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Edlund *et al.* 2011, Bernardes *et al.* 2012, Metska *et al.* 2012, Sogur *et al.* 2012, Tsai *et al.* 2012, Liang *et al.* 2014). The studies suggest that CBCT is more sensitive than conventional methods with regard to detecting apical periodontitis, root resorption and root fractures (Stavropoulos & Wenzel 2007, Hassan *et al.* 2009, Patel *et al.* 2009, de Paula-Silva *et al.* 2009, D'Addazio *et al.* 2011, Edlund *et al.* 2011, Bernardes *et al.* 2012, Metska *et al.* 2012, Sogur *et al.* 2012, Tsai *et al.* 2012, Liang *et al.* 2014). More sensitive technology has been considered as a cause of overdiagnosis, which can potentially harm healthy people (Moynihan *et al.* 2012). Recent data suggest that this applies for CBCT in endodontics (Pope *et al.* 2014). The European Commission has issued evidence-based guidelines to guide clinicians regarding the best use of CBCT (European Commission 2012). The European Commission guidelines are based on an extensive review of the literature (European Commission 2012). In these guidelines, when evidence was lacking, basic radiological principles were used as the basis for the recommendations (International Commission on Radiological Protection 2007, Horner *et al.* 2009).

The different levels of diagnostic imaging efficacy are based on an evaluative framework, summarized in Fig. 1 (Fryback & Thornbury 1991). In this framework, positive impacts on the patient's health and on society, if a test is cost-effective, are considered the goals (levels 5 and 6). Levels 5 and 6 are therefore the highest levels. The levels of efficacy immediately below the highest levels are the impact of diagnostic tests on the choice of diagnosis and

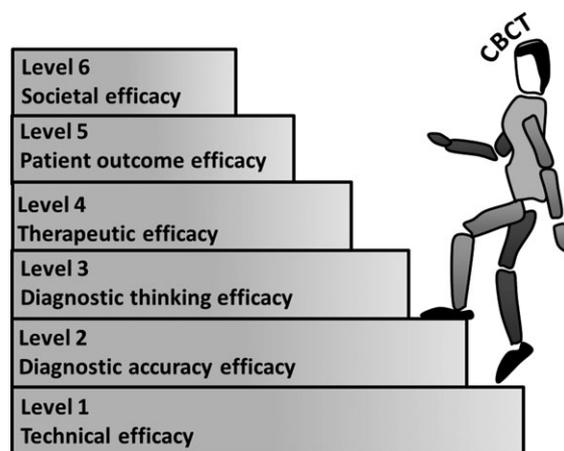


Figure 1 Fryback & Thornbury (1991) framework for the efficacy of diagnostic.

therapy (levels 3 and 4) (Fryback & Thornbury 1991). Knowledge of the role of CBCT in the higher levels of efficacy (levels 3–6) is sparse (European Commission 2012). Despite the limited scientific evidence available on CBCT, its use is growing rapidly. However, the patient groups that benefit from CBCT are currently unknown. If CBCT is beneficial, it should at least have an impact on diagnoses; otherwise, it is most likely unhelpful (Fryback & Thornbury 1991).

The aim of this study was to determine whether the outcome of CBCT examinations, performed in accordance with current guidelines, has an impact on the endodontic diagnoses. The secondary aim was to assess whether conventional CT would have been used if the examiner did not have access to CBCT.

Patients and methods

Study population

The population was selected from consecutive patients recruited from two endodontic specialist clinics in Sweden (Luleå & Uppsala) from October 2011 to December 2012. These are the only reference clinics for endodontics in the respective counties, and they only treat patients by referral. Together, the two counties have a population of more than half a million people. Three board-certified specialists in endodontics and four post-graduate residents participated in the study as examiners. The specialists individually had 11, 31 and 36 years of experience. All the post-graduate residents were in the second year of training, and their evaluations were checked by a specialist. The residents individually had 4, 9, 12 and 16 years of clinical post-graduate experience.

All patients referred to the specialist clinics were examined extra- and intra-orally at the endodontic clinics. The examination consisted of a proper medical history and clinical examination, such as inspection, palpation, probing and percussion of the area of interest. When appropriate, additional tests such as sensitivity tests (cold and electric pulp tests) and conventional radiography were performed. The pre-defined form ensured that good and, as much as possible, identical clinical examinations were performed by all examiners to allow a sound foundation for the subsequent assessments. The harvesting of data was monitored in both clinics by the lead author. After the initial examination, patients judged to be in need of CBCT examination were referred to a radiology department.

Criteria for CBCT examination

Inclusion criteria

The inclusion criteria for referring patients for CBCT examination were in accordance with the current European guidelines and can be grouped as follows (European Commission 2012):

1. Patients in whom disease had to be ruled out:
 - Patients with symptomatic teeth with vital pulps otherwise judged as healthy (no exposed dentine, normal sensitivity pulp tests, no tenderness to palpation or percussion, radiographic apical/marginal periodontal normalcy and no cracks/fractures).
 - Patients with symptomatic root filled teeth otherwise judged as healthy (good quality of root filling that did not need to be revised or completed, no tenderness to palpation or percussion, radiographic apical/marginal periodontal normalcy and no cracks/fractures).
 - Patients in whom conventional radiology failed to demonstrate whether a finding was a pathological process or a normal anatomical structure.
2. Patients in whom suspected disease had to be confirmed:
 - Suspected dental fractures that could not be confirmed without explorative surgery.
 - Suspected external or internal resorption.
3. As aid in performing the therapeutic intervention:
 - In establishing external or internal resorptions to assist in complex cases.
 - Before apical surgery when important anatomical structures interfered with the surgical approach.
 - In diagnosing foreign body structures, locating them and, when needed, guiding their surgical removal.
 - In understanding the anatomy of abnormal teeth in need of root canal treatment.
 - In assessing the number and location of root canals (pulp obliterated or not) after at least an unsuccessful attempt to find them under a microscope.

Exclusion criteria

Patients were not referred for CBCT examination if they

1. Presented with the results of a previous volume tomography (CT, CBCT) examination in the

region of interest that was performed for endodontic or other medical reasons. This was, however, not a strict restriction if the examiner believed that new and relevant information could be obtained by a new CBCT examination.

2. Had a definite diagnosis and treatment plan following a complete clinical and conventional radiographic examination. This group represented the large majority of the patients.
3. Required any other special imaging technique for soft tissue assessment such as CT or magnetic resonance tomography.

Stages of evaluation

These guidelines had been implemented in the clinics before this study was initiated and were well established in the local directives for CBCT examination referral.

For calibration purposes, four cases, in which CBCT examination was performed, were discussed amongst all of the examiners prior to the study. These cases were not part of the study.

Stage 1 (before CBCT examination)

All consecutive patients at both endodontic clinics who were referred for CBCT examination during the period from October 2011 to December 2012 were included. Before referral, the examiner responsible for the patient wrote down the best available diagnosis, attempting to approach the case as if a CBCT examination did not exist. According to the inclusion criteria, a patient could have more than one tooth with a related endodontic problem in need of CBCT examination.

Stage 2 (after CBCT examination)

After the CBCT examination was performed, the radiologist wrote a detailed radiological report that was sent to the referring examiner. The examiners had access to all image reconstructions performed by the radiologists. These reconstructions always included images in the axial, coronal and sagittal planes throughout the entire volume. The previous diagnosis was considered and, if needed, a new diagnosis was selected by the same examiner, taking into consideration all of the data. There was no contact with the patient until the CBCT examination report had arrived and the new diagnosis had been determined by the examiner.

Diagnostic understanding. For this tooth, the CBCT examination...	
D1	... confused my understanding of the patient's disease and led to investigations I would not otherwise have done.
D2	... confused my understanding of the patient's disease but did not lead to any additional investigations.
D3	... had no effect or little effect on my understanding of the patient's problem.
D4	... provided information that significantly improved my understanding of the patient's problem.
D5	... provided THE ONLY information that aided my understanding of this patient's problem.

Figure 2 Questionnaire regarding the usefulness of CBCT examination, inspired by the original work of Wittenberg *et al.* (1978).

Stage 3 (patient dismissal)

After performing therapy and discharging the patient, the same examiner reviewed the patient's files and filled out a form about the subjective usefulness to the examiner of the CBCT examination in assessing the

patient's disease or problem. The alternatives from which the examiner could choose from are shown in Fig. 2. This form is a modification of the form used by Wittenberg *et al.* (1978). Finally, before dismissing the patient, the examiners answered a yes/no question regarding whether CT would have been used if the examiner did not have access to CBCT.

The study flow is shown in Fig. 3.

Radiological investigations

When intra-oral radiographs included in the original referral from the general practitioner were deemed to be insufficient, new intra-oral radiographs were obtained at the endodontic clinics using the parallel technique, as much as clinically possible. Pre-defined protocols were used. At both specialist clinics and the referring general practitioners' clinics, a variety of different intra-oral digital radiograph systems were used. It was beyond the scope of this study to compare these intra-oral X-ray systems.

The CBCT examinations took place at two separate radiological clinics. The patients referred from the Luleå endodontic clinic were examined at County Hospital, Luleå, Sweden, and the Uppsala patients

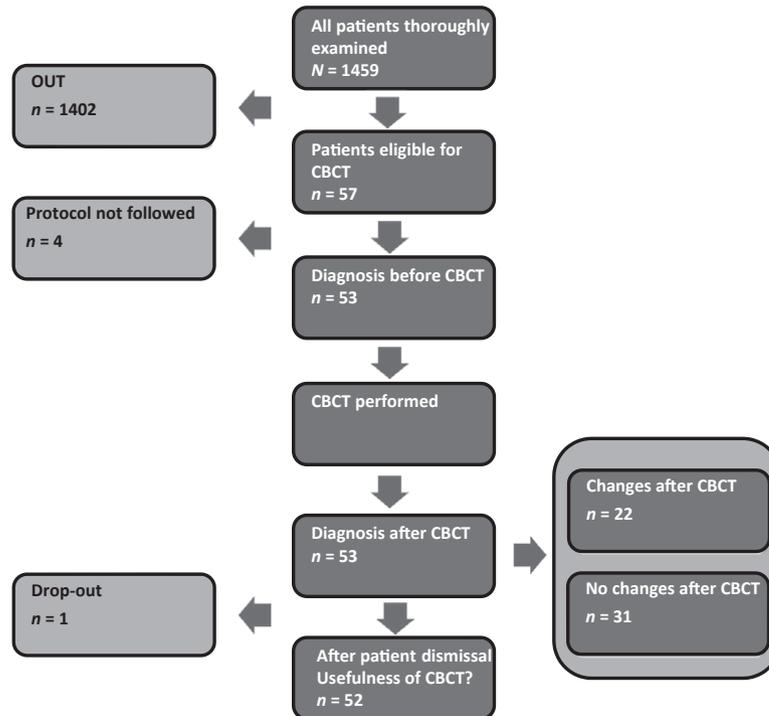


Figure 3 Study flowchart.

were referred to the Uppsala University Hospital, Uppsala, Sweden. Three board-certified dentomaxillofacial radiologists were involved in the study, namely one in Luleå and two in Uppsala. All CBCT examinations were performed with a 3D-Accuitomo 170 (J. Morita Mfg. Corporation, Kyoto, Japan). The radiologists selected one protocol of four pre-defined protocols tailored for the different diagnostic tasks. The protocols used were the same at both hospitals. All protocols consisted of the following exposure parameters: 85 kV and 5 mA. They differed in rotation (180° and 360°) and exposure time (9 s, 17.5 s and 30.8 s). Isotropic voxels with a size of 0.08 mm for 40 × 40 mm volumes and 0.125 mm for volumes of 60 × 60 mm volumes were used. Image reconstruction was performed in the axial, coronal and sagittal planes. Slice thickness varied between 0.24-, 0.48-, and 1.0-mm, with 0.16-, 0.24-, 0.75-mm intervals, respectively. The radiological evaluation was performed by the dentomaxillofacial radiologists who had access to the raw data and who always wrote detailed reports. The radiologists performed the evaluations on medical radiology screens (RadiForce G22, Eizo Nanao Corporation, Hakusan, Ishikawa, Japan) that were located within the radiology departments of the hospitals, which are optimized for radiological work.

Data analysis

Differences in diagnoses between stages 1 and 2 were plotted in two graphs. The data was presented for the most relevant tooth in each patient (patient level) and for all teeth with related endodontic problems requiring a CBCT examination (tooth level). The most relevant tooth was defined as the tooth in which a change in diagnosis was noted. The data were analysed with descriptive statistics.

Ethical approval

This study was approved by Umeå's regional ethics board (DNR 2011-443-31M), and informed consent was waived for this study.

Results

Fifty-seven patients met the inclusion criteria, representing four per cent of the total population of 1459 patients examined at both endodontic clinics during the study period. Of these 57 patients, four patients

were excluded from further analysis because the protocol was not correctly followed. There were 53 patients and 81 teeth included in the final analysis. Thirty-five of the patients were women (66%), and the mean age was 56.8 years (range 12–86 years). Only one CBCT volume at one examination was performed for each patient.

The diagnosis changed in 22 patients (42%) between Stage 1 (before CBCT examination) and Stage 2 (after CBCT examination). There were 28 changes in diagnoses amongst all teeth examined (35%) (Table 1). The results are shown in Tables 1 and 2.

Fifty-two patients (80 teeth) reached Stage 3 (patient dismissal stage) by March 2013. One patient did not complete the treatment; this patient was excluded from the analysis at this stage. The responses to the retrospective questionnaire regard-

Table 1 Diagnoses before and after CBCT examination, patient level

Diagnoses (n)	After CBCT							Total
	Before CBCT	A	B	C	D	E	F	
A	7	–	4	–	–	1	–	12
B	–	–	1	–	1	–	–	2
C	2	2	17	–	1	1	3	26
D	–	–	1	2	–	–	–	3
E	–	–	1	–	3	1	–	5
F	–	–	1	–	–	–	–	1
G	–	–	1	–	1	–	2	4
Total	9	2	26	2	6	3	5	53

Diagnoses for the patients' main problematic tooth. A) Healthy; B) Pulp necrosis; C) Apical periodontitis; D) External resorption; E) Root fracture; F) Nonendodontic diagnosis; G) Other.

Table 2 Diagnoses before and after CBCT examination, tooth level

Diagnoses (n)	After CBCT							Total
	Before CBCT	A	B	C	D	E	F	
A	19	–	6	–	–	2	–	27
B	–	–	1	–	1	–	–	2
C	3	2	27	–	1	2	3	38
D	–	–	1	2	–	–	–	3
E	–	–	1	–	3	1	–	5
F	–	–	2	–	–	–	–	2
G	–	–	1	–	1	–	2	4
Total	22	2	39	2	6	5	5	81

Diagnoses for all examined teeth. A) Healthy; B) Pulp necrosis; C) Apical periodontitis; D) External resorption; E) Root fracture; F) Nonendodontic diagnosis; G) Other.

Table 3 Estimated usefulness of CBCT examination after patient dismissal

Examiner's response	Patients' main problematic tooth <i>n</i> (%)	All examined teeth with related endodontic problems <i>n</i> (%)
D1	3 (6)	3 (4)
D2	1 (2)	1 (1)
D3	3 (6)	16 (20)
D4	40 (77)	53 (66)
D5	5 (9)	7 (9)
Total	52 (100)	80 (100)

D1) CBCT examination confused the examiner's understanding of the patient's disease and led to investigations that the examiner would not otherwise have performed; D2) CBCT examination confused the examiner's understanding of the patient's disease but did not lead to any additional investigations; D3) CBCT examination had no effect or little effect on the examiner's understanding of the patient's problem; D4) CBCT examination provided information that significantly improved the examiner's understanding of the patient's problem; D5) CBCT examination provided the only information for the examiner's understanding of this patient's problem.

ing the effect of CBCT examination on patient care modified after Wittenberg *et al.* (1978), shown in Fig. 2, are presented in Table 3. In 19 of the 52 patients (37%) who reached the final stage, the examiners responded that they would have used conventional CT if they did not have access to CBCT examination.

The mean time between the last intra-oral radiograph and the CBCT examination was 38 days (range 0–196). Sixty-two per cent of the patients underwent CBCT examination within the first 4 weeks after the last intra-oral radiograph was obtained.

Discussion

The patients included in this study were chosen according to evidence-based guidelines for the use of CBCT in dental and maxillofacial radiology issued by the European Commission (European Commission 2012). All of the results and conclusions are based on that premise. Only a few of the patients referred to endodontic specialist clinics in this study were candidates for CBCT examination according to the guidelines. The guidelines can be challenged as being too strict; however, there is no evidence that CBCT would be effective in the patient groups excluded by the guidelines, and any such effect remains to be proven. The study did not have such intentions; the goal was to assess the efficacy of the technique in a group for

which efficacy was expected but not yet demonstrated.

The aim of this study was to determine whether the outcome of CBCT examinations, performed in accordance with the European Commission guidelines, had an impact on endodontic diagnostics. This objective was framed in the model proposed by Fryback & Thornbury (1991) as the third level of diagnostic imaging efficacy, that is diagnostic thinking efficacy (Fig. 1). The fourth level included in the current study, therapeutic efficacy, has been presented elsewhere (Mota de Almeida *et al.* 2014). The most important objectives of any diagnostic test are to have a positive impact on patient outcome, level 5, and to be cost-effective, level 6. To assess these efficacy levels, randomized controlled trials are necessary (Fryback & Thornbury 1991). Such studies are difficult to perform in radiology due to methodological and ethical issues (e.g. blinding, radiation doses, and prevention of patients from receiving access to potentially helpful technology), which are challenging to resolve. Most of the published studies on the role of CBCT in endodontics are limited to assessments of diagnostic accuracy efficacy, which is level 2 (European Commission 2012). These studies suggest that CBCT is a more accurate diagnostic tool than intra-oral radiography (Pettersson *et al.* 2012). CBCT is, however, a more costly examination for the patient both financially and with respect to radiation exposure (European Commission 2012). Therefore, there is a need to demonstrate that the extra cost is justifiable.

Endodontists diagnose patients based on several types of data, such as medical history, clinical findings, and other diagnostic tests, and not merely based on a single test, meaning that an increased accuracy of a single test does not necessarily change the diagnostic outcome (Fryback & Thornbury 1991). For a test to have a positive impact on a patient's health, it first needs to have a positive impact by facilitating a change in the diagnosis and the subsequent therapy (Fryback & Thornbury 1991).

This study is considered a before-and-after study, which is a design that has been appraised and is used to study the impact of diagnostic tests on diagnostic and therapeutic choices at levels 3 and 4 (Fineberg *et al.* 1977, Wittenberg *et al.* 1978, Fryback & Thornbury 1991, Hobby *et al.* 2001, Bearcroft *et al.* 2006, Shelley *et al.* 2014). The recommendations proposed by Guyatt *et al.* (1986) were followed to optimise such study designs, which include a prospective study design with a well-defined consecutive population and

a meticulous pre-test examination. Almost all of the cases were discussed with colleagues in therapy meetings. Furthermore, a multicentre study was designed in a clinical setting within the normal flow of specialist care in Sweden that was monitored at both clinics by the lead author. This design provides the study with high internal and external validity. However, the design is not without limitations. Considering the tool developed by Meads & Davenport (2009) to evaluate before-and-after studies, a limitation of the present study could be that the CBCT examinations were interpreted based on the knowledge of all tests and findings performed before CBCT. However, any other protocol would have been unfeasible. CBCT examinations in a clinical setting are and should always be interpreted within a clinical context. Another point of concern is the risk for maturation bias due to the long intervals between the different tests. In five patients, the time between the clinical and radiological examinations was greater than 100 days (Gillan *et al.* 2001, Meads & Davenport 2009). This factor was not taken into account when designing the study, and those cases were not excluded, as they were left to follow their natural course in the referral system. The diagnosis was changed in three of these five patients, and in these patients, it is possible that the time period between the clinical and CBCT examinations is a better explanation for the change in diagnosis than the use of CBCT. For example, in one patient, previously unrecognized apical periodontitis was diagnosed with CBCT. This progressing lesion would have most likely been recognized on a new intra-oral radiograph at the time of CBCT examination. Another limitation is that the diagnoses proposed before CBCT examination may have been different if CBCT had not been available, as the examiners knew that they would have a second chance to correct their initial diagnoses. These problems were minimized as much as possible by instructing and repeatedly reminding the examiners to be as neutral as possible in all assessments. A third limitation is that despite this being a multicentre study, it was conducted in a Scandinavian clinical setting, and the results should be treated with some caution before translation into international settings. In Sweden, for example, it is always the board-certified radiologist's prerogative to decide whether CBCT should be performed, as well as which protocol to use, depending on the diagnostic task. Non-radiologists cannot

independently operate CBCT equipment (Swedish Radiation Safety Authority 2008).

The results show that CBCT has the capacity to cause changes in endodontic diagnoses when the European Commission guidelines are applied. The frequency of diagnostic changes that could be attributable to CBCT examinations was substantial, namely 37% of the included teeth in 42% of the patients. In relation to other diagnostic modalities, CBCT had a major positive impact on changing endodontic diagnoses (Wittenberg *et al.* 1978, Callender & Brooks 1996). The strict selection of patients is most likely the single most important factor explaining the high proportion of diagnostic changes. Confining the use of CBCT examination to the current guidelines will assure clinicians that CBCT examination has an impact on their diagnostic choice in endodontics. When it does not change the diagnosis, CBCT seems to contribute useful information for the clinician in many cases, as shown in Table 3. This last statement is, however, based on a subjective and retrospective evaluation and should be interpreted cautiously. In some cases, the clinicians even responded that the CBCT examination confused their diagnostic task, which may be a sign that we do not fully understand what is depicted in a CBCT examination.

CT examinations, which only evaluate bone lesions, can be performed with moderate radiation doses that are comparable to CBCT doses (Öhman *et al.* 2008). However, CT has much lower spatial resolution than CBCT and presumably has lower diagnostic accuracy, although this has not been investigated for endodontic cases in the scientific literature. The examiners would not have used CT if CBCT had not been available in 63% of the cases. One reason for this result may be the lower accessibility to CT for dental care. CBCT thus facilitates access to more advanced and precise radiological techniques in dentistry for the general population.

To the best of our knowledge, there are no studies in endodontics that have examined the efficacy of CBCT at the diagnostic thinking efficacy level. There are, however, two studies that have reported on the therapeutic efficacy of CBCT in endodontics. According to Balasundaram *et al.* (2012), CBCT had no influence on therapy for apical lesions that were easily observed on intra-oral radiographs but it had the ability to cause endodontic therapy changes when applying the same strict criteria as those applied in the present study (Mota de Almeida *et al.* 2014).

Conclusions

Volume tomography with CBCT, when used in accordance with the current European Commission guidelines is recommended for only a small group of patients with complex endodontic problems, has a substantial impact on diagnostic thinking efficacy in endodontic cases, and facilitates patient access to more advanced and precise radiological techniques.

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