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Evaluation of a new low-dose digital X-ray device: first dosimetric and clinical results in children

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Abstract *Background.* A new low-dose digital X-ray device, based on Charpak's Nobel prize-winning multiwire chamber, enables the production of images at very low doses.
Objectives. To present the first dosimetric and clinical results.
Materials and methods. The analysis was performed on 93 children with scoliosis and 47 undergoing pelvic radiography. The comparative study between conventional X-ray and the new technique focused on three points: (1) the dose delivered by each system (2) the diagnostic information provided by each system and (3) comparison of image quality criteria with European guidelines.
Results. The mean ratio of conventional dose to that of the low-dose technique was 13.1 for the spinal examination and 18.8 for the pelvis. There was no significant difference in diagnostic information available from each modality, but there was a slight difference in quality criteria in favour of the conventional technique.
Conclusion. This new device allows spectacular dose reduction, consistent with adequate clinical information. Improvements of the prototype will lead to extension of potential indications and industrial development.

Introduction

In 1992, the Nobel Prize was awarded to the physicist Georges Charpak for his work on multiwire proportional chambers [1]. Such a system allows precise detection of elementary particles which can be used in diagnostic radiology to produce images at very low doses [2].

Based on Charpak's work, a team of Russian physicists developed a prototype radiological device in the late 1980 s [3], which has provided encouraging dosimetric results [4]. Since then, technological improvements have been made and an upgraded version of the radiological device has been constructed by the Russian team and installed at Saint-Vincent de Paul Hospital in Paris for clinical evaluation.

The objectives of this study were:

1. To assess the effective dose reduction associated with the use of this new radiological device in comparison to a conventional system
2. To quantify and compare the image quality obtained with both systems

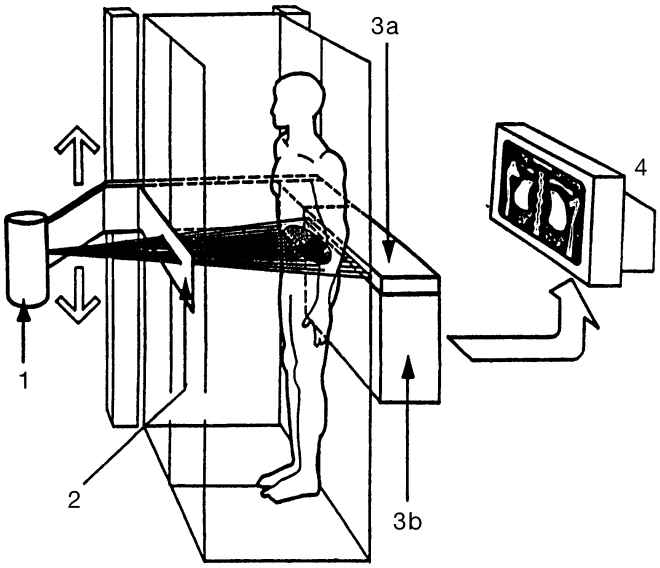

Fig. 1 The Charpak system (*1* X-ray tube, *2* anterior collimation, *3 a* multiwire chamber, *3 b* electronic device, *4* computer and reading device)

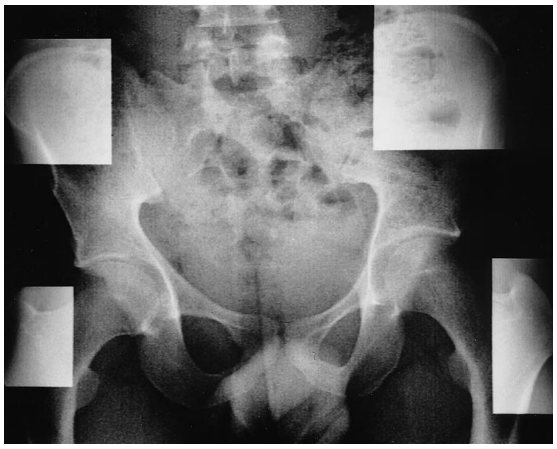

Fig. 2 Image from the Charpak system. Follow-up film of a 16-year-old boy with Perthes' disease. There is good anatomical detail. Note separate windowing of the iliac crests and greater trochanters

Fig. 3 Image from the Charpak system. Follow-up film of congenital hip dislocation in a 7-year-old boy. Note satisfactory visualisation of the femoral architecture and bone texture

Materials and methods

Technical aspects

The device consists of a conventional X-ray tube and a side-opening, vertical Plexiglas cabin in which the patient is positioned (Fig. 1). The multiwire chamber is housed in an aluminium box, 50 cm in diameter, within which is a 320-wire chamber optimised to 640 detection channels. Each wire is 50 cm long and 10 mm diameter. The long axis of each wire faces the X-ray source. The principle consists in measuring the movement of each elementary particle. The wires are in a detection gas made of 80 % xenon and 20 % carbon dioxide. The X-ray generator is an integral part of the detection system. Collimation of the X-ray beam is provided by two 0.6-mm slits on the front and back surfaces of the cabin. The tube and multiwire proportional chamber (MWPC) are displaced together at a speed of 3 cm/s and each line is exposed for 30 ms. The digital information is sent to a computer where it is processed and stored. The image is made visible on the screen of this computer, which is connected to a Kodak laser printer.

Patients and methods

Inclusion criteria were a population at potentially higher risk due to X-ray exposures (paediatric patients with repeated examinations). From December 1994 to January 1996, we intended to recruit 150 patients into two groups:

1. Fifty children over the age of 5 years undergoing follow-up examinations for known hip disease, e. g. congenital dislocation and osteonecrosis.
2. One hundred children undergoing follow-up radiography for scoliosis.

These numbers were calculated to allow sufficient discriminatory power between the conventional system and the low-dose device, according to the expected reduction [1]. According to the design of the trial, each patient had to be exposed to the two different imaging systems at the same time. The conventional system consisted of a generator, X-ray tube and screen cassettes. As requested by French law, the study protocol was submitted to an ethics committee (Comité Consultatif pour la Protection des Personnes en Recherche Biomédicale), and personal or parental informed consent was obtained for each patient. A similar study was conducted on chest films in adults.

All images were analysed separately by two senior radiologists and bone detail was reviewed by a senior orthopaedic surgeon. Digital images from the low-dose system were always analysed on radiographic laser film and not on the screen. All discordant results between independent viewers were further reviewed to achieve a consensus verdict. In a few cases, no agreement could be reached. The assessors completed standardised forms which itemised diagnostic information and quality criteria.

Dosimetry was performed with individually calibrated thermoluminescent calcium fluoride pellets. They were placed on the pa-

Table 1 European image quality criteria

Pelvis
The following structures are clearly seen or not
- Symmetry
- Femoral neck
  - Deformity
  - Details
- Sacrum
  - Details
- Sacro-iliac joints
- Greater trochanters
- Cancellous bone
- Cortical bone

Spine
The following structures are clearly seen or not
- Skull base
- Coccyx
- Iliac crests
- Articular parts of different vertebra
- Pedicles
- Spinous process
- Transverse process
- Psoas
- Kidneys
- Gastric pouch

Table 2 Dosimetric assessment (mGy)

	Conventional system			Low-dose device			Ratio of means
	Min.	Mean	Max.	Min.	Mean	Max.	
Spine							
AP	0.47	0.93	2.15	0.02	0.08	0.19	11.6
PA	0.44	0.92	2.14	0.01	0.07	0.2	13.1
Lateral	0.46	1.96	3.43	0.03	0.13	0.84	15.1
Pelvis	0.47	1.13	7.48	0.01	0.06	0.21	18.8

tient's skin in the centre of the X-ray beam and measured entrance surface dose in the range 0.01 mGy to 1 Gy.

A full quality control programme (generator, X-ray tubes, cassette screens, assembly, processors and viewing boxes) was installed to check performance of the conventional equipment as well as the digital system.

The comparative study focused on three points:

1. The radiation exposure delivered by each system.
2. The diagnostic information provided by each system (Figs. 2, 3). No information was available on the true result and we could not assess sensitivity or specificity. Image quality was assessed as 'good' 'poor' or 'no agreement' (between assessors).
3. Image quality criteria were compared with those defined by the Commission of the European Communities [5]. These are listed in Table 1. Comparison between the two systems was made on the frequency with which each radiologist perceived the information as 'available' or 'not available'. There was no attempt to obtain consensus between readers. In the analysis, two approaches were used:
   (a) a criterion was considered present if seen by one reader
   (b) a criterion was considered present if seen by both readers

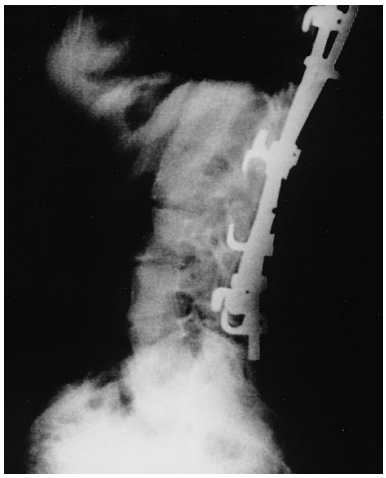

Fig. 4 Image from the Charpak system. Follow-up film after surgery for scoliosis. There is movement artefact because the child moved during the 12-s acquisition time

Agreement was analysed using the kappa coefficient. The potential for unbalancing of agreement in favour of one system was assessed by MacNemar's test (2 by 2 tables) or Bowder's test of symmetry (3 by 3 tables). Sensitivity and specificity were compared by means of chi-square test or Fisher's exact test, according to sample size. All statistical analyses were performed on SAS statistical software.

Results

From December 1994 to January 1996, 176 patients were examined. Information was unavailable in 36 because the examination was inadequate, because conventional film was given to the patient without a duplicate being retained, or on grounds of double inclusion. The analysis was performed on 93 children with scoliosis and 47 having pelvic radiography.

Dosimetry

The doses delivered by the low-dose device for pelvic and spinal examinations were always lower than those delivered by the conventional system. The maximum doses with the low-dose device were lower than the minimum doses with the conventional system for pelvic examinations, and near to the minimum doses for spinal and chest examinations (Table 2).

For the pelvic examination, the maximum dose delivered by the low-dose device was 0.2 mGy compared with 7.5 mGy for the conventional system. The ratio of mean dose with conventional system to low-dose device was 19.

For the spinal examination, the maximum dose with the low-dose device was 0.8 mGy compared with 3.4 mGy for the conventional system. The ratio of the

Table 3 Comparison of image quality between the two systems

Conventional system	Low-dose system		
	Good	Poor	No agreement
Spine			
Good	61	2	9
Poor	5	1	1
No agreement	10	0	4
Kappa coefficient 0.15 (SE 0.10)			
Bowder's test *P* value 0.50			
Pelvis			
Good	44	1	0
Poor	2	0	0
No agreement	0	0	0
Kappa coefficient – 0.03 (SE 0.02)			
Bowder's test *P* value 0.56			

mean dose with conventional system to low-dose device was 13 for the PA view, 12 for the AP and 15 for the lateral.

(For the chest examinations in adults, the ratio of the mean dose with conventional system to low-dose device was 5 for the AP view and 7 for the lateral.)

Diagnostic contribution

For both pelvis and spine each modality was considered to contribute equal information (Table 3). The kappa coefficients were low but the results tables were symmetrical.

European image quality criteria

Significant disagreements between readers were observed for both systems, leading to difficulties with the analysis of this part of the study. However, the following observations were made:

1. For the pelvis, certain criteria were slightly less favourable with the prototype, especially details of cancellous bone, fine analysis of the cortex and visibility of periarticular fat lines.
2. For the spine, no significant difference was observed in terms of the quality criteria, apart from improved visibility of iliac crests and vertebral pedicles with the low-dose device compared to conventional films.
3. The long acquisition time (approximately 12 s for a 36-cm examination) may induce artefacts and the patient is required to be immobile during the examination (Fig. 4). Among other things, this long acquisition time is responsible for the 'staircase' appearance of the cardiac outline due to movement between systole and diastole.

Discussion

This study confirms that the expected reduction in dose is real, with dose reductions of 80 % for AP chest radiographs and 95 % for pelvic examinations. This is in excess of the marketing announcement of 50 % dose reduction with other digital devices. This reduction is related to collimation of the beam, which eliminates most of the scattered radiation, and to the high detection capacity of the MWPC, which allows photon-by-photon analysis and use of low X-ray exposure. This is a real new step in radiology and may lead to a new generation of equipment.

The study also provides information on some of the advantages and limitations of the experimental device regarding diagnostic information and image quality. The digital images provided by the new device have the advantage of allowing different window settings, e. g. thoracic intervertebral disks can be adequately analysed on a chest film. This windowing is also particularly useful to obtain images of the iliac crests on a pelvic film. This constitutes another advantage of digital radiology, in addition to image transmission and storage.

The low-dose device showed a lack of spatial resolution compared with the conventional system, but this drawback affects many digital systems currently available on the market. It is an important factor in the early diagnosis of very small lesions. However, for follow-up of known diseases or diagnoses which do not require detailed information, this type of device allows good quality results with real improvement in dose.

Most importantly, we need to develop a new imaging philosophy. Over recent years image quality has improved, but it is now time to question the usefulness of available information. The first concept to be developed is that of the minimum diagnostic information requirement: What questions are raised by the clinical problem, and what are the expected answers? The fundamental issue is what is useful to the patient.

In conclusion, we have demonstrated that conventional imaging systems will soon be in competition with new low-dose devices and provide a solution to a major public health concern regarding exposure to medical ionising radiation. The desire for highest quality images will have to be balanced against the minimum information needed to obtain a diagnosis. The isolated diagnostic X-ray examination is certainly cost-effective, but a major part of medical activity is follow-up of chronic diseases. Irradiation of sensitive areas, e. g. from chest X-rays and skeletal films during rheumatology and orthopaedic follow-up, comprises a large proportion of radiology examinations in France. The low-dose device is certainly adequate for orthopaedic follow-up (plastered fractures, lower limb deformities etc.) and for determination of bone age.

New devices based on non-film detectors are challenging conventional film images, and the currently limited resolution and speed of image acquisition should improve rapidly, widening the potential applications and justifying more intensive industrial development.

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ERRATUM

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Idiopathic arterial calcification of infancy: sonographic and magnetic resonance findings with pathologic correlation

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The name J. McIlhenny was accidentally left out. The authors are correctly listed above.