

Feasibility of optimized ultralow-dose pulsed fluoroscopy for upper gastrointestinal tract examinations: a phantom study with clinical correlation

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Abstract

Purpose To establish an optimized ultralow-dose digital pulsed fluoroscopy (FP) protocol for upper gastrointestinal tract examinations and to investigate the radiation dose and image quality.

Materials and methods An Alderson-Rando-Phantom with 60 thermoluminescent dosimeters was used for dose measurements to systematically evaluate the dose–area product (DAP) and organ doses of the optimized FP protocol with the following acquisition parameters: 86.7 kV; 77 mA; 0.9 mm³, automatic image noise and contrast adaption. Subjective image quality, depiction of contrast agent and image noise (5-point Likert scale; 5 = excellent) were assessed in 41 patients, who underwent contrast-enhanced FP with the aforementioned optimized protocol by two radiologists in consensus. A conventional digital radiograph (DR) acquisition protocol served as the reference standard for radiation dose and image quality analyses.

Results Phantom measurements revealed a general dose reduction of approximately 96% per image for the FP protocol as compared to the DR standard. DAP could be reduced by 97%. Significant dose reductions were also found for organ doses, both in the direct and scattered radiation beam

with negligible orbital (FP 5.6×10^{-3} vs. DR 0.11; $p = 0.02$) and gonadal dose exposure (female FP 2.4×10^{-3} vs. DR 0.05; male FP 8×10^{-4} vs. DR 0.03; $p \leq 0.0004$). FP provided diagnostic image quality in all patients, although reading scores were significantly lower for all evaluated parameters as compared to the DR standard ($p < 0.05$).

Conclusion Ultralow-dose FP is feasible for clinical routine allowing a significant reduction of direct and scattered dose exposure while providing sufficient diagnostic image quality for reliable diagnosis.

Keywords Abdomen · Gastrointestinal imaging · Ultralow-dose fluoroscopy · Technical evaluation

Introduction

Dynamic fluoroscopic examinations of the upper gastrointestinal tract (UGI) are a comprehensive diagnostic tool to assess a variety of disorders and pathologies [1]. Although endoscopy has become the diagnostic gold standard for UGI examinations, fluoroscopy is still frequently used in clinical routine, as it provides additional functional and dynamic information [2–6]. This applies in particular to the evaluation of gastrointestinal passage disorders, dynamic evaluation of the swallowing process or leakage of oesophageal and gastric anastomoses, since fluoroscopy is more simple and cost-effective to perform than CT or MRI [6–9]. Furthermore, in paediatric radiology, fluoroscopy, often combined with ultrasound, serves as an alternative to CT to reduce dose exposure in both gastrointestinal and urogenital tract examinations [1, 10–13].

According to the ALARA principles, continuous optimization of examination protocols is demanded to reduce the cumulative dose exposure of the patient to minimize the risk

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of radiation effects [14, 15]. This is of particular interest, if frequent examinations are necessary, e.g. to evaluate the postoperative course or disease follow-up. Conventional DR acquisition was the examination of choice for the dynamic evaluation of UGI pathologies after changing from analogue to digital acquisition techniques, providing high-resolution images, however, at a considerable radiation dose [16, 17]. To account for this, several improvements of fluoroscopic hardware and dedicated post-processing software have been developed in recent years allowing for a substantial dose reduction [18–21]. However, focused research evaluating the benefits of these technical advances for fluoroscopic examinations of the upper gastrointestinal tract in adults are outstanding so far [16, 19]. Moreover, it is still difficult to estimate the actual organ dose applied during such examinations, since dose monitoring in fluoroscopy is commonly performed using the dose–area product (DAP) [22, 23]. Dedicated phantom studies investigating absorbed organ doses of radiosensitive organs are rare [1, 11, 24] although it is important to know in favour of patient safety [25].

Therefore, the aim of this study was to establish an optimized dynamic ultralow-dose digital pulsed fluoroscopy (FP) protocol for upper gastrointestinal tract examinations and to investigate the resulting organ doses and its clinical feasibility with conventional digital radiograph (DR) acquisitions as reference standard. We hypothesized that ultralow-dose digital pulsed fluoroscopy allows for sufficient diagnostic image quality to provide reliable diagnosis while significantly reducing direct and scattered dose exposure.

Materials and methods

The institutional review board approved this retrospective study and waived the requirement of written informed consent.

Detector system and protocols

A multifunctional fluoroscopy system (Artis Zee MP, Siemens Healthcare, Erlangen, Germany) with a flat-panel detector [amorphous silicon (a-Si) with caesium iodide (CsI) scintillator; size: 30 × 40 cm; pixel size 154 × 154 μm; spatial resolution of 3.25 LP/mm; digitization depth 14 bit] was used for all phantom and patient measurements.

The acquisition parameters of our optimized ultralow-dose digital pulsed protocol were as follows: 86.7 kV; 77 mA; 3.2 ms; a copper filter of 0.9 mm was applied for beam hardening; to compensate for the resulting decrease in image contrast, an automatic post-processing algorithm was implemented to improve contrast ratios; in addition, automatic noise reduction was used to balance the low mA–s product; a resolution of 512 × 512 was chosen with an

acquisition pulse rate of 30/s for high temporal resolution. The conventional reference DR acquisitions were performed with 80.0 kV, 283 mA, 9.0 ms, a copper filtering of 0.2 mm, a resolution of 1024 × 1024 and a frame rate of 30/s.

For both protocols, the field of view was chosen as small as possible (refer to Fig. 1). The last image hold was used for table and collimator adjustments.

Phantom studies

To systematically investigate the potential of our optimized FP protocol to reduced radiation burden and to objectify organ dose exposure, we conducted a phantom study using an anthropomorphic male Alderson-Rando Phantom (Type RT200, Humanoid Systems, CA, USA) representing a male patient (175 cm height and 73.5 kg weight) with similar

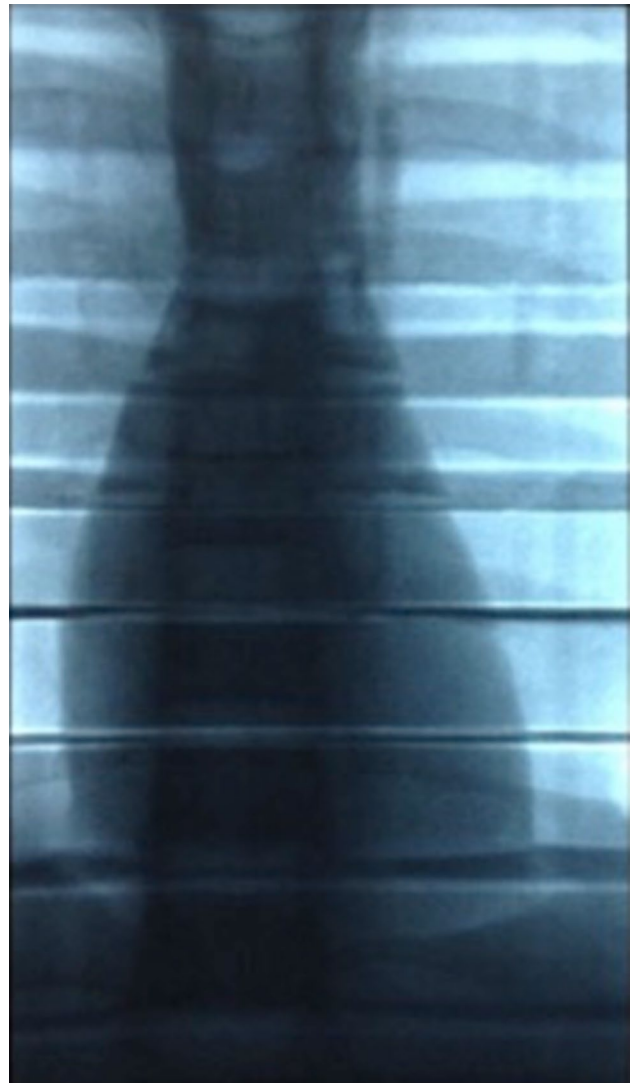


Fig. 1 Field of view for low-dose fluoroscopy and digital radiograph image acquisition in the phantom study

X-ray absorption and scattering as human body tissue. For dose measurements, 60 thermoluminescent dosimeters (TLD, LiF (lithium fluoride), TLD Type-100; Harshaw, Chemical Company, Ohio, USA) were placed in radiosensitive organs in the direct (bone marrow; lungs; oesophagus; stomach; thymus) and scattered (eyes; liver; gonads; thyroid) beam. To ensure reliable measures and taking into account the radiation absorption along the examined object in the p.a. direction, each organ was equipped with at least two (2–6) TLDs including the most ventral and most dorsal part to homogeneously cover the whole organ. The final organ doses were then calculated by averaging the detected doses of all TLDs per organ. To consider the extremely low-dose exposure of the FP protocol and to allow for reliable dose detection by the TLD, images were acquired until the detector system indicated a cumulative dose of 500 mGy. Between FP and DR acquisition, all TLDs were recalibrated. The phantom–tube distance was 36 cm, while the distance between the phantom and the detector was 28.5 cm. The measured values for the DAP and the organ doses were normalized to the mean examination time in the patient study (see below) to provide a useful measure for clinical routine.

Patient study

To assess the image quality of the investigated FP protocol in clinical routine, we included 41 patients, who underwent clinically indicated contrast-enhanced (Imeron 400, Bracco, Konstanz, Germany; Peritrac 400, Dr. Franz Köhler Chemie GmbH, Bensheim, Germany) fluoroscopy with our optimized FP protocol and of whom a historical conventional DR acquisition was available in the PACS archive. Patients under the age of 18 years and incomplete examinations were excluded from the analysis. A summary with detailed patient demographics is given in Table 1.

Analysis of image quality

Image quality was subjectively evaluated on a dedicated workstation (syngoMMWP VE26A; Siemens Healthcare, Erlangen, Germany) by two radiologists in consensus with 3 (A.P.) and 6 years (M.N.) of experience in fluoroscopy. Readers were blinded to the acquisition protocol and the clinical diagnosis and images were presented in a random order. A five-point Likert scale was used to assess the following parameters: 1) overall image quality; 2) delineation of contrast agent; 3) image noise (5 = excellent image quality and delineation, no image noise; 4 = good image quality and delineation, subtle image noise; 3 = fair image quality and delineation, moderate image noise; 2 = poor image quality and delineation, severe image noise; 1 = non-diagnostic).

Table 1 Demographics of the patients included in this study

Variables	Mean \pm SD	N
Age	65 \pm 11 (range 42–85)	
Sex (m/w)		25/16
Height (cm)	174.4 \pm 8.1	
Weight (kg)	80.4 \pm 16.0	
Body mass index	26.3 \pm 4.7	
Clinical diagnosis		
Post-whipple's OP		12
Post-gastrectomy		12
Sleeve gastrectomy		5
Hernia		4
Oesophagus motility disorder		4
Oesophagus carcinoma		2
Zenker's diverticulum		2

Statistical analysis

We performed statistical analysis using SPSS Statistics (Version 22, IBM, Armonk/NY, USA). The results of the DAP and the direct and scattered organ doses of FP and DR examinations were compared by conducting the paired sample *t* test. For the comparison of the qualitative reading scores, Wilcoxon signed-rank test was performed. Two-sided *p* values below 0.05 were considered as statistically significant.

Results

Phantom studies

Phantom dose measurements with the optimized FP protocol allowed for a general dose reduction of approximately 96% per picture as compared to the DR standard (0.004 and 0.12 mGy, respectively).

Time-adjusted measurements of the DAP for an examination time of 30 s (according to the mean examination time of 25 \pm 12 in the patient study) revealed a dose reduction of approximately 97% for the FP protocol in comparison to the DR protocol (80.8 and 2794.6 μ Gym², respectively). Significant dose reductions (FP vs. DR; *p* \leq 0.03) were also found for the measured organ doses with negligible low exposure of radiosensitive organs in the scattered beam, such as the eyes (5.6 $\times 10^{-3} \pm 0.00$ and 0.11 ± 0.01 ; *p* = 0.02, respectively) and the male (8 $\times 10^{-4} \pm 0.00$ and 0.03 ± 0.00 ; *p* = 0.003, respectively) and female gonads (2.4 $\times 10^{-3} \pm 0.00$ and 0.05 ± 0.00 ; *p* = 0.004, respectively). A summary of all organ dose measurements is given in Table 2.

Table 2 Absorbed organ dose (mGy) in direct and scattered radiation for digital radiographs (DR) and low-dose fluoroscopy (FP) images for an average acquisition time of 30 s

Organs	DR		FP		<i>p</i>
	Mean ± SD	Range	Mean ± SD	Range	
Direct radiation (mGy)					
Oesophagus	34.47 ± 10.07	11.80–41.03	1.03 ± 0.51	0.50–1.50	0.01
Stomach	33.81 ± 13.81	18.00–47.44	1.12 ± 0.42	0.64–1.70	0.01
Lungs	29.87 ± 13.53	12.56–49.74	1.07 ± 0.47	0.50–1.80	0.01
Thymus	8.25 ± 4.97	3.33–14.87	0.35 ± 0.20	0.15–0.60	0.03
Bone marrow	8.71 ± 3.37	5.64–11.79	0.32 ± 0.20	0.24–0.50	0.03
Scattered radiation (mGy)					
Liver	16.25 ± 9.61	5.90–27.70	0.42 ± 0.28	0.23–1.10	0.01
Thyroid	2.67 ± 0.64	2.05–3.33	0.12 ± 0.03	0.10–0.15	0.02
Eyes	0.11 ± 0.01	0.10–0.13	$5.6 \times 10^{-3} \pm 0.00$	0.01–0.01	0.02
Gonads male	0.03 ± 0.00	0.03–0.03	$8 \times 10^{-4} \pm 0.00$	8×10^{-4} – 8×10^{-4}	0.003
Gonads female	0.05 ± 0.00	0.03–0.05	$2.4 \times 10^{-3} \pm 0.00$	2.4×10^{-3} – 2.4×10^{-3}	0.004

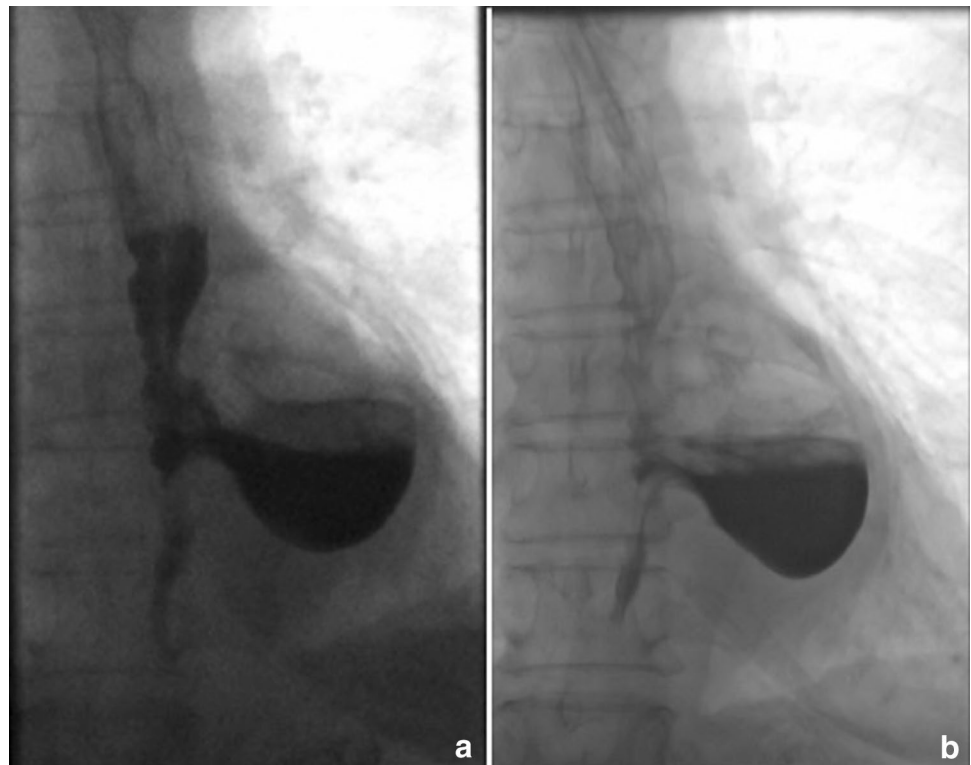
Patient study

Optimized ultralow-dose digital pulsed fluoroscopy was successfully completed in all 41 patients (10 female, 31 male, age 65 ± 11 years, range 42–85 years) and all studies were considered to be of diagnostic value to allow for a reliable diagnosis. All FP examinations were performed by the same operator (A.P.) with a mean image acquisition time of 25 ± 12 s (range 9–56 s).

Analysis of image quality

The image quality of FP images was rated sufficiently good for a reliable diagnosis with the following reading scores: overall image quality: median 4, range 3–5; delineation of contrast agent: median 4, range 2–5; image noise: median 4, range 3–5 but significantly differing from the DR reference standard for all evaluated parameters (median 5; range 4–5; $p < 0.05$). Image examples of FP examinations in comparison to the historical DR acquisitions are provided in Figs. 2, 3, and 4.

Fig. 2 Low-dose fluoroscopy (a) and digital radiograph (b) images of a 72-year-old patient with Zenker's diverticulum partially filled with contrast agent in the left lateral of the oesophagus



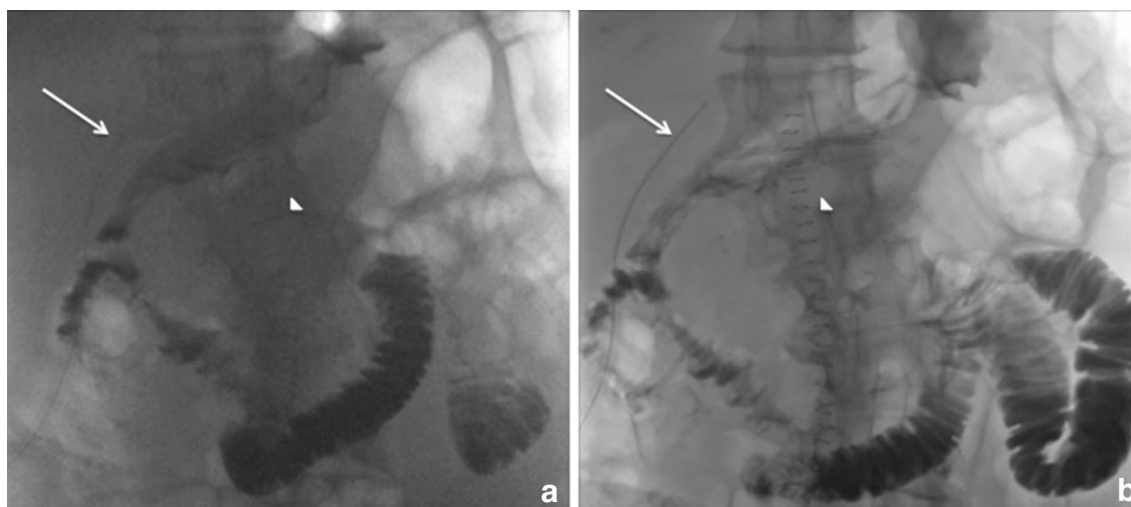


Fig. 3 **a** Low-dose fluoroscopy (FP) and **b** digital radiograph images of a 53-year-old patient post-gastrectomy due to gastric cancer. FP images provide good assessment of intestinal loops, whereas depiction of clip material (*arrowhead*) and drainage is limited in FP images (**a**)

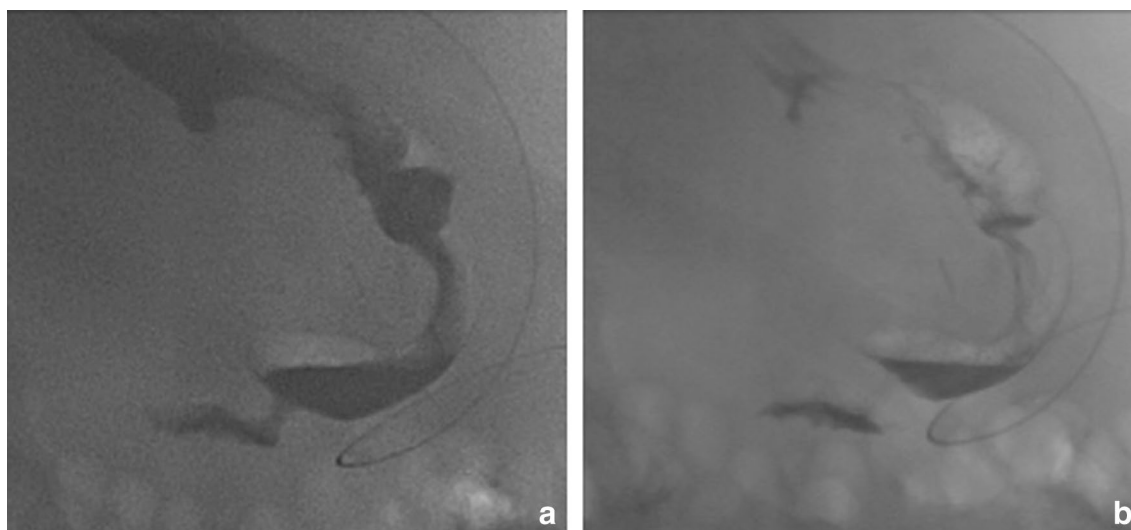


Fig. 4 Low-dose fluoroscopy (**a**) and digital radiograph (**b**) images of a 48-year-old obese patient (BMI > 35) post-sleeve gastrectomy with comparable diagnostic image quality

Discussion

In this study, we investigated the dose exposure and image quality of an optimized ultralow-dose digital pulsed protocol for fluoroscopic examinations of the UGI. We found significantly reduced organ doses in both the direct field of view and in distant radiosensitive organs at a sufficient image quality to ensure a reliable diagnosis.

Due to frequent clinical use, dose saving strategies are mandatory for fluoroscopic examinations of the UGI. This applies in particular to paediatric and obese patients, both commonly undergoing UGI [1, 2]. The first are at

particular risk for developing late radiation damage [11, 26, 27], whereas the latter inevitably receive a higher radiation exposure as compared to normal weight patients, due to the larger body profile and images are often of minor diagnostic quality, in particular when the radiation dose is limited to a reasonable extent [28, 29]. With the introduction of new image acquisition and reconstruction techniques (e.g. improved filtering, pulsed acquisition, last image hold) during the last decade, fluoroscopic examinations with a substantially reduced dose exposure became possible [20, 21]. Several studies investigating these technical advances are available for diagnostic/interventional

procedures of the vascular system [30–32] and for examinations of the GI and urogenital tract in paediatric radiology [1, 11, 13]. However, no dedicated research has been performed evaluating the quality standards for UGI examinations in adult patients. With the investigated ultralow-dose protocol comprising the latest hard- and software technologies in this study, we fill this gap by providing an analysis of the image quality and reference organ dose measures for an average adult fluoroscopic UGI examination in clinical routine.

Nevertheless, the results of this study need to be interpreted in the study setting. Although we consider that the presented organ doses as an overview for a standardized UGI examination in clinical routine using modern hard- and software techniques, it is important to remember that these results only apply for the specific protocol settings and detector system used. Other systems and acquisition parameters will affect the actual dose absorbed by radiosensitive organs; thus, our results may only serve as a general guideline and must not be seen as absolute values.

A well-known fact of X-ray imaging regardless of the chosen modality, is to determine a reasonable trade-off between the required image quality for a reliable diagnosis and the radiation burden of the patient. The results of our phantom and patient study indicate that our FP protocol warrants these conditions, as all examinations were considered to be of sufficiently diagnostic image quality at significantly reduced organ doses. In particular, scattered radiation levels in distant organs such as the eyes and gonads were negligibly low, making radiation effects (e.g. cataract development) unlikely, even if repeated examinations are necessary. This dose distribution pattern is in line with Emigh et al., who also conducted a phantom study to investigate dose exposure in paediatric UGI examinations, although a direct comparison is not possible due to their different patient collective and fluoroscopy system [1].

Our study has the following limitations. Images in both protocols were acquired with the highest possible pulse/frame rate/s. This allows for a high temporal resolution, which is of importance to evaluate discreet and subtle findings during the contrast agent passage. On the other hand, depending on the acquisition time, this can result in a considerably high dose exposure, especially with the historical DR protocol. For indications, in which high temporal resolution is not the primary focus of interest, reducing the pulse/frame rate is advisable to further reduce cumulative radiation dose. Moreover, phantom measurements were only performed once for each examination protocol; thus, no information about retest reproducibility is available. In addition, no dedicated image quality phantom was used to compare the examination protocols. Finally, we did not perform a subgroup analysis of obese patients, due to the small number of the included patients.

In conclusion, we established an optimized ultralow-dose digital pulsed fluoroscopy protocol for UGI examinations allowing for a significant dose reduction and provided an analysis of the resulting organ doses and image quality to demonstrate its feasibility for clinical routine.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Local IRB approved this study and waived written informed consent.

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