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INTERVENTIONAL

Patient radiation dose in percutaneous biliary interventions: recommendations for DRLs on the basis of a multicentre study

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Abstract

Objective Percutaneous biliary interventions (PBIs) can be associated with a high patient radiation dose, which can be reduced when national diagnostic reference levels (DRLs) are kept in mind. The aim of this multicentre study was to investigate patient radiation exposure in different percutaneous biliary interventions, in order to recommend national DRLs.

Methods A questionnaire asking for the dose area product (DAP) and the fluoroscopy time (FT) in different PBIs with ultrasound- or fluoroscopy-guided bile duct punctures was sent to 200 advanced care hospitals. Recommended national DRLs are set at the 75th percentile of all DAPs.

Results Twenty-three facilities (9 interventional radiology depts. and 14 gastroenterology depts.) returned the questionnaire (12%). Five hundred sixty-five PBIs with 19 different interventions were included in the analysis. DAPs (range 4–21,510 cGy·cm^2) and FTs (range 0.07–180.33 min) varied substantially depending on the centre and type of PBI. The DAPs of initial PBIs were significantly ($p < 0.0001$) higher (median 2162 cGy·cm^2) than those of follow-up PBIs (median 464 cGy·cm^2). There was no significant difference between initial PBIs with ultrasound-guided bile duct puncture (2162 cGy·cm^2) and initial PBIs with fluoroscopy-guided bile duct puncture (2132 cGy·cm^2) ($p = 0.85$). FT varied substantially (0.07–180.33 min).

Conclusions DAPs and FTs in percutaneous biliary interventions showed substantial variations depending on the centre and the type of PBI. PBI with US-guided bile duct puncture did not reduce DAP, when compared to PBI with fluoroscopy-guided bile duct puncture. National DRLs of 4300 cGy·cm^2 for initial PBIs and 1400 cGy·cm^2 for follow-up PBIs are recommended.

Key Points

- *DAPs and FTs in percutaneous biliary interventions showed substantial variations depending on the centre and the type of PBI.*
- *PBI with US-guided bile duct puncture did not reduce DAP when compared to PBI with fluoroscopy-guided bile duct puncture.*
- *DRLs of 4300 cGy·cm^2 for initial PBIs (establishing a transhepatic tract) and 1400 cGy·cm^2 for follow-up PBIs (transhepatic tract already established) are recommended.*

Keywords Biliary system · Interventional radiography · Interventional ultrasound · Radiation exposure · Multicentre study

Abbreviations

ALARA	'As low as [is] reasonably achievable'
cGy	Centigray
cm	Centimetre
DAP	Dose area product (= kerma air product)
DRL	Diagnostic reference level
ERCP	Endoscopic retrograde pancreaticocholangiography
FT	Fluoroscopy time
ICR	Interquartile range
ICRP	International Commission on Radiological Protection
kg	Kilogramme

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mSv	Millisievert
PBI	Percutaneous biliary intervention
SD	Standard deviation
US	Ultrasound

Introduction

Patient radiation protection is an important issue and radiation exposure should be 'as low as reasonably achievable' (ALARA) [1]. Diagnostic reference levels (DRLs) have proven to be an effective tool to optimise diagnostic and interventional radiology examinations with potentially high doses [2]. DRLs indicate whether, in routine conditions, the dose given to the patient is unusually high or unusually low. However, DRLs are not to be confused with dose limit values, which suggest the termination of further radiation exposure. The International Commission on Radiological Protection (ICRP) first introduced the term 'diagnostic reference level' (DRL) in 1996 [3] and added further recommendations to establish national DRLs in medical imaging in 2017 [4]. Recommended national DRLs are set at the 75th percentile of the mean DAPs. The European Commission has also released two EURATOM directives concerning radiation protection in 1997 [5] and 2013 [6], as well as Referral Guidelines for Medical Imaging [7], and requested all EU member states to establish national DRLs for diagnostic imaging and interventional radiological procedures. Upon the announcement of updated DRLs for diagnostic and interventional X-ray applications in Germany, as published by the Federal Office of Radiation Exposure in 2016 [8], a DRL of 2500 cGy·cm^2 is proposed for endoscopic retrograde pancreaticocholangiography (ERCP). DRLs for percutaneous biliary interventions (PBIs) are not included in this announcement. However, an increased amount of patient radiation exposure is expected compared to ERCP, according to the national patient dose database of the UK [9, 10]. Furthermore, a single Greek centre study showed dose area products over 6000 cGy·cm^2 and effective doses over 12 mSv in PBIs comparable to those of abdominal computed tomography [11]. The aim of this German multicentre study was to investigate patient radiation exposure in different PBIs, in order to recommend national DRLs. Interventional radiologists and gastroenterologists were invited as they probably use different techniques in PBI (i.e. PBI with rendezvous ERCP by gastroenterologists). Beside the dose area product, the fluoroscopy time and the additionally acquired images, the study asked for different parameters which may influence patient radiation exposure in PBIs, such as the use of ultrasound-guided bile duct access [12].

Materials and methods

The study was approved by the local ethics committee (approval number: 2018-811R-MA) and registered by ClinicalTrials.gov with the ID NCT03538782. Considering the methods of previous surveys [13, 14], a questionnaire (excel file) was developed which asked for retrospective data concerning patient radiation exposure in PBIs. According to the above-mentioned ICRP recommendations for the national DRLs of interventional radiological procedures, this questionnaire was intended to achieve data from 20 to 30 facilities of different healthcare providers with sufficient workloads and a representative selection of at least 20 patients (preferably 30). For this reason, the questionnaire was sent to 100 interventional radiology departments and 100 gastroenterology departments of major regional hospitals and all university hospitals ($n = 37$) throughout Germany. Only data from adult patients with weights within a range from 50 to 90 kg (to assume a mean weight of about 70 kg) were accepted. A minimum quantity of ten performed PBIs per year and centre was required as an inclusion criterion. No patient data were documented in the questionnaire, in order to comply with common data safety regulations. In detail, the questionnaire asked for the name of the fluoroscopy equipment (trademark and model), the year of commissioning, the date of each examination, the DAP, the fluoroscopy time, the number of additional images taken, whether it was an initial or a follow-up examination with an established transhepatic tract, whether ultrasound-guided or fluoroscopy-guided bile duct puncture was performed in the initial PBI, whether a metal stent or an endoprosthesis was implanted, and whether just an endoprosthesis was exchanged or whether any other procedure was performed (e.g. PBI with cholangioscopy).

Statistics

All data were treated confidentially, and the hospital-specific performance was not revealed. Analysis of data was conducted by the Department of Medical Statistics and Biomathematics of Mannheim University Hospital, at Heidelberg University. All statistical calculations were performed using SAS software, release 9.4 (SAS Institute Inc.). Quantitative data are presented as the median, minimum, maximum, mean and standard deviation in numerical values and in box plot diagrams. The box plot diagrams show the medians, means, upper and lower quartiles, whisker endpoints (defined as the maximum and minimum values within the IQR × 1.5) and the outliers (defined as the values beyond the IQR × 1.5). The DRL was calculated as the third quartile of all DAPs of all centres for the initial and the follow-up PBIs respectively. As the quantitative variables have a positively skewed distribution, nonparametric Mann–Whitney U tests have been

performed in order to compare the data from 2 independent samples, because this test is not sensitive to outliers. Statistical significance has been assumed for p values less than 0.05.

Results

Seven of the 200 invited study centres did not perform PBI (only the interventional radiology dept. or vice versa), while three centres performing fewer than 10 PBIs per year had to be excluded, and one centre was not able to provide data due to technical difficulties. In the end, 23 departments (nine interventional radiology depts. and 14 gastroenterology depts.) throughout Germany (Fig. 1) were enrolled in the study, representing a response rate of 12%. The range of reported, consecutively performed PBIs was 10 to 56 (mean, 25). Overall, data from 565 PBIs performed in the period from 13 March 2015 to 1 August 2018 were included in the analysis, as is shown by a flow chart (Fig. 2). A total of 256 initial PBIs were performed to establish a percutaneous transhepatic tract, while 309 PBIs were follow-up examinations. A detailed listing of the different types of PBI is shown in Table 1. The initial PBIs were combined with ultrasound-guided bile duct puncture ($n = 122$) or with fluoroscopy-guided bile duct puncture ($n = 134$).

All PBIs were conducted with fluoroscopic equipment, which was permitted for performing PBI according to the guidelines of the Federal Medical Association (Bundesärztekammer) for quality assurance in radiodiagnostics (imaging voltage, 70–80 KV; focal spot value, ≤ 1.3, object detector distance: as low as possible; automatic exposure control: central area). Non-mobile angiography units were mainly used, whereas two centres applied mobile c-arm X-ray systems and one used a fluoroscopy equipment with an over couch system (Table 2).

DAPs (range 4–21,510 cGy·cm^2) and FTs (range 0.07–180.33 min) varied substantially depending on centre and type of PBI. The high variability of the DAPs is expressed in the standard deviation, which was rather high when compared to the respective mean values. The DAPs are shown in Table 3. The DAP median of all PBIs was 1098 (4–21,510) cGy·cm^2. The DAPs of initial PBIs were significantly ($p < 0.0001$) higher (median, 2162 [77–21,510] cGy·cm^2) than those of follow-up

Fig. 1 Overview map of participating study centres (red: interventional radiology depts., blue: gastroenterology depts.)

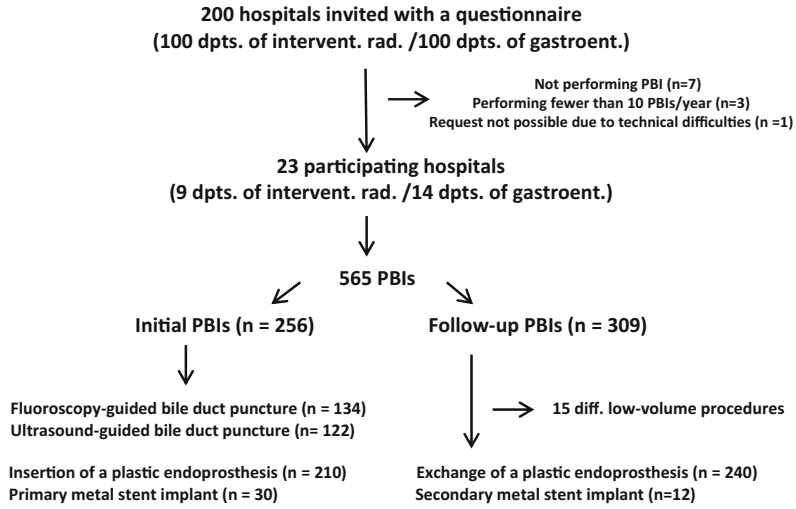

Fig. 2 Flow chart showing the inclusion process of analysed PBIs

PBIs (median 464 [4–14,563] cGy·cm^2). There was no significant difference between initial PBIs with ultrasound-guided bile duct puncture (2162 [77–20,703] cGy·cm^2) and initial PBIs with fluoroscopy-guided bile duct puncture (2132 [118–21,510] cGy·cm^2) ($p = 0.8513$). Initial PBI with the insertion of an endoprosthesis ($n = 210$) was associated with a higher DAP of 1951 [118–15,627] cGy·cm^2 than low complexity PBI with exchange of an endoprosthesis ($n = 240$) with a DAP of only 405 [16–9106] cGy·cm^2, which was the lowest median DAP ($p < 0.0001$). The highest DAP values were documented in complex PBIs with primary metal stent implantation, with a median DAP of 3636 [327–21,510] cGy·cm^2. The centre-specific medians, means, lower and upper quartiles and outliers of DAP are shown for the initial PBIs in Fig. 3 and for follow-up PBIs in Fig. 4. Only one centre did not report data of any follow-up PBI. National DRLs of 4300 cGy·cm^2 for initial PBIs and 1400 cGy·cm^2 for follow-up PBIs were calculated.

Table 1 Different types of PBIs in 23 study centres

No.	Types of biliary interventions	Number (n)
	Initial PBI with	
1	- Insertion of an endoprosthesis	210
2	- Primary metal stent implantation	30
	Follow-up PBI with	
3	- Exchange of an inserted endoprosthesis	240
4	- Secondary metal stent implantation	12
5	- Cholangiography (diagnostic)	10
6	- Bile duct dilatation (bougie or balloon catheter)	10
7	- Cholangioscopy	8
8	- Combined interventions	7
9	- Bile duct stone removal	6
10	- Disrupted intervention	5
11	- Internalisation of an external endoprosthesis	4
12	- Removal of an endoprosthesis	4
13	- Diagnostic brush cytology	3
14	- Bile stone lithotripsy	3
15	- Radio frequency ablation of bile duct cancer	2
16	- Upsizing of an endoprosthesis	2
17	- Rendezvous treatment with ERCP	2
18	- Position correction of a disl. endoprosthesis	1
19	- Metal stent dilatation	1

FTs of all analysed PBIs are shown in Table 4. The medians of the initial and the follow-up PBIs were 11.3 [0.73–180.33] min and 3.51 [0.07–50.62] min respectively ($p < 0.0001$). FTs did not differ when the initial PBIs with ultrasound-guided bile duct puncture (11.22 [1.25–180.33] min) were compared with initial PBIs with fluoroscopy-guided bile duct puncture (11.48 [0.73–56.00] min; $p = 0.5643$). PBIs with an exchange of an endoprosthesis had the shortest FT (median, 3.0 [0.07–50.62] min). The centre-specific medians, means, lower and upper quartiles and outliers of FT are shown for the initial PBIs in Fig. 5 and for the follow-up PBIs in Fig. 6.

The number of images could not be reasonably analysed as the participating study centres did not differentiate clearly between 'last image hold' images and the additionally acquired images in their data reports.

Discussion

This first multicentre study on patient radiation exposure in percutaneous biliary interventions in interventional radiology and gastroenterology departments in Germany had a questionnaire response rate of just 12%. Therefore, the representativeness of this study is limited. Not only that, more gastroenterology departments ($n = 14$) were included in the analysis than interventional radiology departments ($n = 9$). Hence, the study may be less representative for PBIs performed by interventional radiologists. However, advanced care hospitals ($n = 13$)

Table 2 Fluoroscopy/angiography equipment list

Company name	Product	Year of Commissioning
Siemens	Arcadis (mobile C-arm)	2007
Philips	Veradius (mobile C-arm)	2010
Siemens	Luminos Agile (fluoroscopy unit with over couch system)	2012
Philips	FD20 Azurion (+ Allura Clarity) (angiography unit)	2017
Philips	Allura XP Xper FD20 (angiography unit)	2006
Philips	Multi diagnost eleva (angiography unit)	2010
Philips	Multi diagnost eleva (angiography unit)	2005
Philips	Multi diagnost eleva (angiography unit)	2015
Philips	Multi diagnost 3 (angiography unit)	1995
Siemens	Artis MP (angiography unit)	2018
Siemens	Artis zee multi-purpose (angiography unit)	2015
Siemens	Artis zee (angiography unit)	2013
Siemens	Artis zee (angiography unit)	2012
Siemens	Artis zee (angiography unit)	2015
Siemens	Axiom Artis (angiography unit)	2005
Siemens	Artis zee (angiography unit)	2008
Siemens	Axiom Artis (angiography unit)	2007
Siemens	Artis zee ceiling (angiography unit)	2010
Siemens	Axiom Artis FA (angiography unit)	2007
Siemens	Axiom Artis zee (angiography unit)	2009
Siemens	Artis zee biplane (angiography unit)	2016

and university hospitals ($n = 10$) from throughout Germany (Fig. 1) could be enrolled in the study.

DAPs and FTs of the reported PBIs varied substantially. This is not unexpected for interventional radiologic procedures [9, 10] and may have many reasons in this study. First, 19 different types of PBIs ($n = 564$) were reported (Table 1). As interventional radiology depts. and gastroenterology depts. have different focus areas of PBI (e.g. PBI with cholangioscopy or rendezvous-PBI with ERCP in gastroenterology), the whole spectrum of PBIs could be mapped [15]. However, it seemed unreasonable to calculate the medians or the means for each type of PBI. With regard to a recommendation of national DRLs, PBIs were summarised into groups of initial and follow-up PBIs, leading to a mixture of different PBIs in each group. Second, 23 centres were included in the analysis with probably different volumes, expertise, case mix, number of included PBIs per centre ($n = 10$–56), PBI techniques and investigators. Very low volume centres (< 10 PBIs per year), with possibly higher DAPs, were initially excluded. Furthermore, the different fluoroscopy equipment per centre (Table 2) may have also influenced variety. For example, the highest DAPs were observed in the two facilities with mobile C-arm fluoroscopic equipment (data not shown separately). It appears to be the case, but it is not shown in any study that examinations with mobile C-arm fluoroscopic equipment, which are still commonly used, cause higher patient radiation doses than fixed angiography units with a generator installed. The uncomfortable positioning of the C-arm by hand and the functional principle of continuous, non-pulsed fluoroscopy are only

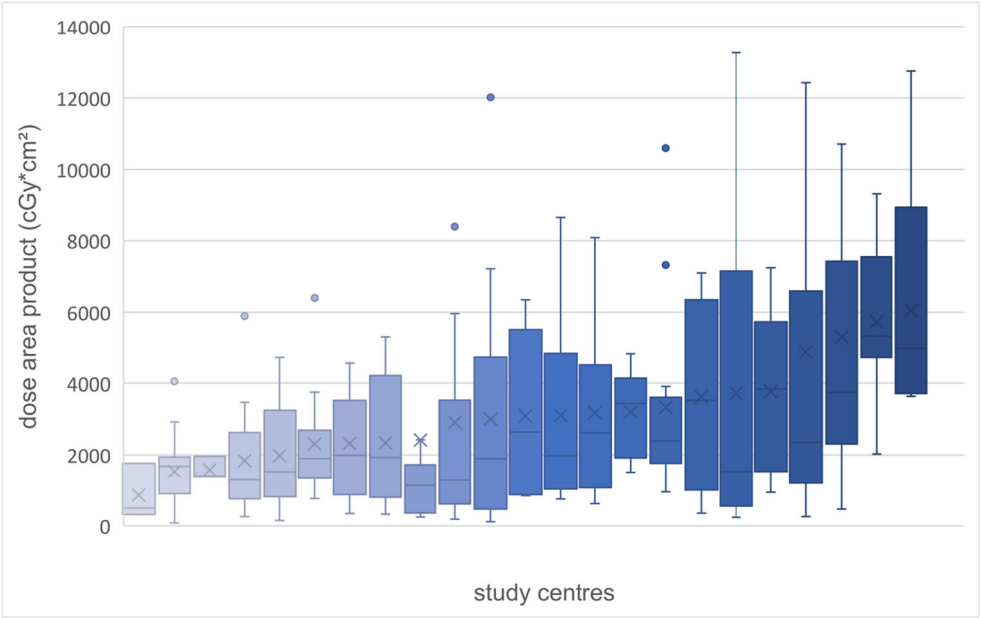

Fig. 3 DAP box plot diagram of each study centre in initial PBIs (10–56 PBIs/centre). The box plots are arranged according to the amount of the mean values (cross)

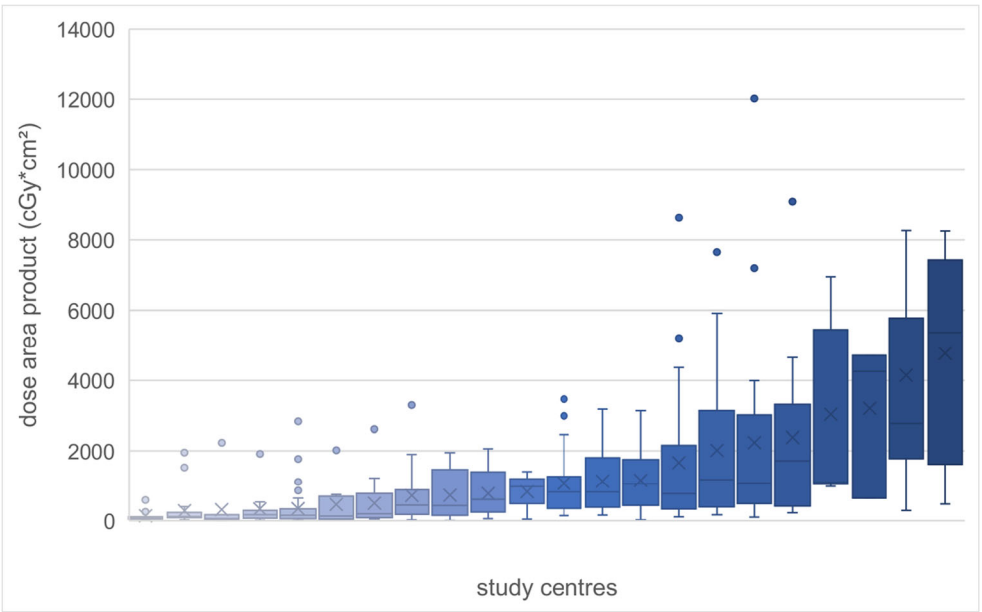

Fig. 4 DAP box plot diagram of each study centre in follow-up PBIs (10–56 PBIs/centre). The box plots are arranged according to the amount of the mean values (cross). One centre reported no follow-up DAP data

Table 3 Dose area product ($cGy{\cdot}cm^2$) with median, range, mean and SD of all analysed PBIs

Biliary intervention	*n*	Median	Min.	Max.	Mean	SD
All PBIs	564	1098	4	21,510	2137	2854
Initial PBIs	256	2162	77	21,510	3256	3361
Follow-up PBIs	308	464	4	14,563	1206	1908
Initial PBI with US-guided bile duct puncture	134	2162	77	20,703	3173	3137
Initial PBI with fluoroscopy-guided bile duct puncture	122	2132	118	21,510	3349	3602
PBI with insertion of an endoprosthesis	210	1951	118	15,627	2796	2649
PBI with exchange of an endoprosthesis	240	405	16	9106	994	1542
PBI with metal stent implantation	52	2481	173	21,510	4435	4692
PBI with primary metal stent implantation	30	3636	327	21,510	5282	5112

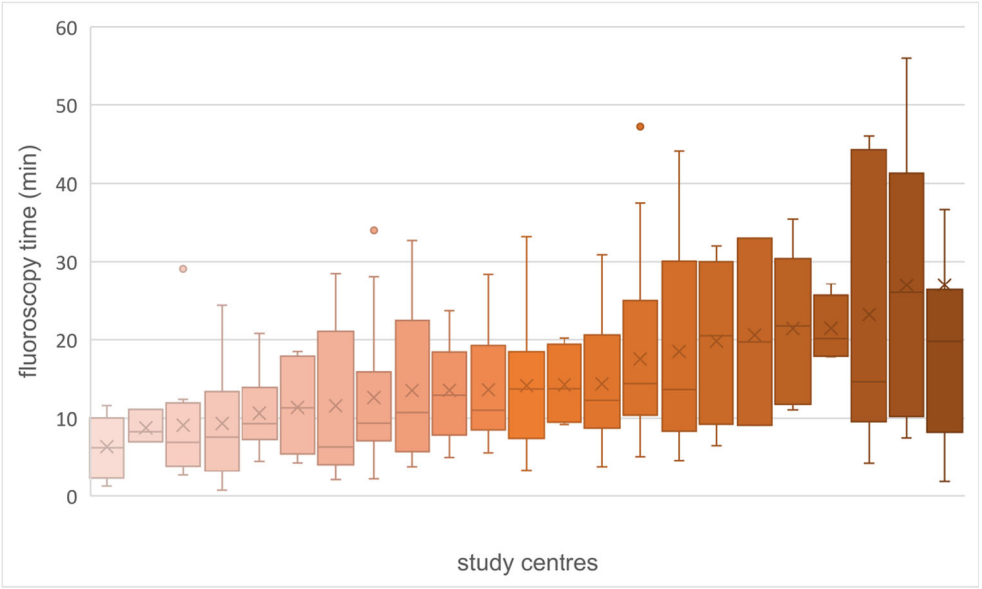

Fig. 5 FT box plot diagram of each study centre in initial PBIs (10–56 PBIs/centre). The box plots are arranged according to the amount of the mean values (cross)

two of the disadvantages of mobile C-arm fluoroscopic units that should be mentioned here. A further prospective study has to show whether mobile C-arm fluoroscopic units are associated with significantly higher patient radiation doses than fixed angiography units. Third, DAP and FT both depend on further variables, such as fluoroscopy technique and patient circumstances. Known cofactors are patient size, pulse rate, number of additionally acquired radiographic images, detector patient distance or angulation. Unfortunately, centres did not clearly differentiate between 'last image hold' images and additionally acquired radiographic images, so that this aspect could not be analysed separately.

In respect of national DRLs, it was decided to divide the PBIs into 'initial PBIs', in which a percutaneous transhepatic tract has to be established, and 'follow-up PBIs', in which the percutaneous transhepatic tract is already established. This classification was made because initial PBIs can be very difficult and time-consuming, whereas follow-up PBIs, which were most often performed as an exchange of an endoprosthesis ($n = 240$; lowest DAP and FT in this study), can be carried out very easily and quickly. The DAP difference between initial and follow-up PBIs was significant ($p < 0.0001$). Therefore, a national DRL of 4300 cGy·cm^2 for initial PBIs and of 1400 cGy·cm^2 for follow-up PBIs is recommended. These values fall within the expected range of the recommended DRLs for ERCP with 2500 cGy·cm^2 and transcatheter arterial chemoembolisation (TACE) of 30,000 cGy·cm^2 [9]. A recently published Spanish study [16] classified seven radiological interventions including

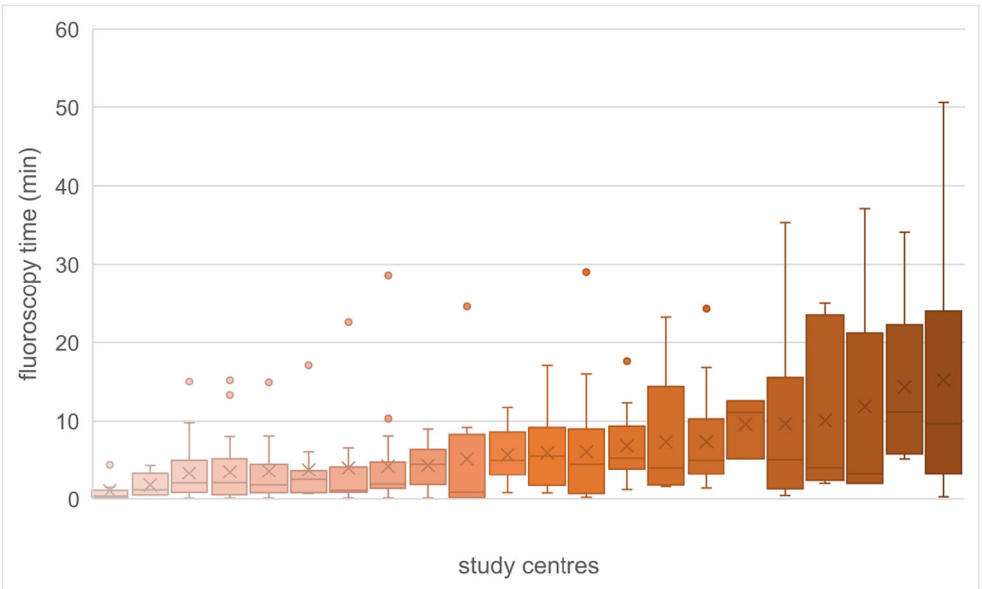

Fig. 6 FT box plot diagram of each study centre in follow-up PBIs (10–56 PBIs/centre). The box plots are arranged according to the amount of the mean values (cross). One centre reported no follow-up FT data

Table 4 Fluoroscopy time (minutes) with median, range, mean and SD of all analysed PBIs

Biliary intervention	*n*	Median	Min.	Max.	Mean	SD
All PBIs	564	6.53	0.07	180.33	10.14	12.13
Initial PBIs	256	11.30	0.73	180.33	15.29	14.59
Follow-up PBIs	308	3.51	0.07	50.62	5.86	7.25
Initial PBI with US-guided bile duct puncture	134	11.22	1.25	180.33	16.25	17.63
Initial PBI with fluoroscopy-guided bile duct puncture	122	11.48	0.73	56.00	14.24	10.24
PBI with insertion of an endoprosthesis	210	11.04	0.75	180.33	14.74	14.98
PBI with exchange of an endoprosthesis	240	3.00	0.07	50.62	5.00	6.74
PBI with metal stent implantation	52	10.17	0.73	44.00	11.8	8.21
PBI with primary metal stent implantation	30	11.10	0.73	44.00	13.73	9.19

PBIs ($n = 314$) into low, medium or highly complex with regard to patient radiation dose. However, it has to be clarified whether the proposed three complexity parameters including liver anatomy, intrahepatic bile duct dilation (which is perhaps the most influencing factor) and location of the bile duct obstruction can be applied to all PBIs (e.g. how can PBIs with lithotripsy be classified by these parameters?).

Previous studies [10, 13, 17–20] used DAP mean values in their reports (Table 5). This is why we also present mean values in our study, in order to enable direct comparisons (Tables 3 and 5). The DAPs of this study were lower than those in previous studies, with DAP values of 3040 cGy·cm^2 [13] and 24,400 cGy·cm^2 [19]. One single-centre study had calculated mean values of up to 21,340 cGy·cm^2 [20], which probably suggests the need to check the technical performance of biliary interventions to reduce patient radiation exposure. Hence, the comparability of the study mean values may be restricted as the number of included interventions was different, technical progress in fluoroscopic/angiographic equipment has been made since 2000 [17], and PBIs performed in gastroenterological facilities had not been included, which could have influenced radiation dose (Table 2).

The use of ultrasound-guidance in the initial bile duct puncture did not lead to a significant reduction of radiation dose in comparison with fluoroscopic-guided bile duct puncture ($p < 0.8513$), as may have been supposed. Nevertheless, US guidance may be a helpful tool for an easier bile duct access without vessel injuries [12, 21].

The highest DAP values in this study were observed in initial PBIs with primary metal stent implantation, which can be a complex and long-time procedure [12]. However, it remains to be demonstrated whether the

Table 5 Comparison of published studies concerning patient radiation exposure in PBIs since 2000 (mean values)

Author	Study type	Number of centres (*n*)	Facility	Study period (year)	Number of PBIs (*n*)	PBI subtypes	DAP mean (cGy × cm^2)
Marshall et al (2000) [17]	Retrospective	40	Radiology	1997–2000	153	No subtypes	5400
Miller et al (2003) [18]	Prospective	12	Radiology	1999–2000	127	No subtypes	7060
Aroua et al (2007) [19]	Prospective	14	Radiology	2004–2005	56	PTBD with stent insertion	24,400
Klöckner et al (2011) [20]	Retrospective	1	Radiology	2006–2009	22/61	PTBD left/right	21,340/15350
					165	PTBD control	9940
					127	PTBD change	9640
Hart et al (2012) [10]	Retrospective	10	Radiology	2006–2010	279	No subtypes	3200
Ruiz-Cruces et al (2016) [16]	Prospective	8	Radiology	2010–2013	129	PTBD all	3040
					85	PTBD low complex	400–1200
					32	PTBD med. complex	550
					12	PTBD high complex	4600
This study (2018)	Retrospective	23	Radiology and gastroenterology	2015–2018	565	PTBD all	2854
					256	PTBD (initial)	3256
					308	PTBD (follow-up)	1206

cumulative patient radiation dose with two or three consecutive biliary interventions in one patient instead of one unique intervention is associated with more or less radiation exposure. The calculation of cumulative patient radiation dose and patient radiation dose registry was not an issue of this study, but this could be an important issue in the future for interventional radiology, neuroradiology, cardiology and gastroenterology [22].

As mentioned above, FTs varied substantially with a range from a few seconds to 180 min (Table 4). However, fluoroscopic time does not necessarily correlate with DAP, and DAP can even be very high when fluoroscopic time is low [23–25].

Nevertheless, the monitoring of the FT as well as an implemented warning system in the fluoroscopic/angiographic unit (i.e. warning signal every 5 min) are both valuable additional tools to minimise patient and staff radiation doses.

As has been discussed elsewhere, diagnostic reference levels (DRLs) do not refer to patient skin dose or organ-specific dose distributions [26]. Moreover, the use of collimation has no influence on DAP. Therefore, further improvements are necessary for patient safety and radiation protection. Real-time skin-dose monitoring and estimated absorbed organ doses with the use of dose coefficients (DCs) measured by a computerised track system integrated into the fluoroscopic unit [27–30], as well as individualised and patient-protection-based dose repository may all be additional tools for dose management and clinical audit to chart improvement, as was proposed by the ESR statement on radiation protection in 2013 [31].

This study has several limitations. Data collection was retrospective but included all consecutively conducted biliary interventions in each study centre. As mentioned above, the questionnaire response rate was only 12%, a statistic which impaired the representative character of the study. However, the number of analysed PBIs was the highest in comparison with previous studies (Table 5). Besides, both university and non-university hospitals, and both interventional radiology and gastroenterology depts. throughout Germany were enrolled in the study. Moreover, we did not perform multivariate analysis, which could have better adjusted the analysis to clustering effects in the final findings. And at last, the measurement of the DAP can be associated with an inaccuracy up to 25% (usually < 10%). It was assumed that every fluoroscopy unit was proved regularly in the context of quality management measurements according to the legal requirements (German X-Ray regulations).

Conclusions

DAPs and FTs in percutaneous biliary interventions showed substantial variations depending on the centre and the type of PBI. PBI with US-guided bile duct puncture did not reduce DAP as compared to PBI with fluoroscopy-guided bile duct puncture. National DRLs of 4300 cGy·cm^2 for initial PBIs and 1400 cGy·cm^2 for follow-up PBIs are recommended.

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Informed consent Written informed consent was not required for this study because the retrospectively collected data were acquired routinely in all percutaneous biliary interventions and documented data were completely anonymised for this manuscript.

Ethical approval Institutional Review Board approval was obtained.

Methodology
- retrospective
- observational study
- multicentre study

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