multidisciplinary GDP was established which included clinicians and medical physicists. The GDP agreed the areas that were to be addressed in the guidelines as: radiation dose and risk, diagnostic reference levels, optimization, quality standards, cost/benefit analysis and diagnostic accuracy studies. Members of the GDP were divided into sub-groups and assigned to topic areas on the basis of their personal expertise and skills.

Initial scoping searches of the FDI guideline database, the National Guidelines Clearing House and MEDLINE (OVID) was undertaken to identify existing guidelines. A final search strategy was developed for MEDLINE (OVID, 1950 onwards), using a combination of free text and controlled vocabulary and the following databases searched: EMBASE (1980 onwards), the Cochrane Central Register of Controlled Trials (Central), Web of Science, Scopus, UK Clinical Research Network, Clinical Trials.gov, Register of Controlled Trials (www.controlled-trials.com), NICE guidelines (www.nice.org.uk). Every attempt was made to include both unpublished literature (by contacting experts in the field) and through searching SIGLE (until 2005) (opensigle.inist.fr/) and FADE (www.fade.nhs.uk/)) and non-English language articles. All searching was undertaken by an experienced information officer and the results imported into Endnote (version 9) for coding. Two members of the GDP screened the abstracts and coded articles. All identified studies and predefined data extraction/quality assessment forms were distributed to the relevant sub-groups via the SEDENTEXCT website intranet. Reviewers undertook data extraction and quality assessment independently, with each article being assessed in duplicate. Each paper was coded as to study design and potential risk of bias [high risk of bias (-), moderate risk of bias (+), low risk of bias (++)].

The results from the assessment of all identified articles were tabulated to produce evidence tables. A meeting of members of the GDP was held to discuss these, and to formulate and grade provisional recommendations. When producing these, members of the GDP were asked to consider the volume of evidence, its applicability to clinical practice, generalizibility, consistency of the results and clinical impact. Each provisional recommendation was graded according to an adaptation of the SIGN grading system [6]. A draft guideline document was produced, and subjected to both internal and external review before publication.

2.3 Definitive guideline development

The process for development of definitive guidelines was commenced shortly after the publication of the provisional document. The guideline development process was amended to take into account changes in methodology and feedback from the GDP. The search strategy used was modified to increase sensitivity. National guidelines which had been published in the intervening period were also searched for and used as source material, along with research results from other work packages of the SEDENTEXCT project. For all papers coded as "Justification for referral", an assessment sheet was produced based on the relevant SIGN and QUADAS checklists [7]. For all other areas (apart from CBCT uses) a generic proforma was used to tabulate the key features of the study and identify any potential weaknesses. Data extraction, quality assessment, production of evidence tables and guideline development were otherwise identical to those described in section 2.2. In addition to the internal and external review of the final guideline document, it was subsequently reviewed by members of the group of scientific experts referred to in Article 31 of the Euratom Treaty.

3. RESULTS

3.1. Basic principles for use of dental CBCT

Twenty "basic principle" statements were agreed by the consensus process [3]. These were used as a core element of the subsequent guideline documents.

3.2. Provisional guideline development

Fifty-three guideline statements were developed and presented in the provisional guideline document. Of these, 34 were related to aspects of justification and referral criteria, reflecting the predominance in the literature of case series and reports describing clinical uses of CBCT. Inevitably, many of these had a low evidence grade and several were "negative" recommendations to indicate situations when CBCT should not be used. In other categories, many recommendations merely highlighted the need for further research. For example, the five recommendations related to quality assurance demonstrated the need to develop image quality standards, protocols for routine testing for equipment and diagnostic reference levels. The provisional guideline document was posted on the SEDENTEXCT project website and disseminated widely through direct email to individuals and organizations, accompanied by a press release.

3.3. Definitive guideline development

Sixty-eight guideline statements were developed and presented in the definitive document, 43 of which were referral criteria or related to the justification process. It was shown that CBCT has been used for a wide variety of clinical situations within dentistry, such as identifying the position of unerupted teeth, assessment of cleft lip and palate, diagnosis of caries, the effects of gum disease and trauma. The research evidence suggests that CBCT is only indicated for certain situations, particularly those where CT is the current imaging method of choice, or when the question for which imaging is required cannot be answered adequately by lower dose conventional (traditional) radiography. CBCT is associated with doses which are typically an order of magnitude greater than traditional dental radiographic techniques, although some equipment gave much higher doses, but lower than for CT. Clear guidance on optimizing doses for patients were included, notably the use of restricted fields of view and the need to adjust exposures according to each patient and clinical situation.

The guidelines highlighted that it is essential that a qualified expert is consulted over the installation and use of CBCT to ensure that staff dose is as low as reasonably achievable. A quality assurance programme was devised, including advice on image quality assessment to assist in audit, and a practical manual included in the guidelines as an appendix. The adoption of an achievable Dose Area Product of 250 mGy cm^2 for CBCT imaging for the placement of an upper first molar implant in a standard adult patient was recommended. Guidance on training of those involved in CBCT was

developed. In April 2012, the definitive guidelines were published online as "Radiation Protection 172: Cone Beam CT for Dental and Maxillofacial Radiology. Evidence-based Guidelines" [8].

4. DISCUSSION

The need for comprehensive guidelines on dental CBCT is self-evident. Clinical guidelines are a concept of good practice, against which the needs of individual patients and situations can be judged. They vary in quality, from opinion-based "expert" opinion, through consensus statements, to evidence-based guidelines. In the current work, we aimed for the highest level of quality, using systematic review techniques and a well-recognized methodology [6] including the involvement of a methodologist experienced in guideline development. Wherever there was a lack of evidence, a consensus process using the 300+ membership of EADMFR was employed. The production of the provisional guidelines was always planned to be a quick "holding strategy" while time could be spent on developing a comprehensive "definitive" document. Nonetheless, during preparation of the latter, it became apparent that a number of national guideline documents [9-12], developed during the time of the SEDENTEXCT project, had incorporated many of our provisional recommendations, including the basic principles [3]. No set of guidelines is permanent. In the context of a rapidly emerging new technology like dental CBCT, the need for ongoing review is even more important.

5. CONCLUSIONS

RP172 is a comprehensive set of guidelines relating to the use of dental CBCT, developed by a multidisciplinary group using a rigorous methodology. Wherever possible, the guidelines are evidence-based, but where this was not possible careful consensus processes were employed. The work has already influenced several national guidelines in Europe and it is anticipated that it will act as a significant set of standards in the years ahead.

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