European Radiology (2019) 29:1276–1284
https://doi.org/10.1007/s00330-018-5694-6

VASCULAR-INTERVENTIONAL

C-Arm computed tomography (CACT)-guided balloon pulmonary angioplasty (BPA): Evaluation of patient safety and peri- and post-procedural complications

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Received: 30 May 2018 / Revised: 18 July 2018 / Accepted: 31 July 2018 / Published online: 12 September 2018

Abstract

Aim To assess the frequency and severity of complications of balloon pulmonary angioplasty (BPA) using C-arm computed tomography (CACT) guidance.

Material and methods 266 consecutive interventions in 67 patients (42 females, mean age 66 ± 13 years) were included. Selective CACT was acquired prior to the intervention for three-dimensional (3D) guidance and to select appropriate balloon size based on the measured vessel diameter. Complications during and after the procedure, the need for further interventions and the impact on patient safety and outcome were assessed and categorised according to the SIR Classification System to Complications by Outcome (Grade A–F).

Results Overall, 237 interventions were conducted without any complications (89.1%). Minor complications not requiring additional treatment occurred during or after 25 procedures (9.4%), including recurring dry cough in four patients during a total of 11 interventions (4.1%) (Grade A), three focal dissections of the targeted pulmonary artery (1.1%), four cases of pulmonary haemorrhage (1.5%), one case of reperfusion oedema (0.4%) and six cases of post-interventional short-term hemoptysis (2.3%) (Grade B). Four cases of major complications requiring additional treatment were observed (1.5%): one case of pulmonary haemorrhage (0.4%) and two cases of post-interventional haemoptysis (0.8%), all resolved after medical therapy without requiring further intervention, and one case of atrial tachycardia induced during catheterisation, subsequently requiring pharmacological cardioversion (0.4%) (Grade C). No fatal or life-threatening peri- or post-interventional complications or mortality were observed (Grade D–F).

Conclusion BPA performed under CACT guidance appears to be a safe procedure with a low risk of severe complications.

Key Points

- *CACT guidance of BPA is safe and successful.*
- *CACT-guided BPA procedures have a low complication profile.*
- *CACT guidance is a valuable tool to navigate BPA.*

Keywords Pulmonary hypertension · Cone beam computed tomography · Angioplasty

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Abbreviations

3D	Three-dimensional
BPA	Balloon pulmonary angioplasty
CACT	C-arm computed tomography
CTEPH	Chronic thromboembolic pulmonary hypertension
DSA	Digital subtraction angiography
IVUS	Intravascular ultrasound
LMWH	Low molecular-weight heparin
MDCT	Multidetector computed tomography
mPAP	Mean pulmonary artery pressure

OCT	Optical coherence tomography
PEA	Pulmonary endarterectomy
PVR	Pulmonary vascular resistance
V/Q SPECT	Ventilation/perfusion single photon emission computed tomography

Introduction

Chronic thromboembolic pulmonary hypertension (CTEPH) is a life-threatening disease occurring in 0.1–4.0% of patients who survived one or more episodes of pulmonary embolism [1–5]. CTEPH leads to chronic elevation of the mean pulmonary arterial pressure (mPAP) and pulmonary vascular resistance (PVR) [1]. The median survival of untreated patients with mPAP > 30 mmHg is less than 2 years [6]. The treatment of choice for CTEPH is pulmonary endarterectomy (PEA) with strong evidence for improved patient outcome and a reported peri-operative mortality of 2–4% [1, 7].

However, mostly due to distal and therefore surgically inaccessible thromboembolic material, up to 50% of patients suffering from CTEPH are not suitable for surgery [3, 4, 8, 9]. Besides pharmacological therapy with riociguat, which today is the only approved pharmacological agent in CTEPH treatment [10], balloon pulmonary angioplasty (BPA) is an emerging treatment option. BPA enables treatment of web-like stenoses and intraluminal bands in segmental and sub-segmental pulmonary arteries with a reported improvement of haemodynamics and clinical symptoms [11–18]. Initially, BPA did not get widespread attention as a treatment option for CTEPH, because of the reported fatal complications. However, over the last few years, several centres, mainly from Japan but also from Europe, have started to optimise the BPA technique, and, by use of recent imaging technology, a careful, staged approach and undersizing of the balloons [12, 13, 15, 16].

Due to the risk of life-threatening complications, the BPA technique has been refined and optimised in the last years and is more and more supported by dedicated guiding techniques to increase the therapeutic effect and to minimise the rate of potentially fatal complications such as reperfusion oedema, pulmonary haemorrhage and death [19–25]. C-Arm computed tomography (CACT) is known to visualise peripheral CTEPH lesions in detail and is an accurate technique for procedure guidance in patients undergoing BPA, therefore helping to avoid guidewire perforations, dissection and rupture of targeted vessels [14, 22, 23].

The purpose of this study was to evaluate the severity and frequency of peri- and post-interventional complications in patients with CTEPH undergoing CACT-guided BPA.

Material and methods

This retrospective study was approved by the local ethics committee. In our institution, all patients with suspected CTEPH underwent a standardised diagnostic work-up according to current guidelines, and the treatment decision was made by an inter-disciplinary CTEPH board [26–28]. All patients from August 2013 to January 2017 with a positive CTEPH board decision for BPA were included in the study. Overall, 266 consecutive BPA procedures in 67 patients (42 females, 25 males, mean age 66.2 ± 13.2 years) were included in this study. Of these, 56 patients were anticoagulated with rivaroxaban (83.5%), five patients with other direct oral anticoagulants (7.5%) and six patients with phenprocoumon (9.0%). Phenprocoumon was paused 7 days prior to the intervention and patients received low molecular-weight heparin (LMWH) bridging until the evening before the BPA. There was no bridging for patients receiving direct oral anticoagulants. Except for two, all enrolled patients were treated with target drugs for pulmonary hypertension, such as riociguat, sildenafil or tadalafil. Detailed patient demographics, haemodynamics, and clinical and interventional parameters are shown in Table 1. No patient was excluded.

Balloon pulmonary angioplasty

Anticoagulation was paused for the day of the intervention. During the procedure, patients received 5,000–10,000 IU of unfractionated heparin intra-arterially. All procedures were performed on a monoplane, ceiling-mounted angiographic system (Artis Q, Siemens Healthineers, Erlangen, Germany) or on a monoplane, robotic-arm-mounted angiographic system (Artis pheno®, Siemens Healthineers) under local anaesthesia and by use of CACT guidance. Through femoral access a long 6F sheath (Destination® – peripheral guiding sheath, Terumo) was placed in the main pulmonary artery of interest. A selective CACT was acquired to plan and guide the intervention by use of the full field-of-view (30 × 40 cm) and a dual-barrel injector (Accutron HP-D, Medtron AG, Saarbrücken, Germany; total injected volume 50 ml, comprising 35 ml of iomeprol 300 mg I/ml mixed with 15 ml of normal saline; flow rate 6 ml/s) with the standard preset (6 s DR DynaCT® preset, Siemens Healthineers) [22]. Based on these images, the course of the pulmonary arteries was indicated by drawn centre lines, and BPA positions were identified and marked by coloured lines on the CACT images [22]. In case of occlusions the course of the occluded vessel can be visualised on CACT due to the better soft tissue resolution compared to DSA and centre lines were planned next to the adjacent bronchi as additional anatomical landmarks indicating the course of the vessel. After bone segmentation and subtraction, the CACT images were visualised as a three-dimensional (3D) vascular tree by a volume rendering technique (VRT) with semi-translucent opacity and

Table 1 Characteristics of the study population

Parameter	Value
Gender	42 female (62.7%), 25 male (37.3%)
Age, y	66.2 ± 13.2
Total count of BPA per patient	3.5 ± 1.5
Number of BPA procedure per session, n (%)	1st n=67 (25.2%)
	2nd n=55 (20.7%)
	3rd n=53 (19.9%)
	4th n=40 (15.0%)
	5th n=29 (10.9%)
	6th n=16 (6.0%)
	7th n=5 (1.9%)
	8th n=1 (0.4%)
Pre-interventional mPAP, mmHg (n=46)	42.3 ± 11.5
Post-therapeutic mPAP, mmHg (n=46)	35.1 ± 12.0 ($p < 0.0001$ pre- vs. post-BPA)
Anticoagulation, n (%)	
Rivaroxaban	56 (83.5%)
Apixaban	3 (4.5%)
Edoxaban	1 (1.5%)
Dabigatran	1 (1.5%)
Phenprocoumon	6 (9.0%)
Medication for pulmonary hypertension, n (%)	
Tadalafil	28 (41.8%)
Riociguat	22 (32.8%)
Sildenafil	15 (22.4%)
none	2 (3.0%)

BPA balloon pulmonary angioplasty, *mPAP* mean pulmonary artery pressure

blended with the live fluoroscopic image to allow for a simultaneous visualisation of CACT-based vessel information and real-time fluoroscopic image (3D CACT Roadmap) (Fig. 1). The benefit of a 3D roadmap is twofold; first it allows adaptation of the working projection of the C-arm to the needs, for example when opening up vessel bifurcations; second it creates a 3D CACT roadmap image that can be used instead of acquiring a conventional digital subtraction angiography (DSA) run or conventional roadmap for catheter, guidewire and balloon placement. Based on a 3D CACT roadmap, a 6F guiding catheter (MACH 1^{TM}, Boston Scientific, Marlborough, MA, USA) was advanced next to the targeted pulmonary artery segment and a 0.014-in. guidewire (V-14^{TM}, Boston Scientific) was used to cross the web stenosis or occlusions. Relying on CACT vessel diameter measurements, appropriate rapid exchange balloon catheters (1.2–4 mm, Emerge^{TM}, Boston Scientific) were selected, advanced through the targeted pulmonary lesion and inflated for 15–60 s by hand using an inflation device (Encore^{TM} 26, Inflation Device, Boston Scientific). Overall, 804 pulmonary arteries were treated including 125 (15.5%) occluded pulmonary artery segments.

Assessment of complications

Peri-procedural side effects and complications were documented by the interventionalists. Post-procedural complications and the potential necessity for further treatments were monitored on the ward for the duration of the hospital stay by the pneumologists. Post-procedural complications after discharge and mortality were assessed 30 days after the intervention by the pneumologist outpatient care centre.

All included interventions were categorised whether any complication occurred or not. Within the group of interventions with complications, a further stratification was applied according to the SIR Classification System to Complications by Outcome: Minor complications: Grade A = no therapy, no consequence; Grade B = nominal therapy, no consequence; includes overnight submission for observation only. Major complications: Grade C = requires therapy, minor hospitalisation (< 48 h); Grade D = requires major therapy, unplanned increase in level of care, prolonged hospitalisation (> 48 h); Grade E = permanent adverse sequelae; Grade F = death [29]. Additionally, the length of the post-interventional hospital stay and haemodynamic parameters were assessed and compared between the patients with no, minor or major complications.

Statistical analysis

Statistical analyses of patient demographics, complication rates and average length of post-interventional hospital stay after occurrence of no, minor or major complications were calculated. Values are presented as mean ± standard deviation. Comparisons between pre- and post-interventional parameters

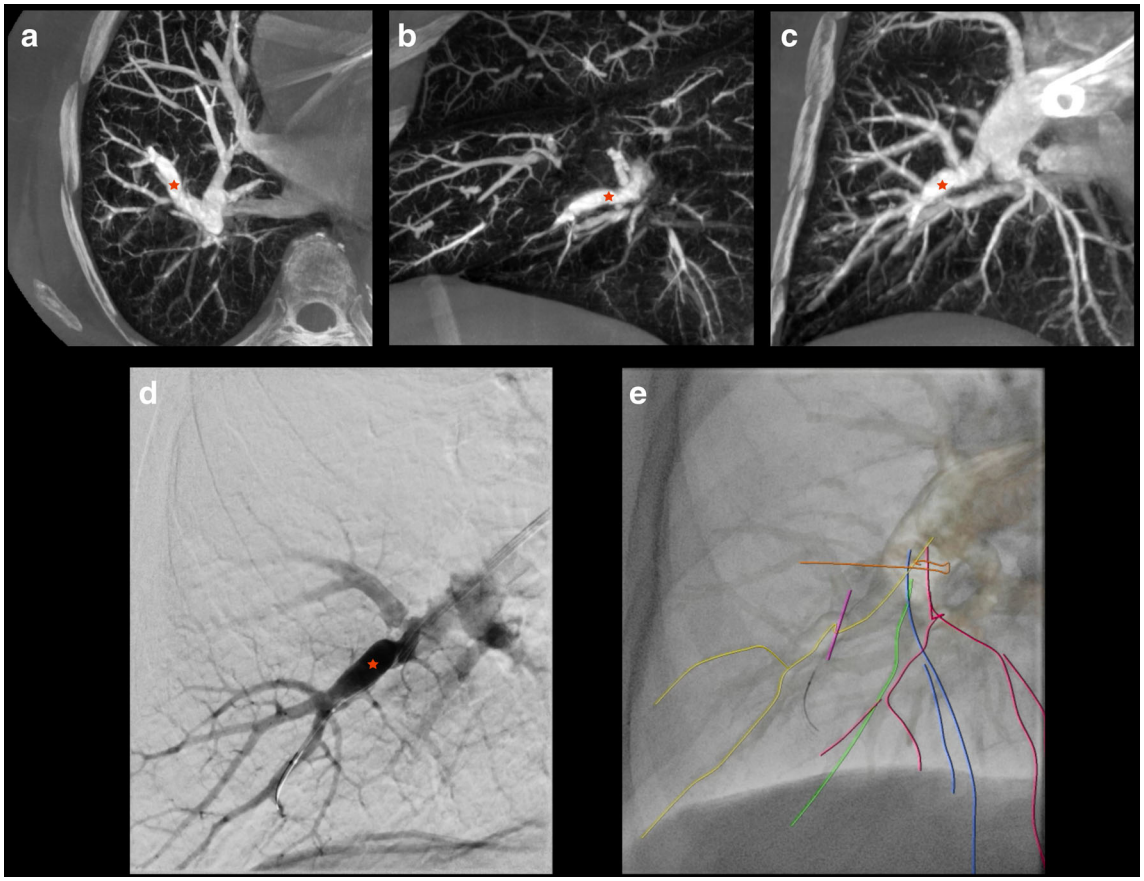

Fig. 1 Example of CACT guidance. **a** Contrast-enhanced CACT of the pulmonary arteries, axial plane. ★ marks the targeted pulmonary artery that is also labelled in images (**b**–**e**); (**b**) contrast-enhanced CACT of the pulmonary arteries, coronal plane; (**c**) maximum intensity projection images (25 mm) of the pulmonary vessels based on the acquired CACT; (**d**) selective, pre-interventional DSA of the pulmonary arteries; (**e**) after successful 'bone removal' in the acquired CACT, centre lines were created in vessels with suspected BPA targets and superimposed on fluoroscopy peri-interventionally in the angiographic suite in order to provide anatomical vessel information

were made using the pairwise Wilcoxon signed-rank test. A p-value < 0.05 was defined as significant. Statistical analyses were conducted using commercially available software (JMP 12, SAS Institute, Cary, NC, USA).

Results

In 237 of the 266 interventional procedures, no complications occurred (89.1%). Minor complications without the need for additional treatment and without consequences occurred in 11 procedures (Grade A, 4.1%). Minor complications not requiring further therapy and without consequences but requiring post-interventional observation occurred during or after 14 interventions (Grade B, 5.3%), including one case of reperfusion oedema becoming clinically apparent by aggravated post-interventional dyspnoea. During four procedures major complications requiring additional treatment were observed (Grade C, 1.5%): One procedure leading to pulmonary haemorrhage (0.4%) and two procedures causing post-interventional haemoptysis (0.8%). All of these were treated successfully with epinephrine inhalation and required no further interventions. One patient developed atrial tachycardia induced by catheterisation, which resolved after pharmacological cardioversion (0.4%); for details refer to Table 2. More severe complications (Grade D and E) or mortality (Grade F) were not observed. Examples of a focal pulmonary artery dissection and a pulmonary haemorrhage due to pulmonary artery perforation are presented in Figs. 2 and 3. On average we treated three pulmonary arteries per BPA session, which is in accordance with current literature (152 (18.9%) right upper lobe; 91 (11.3%) middle lobe; 271 (33.7%) right lower lobe; 90 (11.2%) left upper lobe; 200 (24.9%) left lower lobe). The average amount of contrast media was 191.2 ± 54.2 ml. Mean radiation dose was 7,652 ± 5 190.7 μGym^2 and mean fluoroscopy time was 31.9 ± 11.7 min. No patient developed an acute renal insufficiency or a radio-dermatitis.

The mean post-interventional hospital stay was 1.9 ± 0.8 days regardless of the complications, thus a relevant difference concerning the hospitalisation between the procedures without complications and with minor or major complications could not be demonstrated. In our study the pre-interventional

Table 2 Overview of complications during or following BPA

Parameter	Value
No complications, n (%)	237 (89.1%)
Grade A*, n (%)	
Dry cough	11 (4.1%)
Grade B*, n (%)	14 (5.3%)
Focal dissection	3 (1.1%)
Pulmonary haemorrhage	4 (1.5%)
Reperfusion oedema	1 (0.4%)
Haemoptysis	6 (2.3%)
Grade C*, n (%)	4 (1.5%)
Pulmonary haemorrhage	1 (0.4%)
Haemoptysis	2 (0.8%)
Atrial tachycardia	1 (0.4%)
Grade D*, n (%)	0 (0.0%)
Grade E*, n (%)	0 (0.0%)
Grade F*, n (%)	0 (0.0%)

BPA balloon pulmonary angioplasty

*SIR Classification System to Complications by Outcome: Grade A = no therapy, no consequence; Grade B = nominal therapy, no consequence; includes overnight submission for observation only; Major complication: Grade C = requires therapy, minor hospitalisation (< 48 h); Grade D = requires major therapy, unplanned increase in level of care, prolonged hospitalisation (> 48 h); Grade E = permanent adverse sequelae; Grade F = death'

mPAP was higher (56.5 ± 16.9 mmHg) in patients with major complications compared to the groups with minor (46.9 ± 11.6 mmHg) or no complications (39.9 ± 11.1 mmHg). Regarding the patients with completed BPA therapy (n=46) within the aforementioned groups, the total decrease of mPAP in patients without any peri- or post-procedural complications was higher (-17.5%; 39.9 ± 11.1 mmHg vs. 32.9 ± 10.5 mmHg; n=33; $p < 0.0001$) than in patients with minor (-8.7%; 47.2 ± 8.9 mmHg vs. 43.1 ± 10.8 mmHg; n=10; p=0.1) or major complications (-9.2%; 51.0 ± 15.7 mmHg vs. 46.3 ± 17.0 mmHg; n=3; p=0.3). No other differences regarding clinical parameters were observed.

Discussion

The present study demonstrated a low complication risk of CACT-guided BPA, making it overall a safe treatment option for patients with CTEPH not suitable for surgery.

In an editorial, Matsubara et al stated that diagnostic tools such as selective CACT are ineffective in reducing procedure associated complications [30]. This statement conflicts with the recent observation that dedicated guidance techniques are used more and more to minimise the potentially life-threatening complications of BPA in several countries [19–25]. Thus, we respectfully disagree with the statement of Matsubara et al [30]. Our low complication rate and zero mortality with proven effective treatment indicates that CACT image guidance in this complex procedure is applicable and safe in experienced hands [17].

The currently available literature regarding complications of BPA presents a broad range of complication rates with inconsistency in complication assessment [12–16, 25, 31]. Due to diverse definitions of side effects, minor and major complications, missing documentation or differentiation of complications, a comparison of peri- and post-procedural safety is challenging. By applying the SIR Classification System for Complications by Outcome to the reported complications in the previously published data, the number of reported typical major and, if documented, minor complications after BPA is distinctly higher when compared to our study (Table 3). Thus, procedure guidance with the use of CACT may be valuable. Major complications were detected in approximately 1.5% of the included BPA procedures. The number of reported major complications in the aforementioned Japanese multicentre study was 1.2% and therefore comparable to our results [18]. However, the definition of complications differed essentially as we categorised complications according to the SIR Classification System for Complications by Outcome, which labels any complication at least requiring therapy and minor hospitalisation (< 48 h) as 'severe' (≥ Grade C), whereas the publication from Japan defined a severe complication as at least necessitating tracheal intubation with mechanical ventilation and in some rare cases even extracorporeal membrane oxygenation, which would equate to ≥ Grade D following SIR criteria [18, 29]. Altogether, referring to this classification, the major complications occurring in our patient cohort were less grave as the maximum escalation of inevitable therapy was epinephrine inhalation to induce haemostasis in pulmonary haemorrhage, pharmacological cardioversion and short-term intensified observation (Grade C).

Previous studies have reported a frequency of severe reperfusion oedema of 6–7% and of reperfusion oedema in general of 18%, up to approximately 87% [13, 18]. The higher values were reached without the use of dedicated guidance techniques and by use of routine post-interventional conventional x-rays and CT-scans of the chest with nebulous clinical impact [13], which is not performed in our hospital. In our study, only one patient developed clinically apparent reperfusion oedema without the need for specific therapy (0.4%).

Besides reperfusion oedema, haemoptysis is another frequently reported complication of BPA. In previous series, the occurrence of haemoptysis ranged from 5.6% to 5.7% [13, 18, 31, 32]. In our study the total number of haemoptysis cases made up 3.1%; a quarter of these patients (0.8%) had to be treated with epinephrine inhalation to induce haemostasis. The necessity for tamponade of the

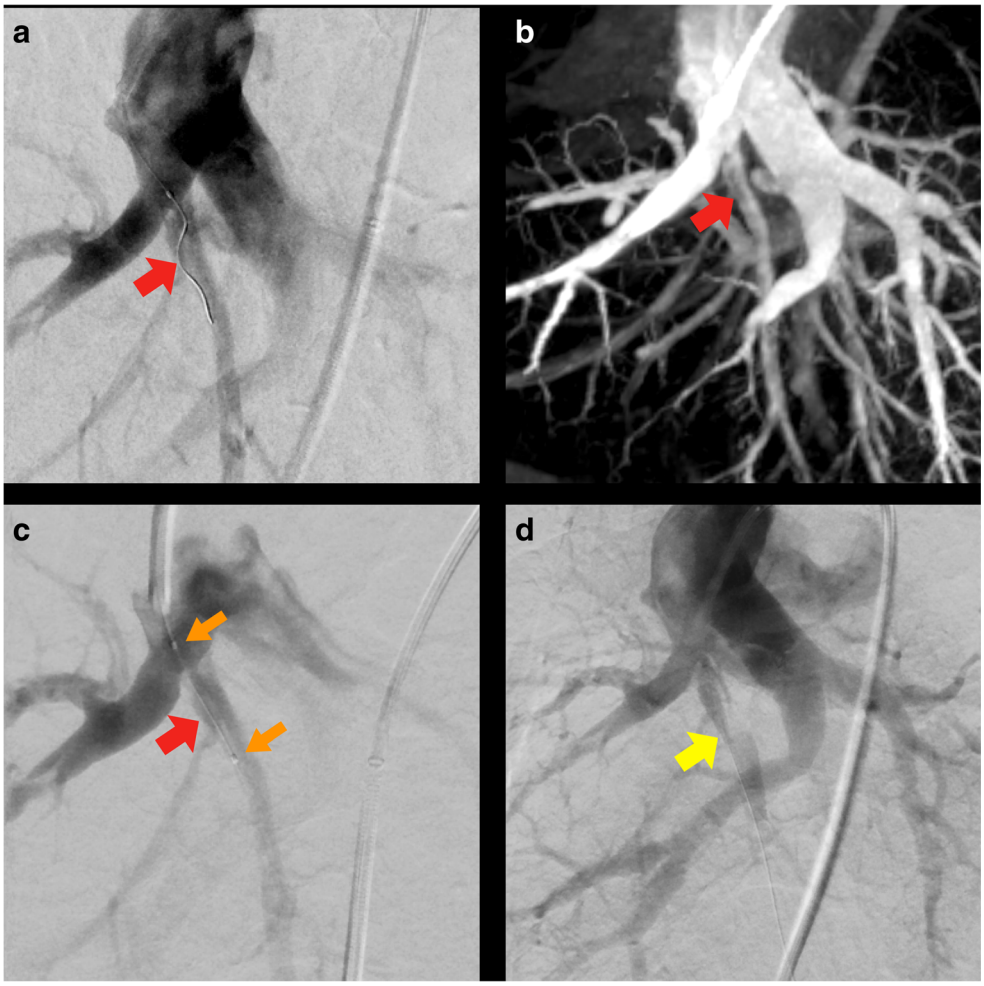

Fig. 2 Example of pulmonary artery dissection. **a** Selective, pre-interventional DSA of the pulmonary arteries, the red arrow marks the targeted vessel. **b** Maximum intensity projection images (25 mm) of the pulmonary vessels based on the acquired CACT. **c** Inflation of the balloon catheter across the targeted stenosis, the orange arrows mark both ends of the inflated balloon. **d** Post-interventional DSA showing a focal dissection of the targeted pulmonary artery due to balloon oversizing, marked by the yellow arrow

bleeding vessel with long-time ballooning, which is prescribed with a frequency of up to 3.3%, was not required in our patient cohort [25, 31, 32].

Other vessel-associated complications in BPA are pulmonary artery perforation, which is reported with a frequency of 2–3% and appeared in our cohort in one case (0.4%), as well

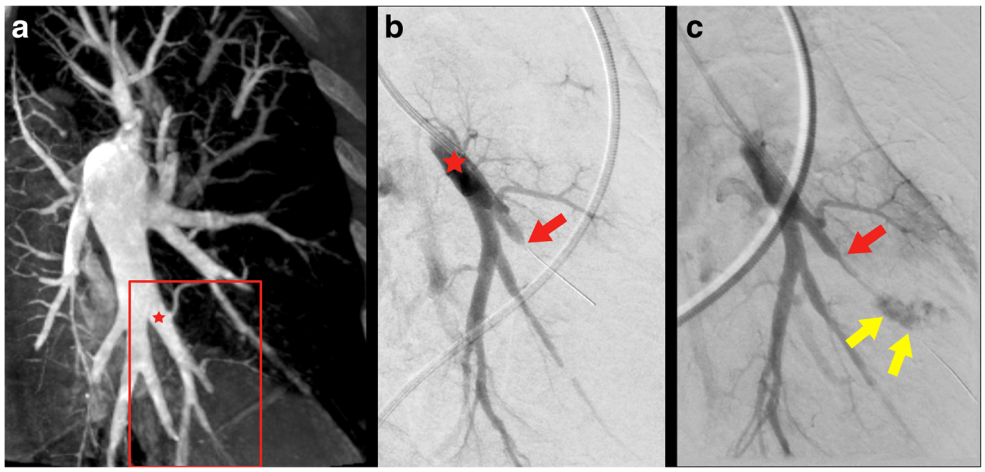

Fig. 3 Example of pulmonary haemorrhage due to pulmonary artery perforation. **a** maximum intensity projection images (25 mm) of the pulmonary vessels based on the acquired CACT, ★ marks the pulmonary segmental artery that is shown in detail in images (**b**) and (**c**). **b** Selective DSA of the targeted pulmonary artery before intervention, the red arrow marks the guidewire crossing the target lesion in the obliterated pulmonary artery. **c** post-interventional DSA, the yellow arrows mark pulmonary haemorrhage due to guidewire perforation of the vessel

Table 3 SIR Classification System to Complications by Outcome applied to recent publications

Grade	Kataoka 2012 [12]	Mizoguchi 2012 [13]	Sugimura 2012 [14]	Andreassen 2013 [15]	Inami 2014 [31]	Fukui 2014 [16]	Taniguchi 2014 [38]	Ogawa 2017 [18]	Current study 2018
A (%)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	4.1
B (%)	1.9	56.9	n.a.	n.a.	n.a.	n.a.	32.6	FX 30.8*	5.3
C (%)	46.2	31.0	50.0	9.5	8	n.a.	27.9		1.5
D (%)	5.7	1.6	0	0	5	0	8.2		0
E (%)	1.9	0.8	0	0	0	0	0	5.5	0
F (%[1]/%[2])	1.9/3.4	0.4/1.5	0	2.7/10.0	0.3/1.0	0/0	1.2/3.4	0.9/3.9	0

n.a. not acquired

* Overall number of complications that needed further treatment without further information regarding the applied therapy

[1] Deaths per total number of interventions

[2] Deaths per total number of patients

as pulmonary artery dissection, which is reported with a frequency of 0.4–2.3% [13, 18, 31, 32], and appeared in our cohort in three interventions (1.1%). However, in our patient cohort, only in one patient with pulmonary vessel injury was further treatment was required. In this patient, haemostastis was also induced by epinephrine inhalation. Coiling or stenting of the injured artery, as described elsewhere with a frequency of up to 40% after vessel injury and in up to 1% of all BPA procedures, was not necessary [13, 18, 31, 32].

We observed an overall higher pre-interventional mPAP in the group of patients with major peri- or post-procedural complications without statistical significance most probably due to the low number of patients with major complications. The effect of a highly elevated mPAP in the occurrence of major complications during or after BPA has not been systematically investigated yet and needs further examination. However, it is conceivable that higher pulmonary artery pressures increase the risks of more severe bleeding in case of injury to the pulmonary vessel wall.

Altogether, we observed an overall complication rate of 10.9%, including recurring peri-interventional dry cough as a mild side effect without clinical impact in 4.1% of BPA procedures. There are different reasons for this relatively low complication rate: First, it might be related to the anticoagulation management used in our patient cohort with direct anticoagulants kept on hold for the day of the intervention without bridging, which is not in agreement with current literature, where anticoagulation is maintained [13, 15, 31]. Second, conventional angiography was supplemented with the use of high-resolution 3D CACT guidance. Its diagnostic accuracy is better when compared to multidetector computed tomography (MDCT) and DSA as it provides more detailed imaging of peripheral pulmonary arteries and web stenosis [17, 22]. This information might add true value to the procedure because vessel structures distal to target lesions like bifurcations and ostia of branches can be assessed on 3D CACT to avoid vascular injury by the guidewire or guiding catheter [33]. This point is of special importance when treating occluded lesions, which are known to have higher rates of complications and where vessel structures distal to the target lesion cannot be adequately assessed by DSA [34]. Third, balloon size was adjusted to the actual vessel size based on 3D CACT information as diameter measurements on DSA are known to be imprecise [35, 36]. This leads to less overdilatation of the respective vessel segments, further lowering bleeding risk. It is well known that CACT guidance for BPA enables the identification of target lesions prior to the procedure and offers not only a luminal view of the arterial vessels but also information on the perivascular soft-tissue and bronchial structures, facilitating easy determination of exact vessel diameter and adequate balloon size [22]. Similar to what was reported for intravascular ultrasound (IVUS) and optical coherence tomography (OCT) [19, 20], CACT helps to reduce the risk of dissections and perforations with potentially severe bleeding complications. Although there are no studies directly comparing these methods, CACT is less invasive and does not increase cost, procedure time and complexity [22, 23]. However, CACT acquisition adds radiation exposure, which needs to be considered when evaluating the applicability and possible significance in procedure guidance for BPA as disadvantage of CACT. The effective radiation dose of thoracic CACT ranges from 1.8–2.6 mSv, which is comparable to that of MDCT and ventilation/perfusion single photon emission computed tomography (V/Q SPECT) [22, 27]. Considering the whole BPA procedure, CACT accounts for a relatively small portion of the overall radiation exposure, which is caused mainly by fluoroscopy [22, 27]. Furthermore, CACT can be utilised for guidance in several positions, thus reducing both fluoroscopy time and number of supplemental angiograms in different angulations. Moreover, CACT from one session can be re-utilised for subsequent BPA procedures, thus reducing the overall radiation dose needed for CACT [22, 27]. Another possible disadvantage of CACT is the additional need for contrast media. Our CACT protocol uses 35 ml

of contrast media and the overall amount of contrast media is 191.2 ± 54.2 ml. The total contrast amount in our cohort is comparable to the literature even though we use CACT [37]. Therefore, CACT seems not to increase the usage of contrast agents. Furthermore, the current literature describes improvements in renal function following BPA despite the use of high contrast doses [37]. CACT acquisition might be impaired by breathing artefacts, which we did not observe in our current study.

Limitations

There are some limitations to our study. First, our study was a single-centre study with a limited number of patients. The reliability of our findings should be further evaluated within a global multicentre study. Second, we did only use CACT guidance. Therefore, peri- and post-procedural complications were compared to data reported in the literature. This is somewhat challenging due to differences in peri-procedural management, reporting standards and definitions of complications, which makes evaluation and judgement of complications and complication severity difficult. Therefore, the use of a structured, consistent and well accepted documentation of possible side effects, for example the SIR Classification System to Complications by Outcome, would be reasonable.

Conclusion

BPA performed under CACT guidance appears to be a safe procedure with a low risk of severe complications.

Funding The study was funded in parts by personal grants from the "Junge Akademie" of Hannover Medical School (Dr. Maschke, Dr. Hinrichs and Dr. Renne).

Compliance with ethical standards

Guarantor The scientific guarantor of this publication is Frank Wacker.

Conflict of interest The authors of this manuscript declare relationships with the following companies: Siemens Healthcare and ProMedicus (Bernhard Meyer and Frank Wacker; outside the submitted work); Bayer (Marius Hoeper and Karen Olsson; outside the submitted work). The remaining authors declare no relationships with any companies whose products or services may be related to the subject matter of the article.

Statistics and biometry One of the authors has significant statistical expertise.

Informed consent Written informed consent was waived by the Institutional Review Board.

Ethical approval Institutional Review Board approval was obtained.

Methodology
- Retrospective
- Experimental/intra-individual comparison
- Performed at one institution

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