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UROLITHIASIS

Renal parenchyma injury after percutaneous nephrolithotomy tract dilatations in pig and cadaveric kidney models

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Introduction Miniaturization of instruments has changed the paradigms of percutaneous nephrolithotomy (PCNL). To date, however, few studies have analyzed the possible renal trauma generated by PCNL tract dilation. The purpose of this study is to evaluate and compare systematically the renal injury of all PNCL dilation techniques in pork kidneys (PK) and cadaveric kidney models (CK).

Material and methods Twelve dilation devices were tested (from 4.8 to 30 French (Fr)) including micro- and mini- PCNL kits, the Alken dilation set, 20 and 30 ATM balloons and the Amplatz set. Each device was tested six times in PK and CK. Morphologic analysis of tract defects of the different models and dilators were made measuring the longest axis and the area of renal parenchymal damage.

Results When comparing the PK and CK dilation tract areas to the device areas, major differences were seen with the 20 ATM 30 Fr balloon ($p = 0.0001$ and 0.008) respectively, the sequential Amplatz dilation to 30 Fr ($p = 0.0005$ and 0.0006) respectively, and the Alken 30 FR dilation ($p = 0.012$ and 0.02) respectively. The 30 Fr dilations were 32.76 mm^2 (mean) larger than the instruments themselves, while the ≤24 Fr dilations were 11.6 mm^2 (mean) larger than the instruments themselves.

Conclusions When comparing devices and tract areas, the dilation tract area exceeded device area by 11.6 mm^2 at dilations up to 24 Fr *vs.* 32.76 mm^2 with dilations of 30 Fr. Overall, PK had significantly larger injuries than CK models.

Key Words: percutaneous nephrolithotomy ‹› dilation ‹› pig ‹› animal ‹› cadaver

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is the current standard of care for renal stones larger than 2 cm [1]. Technological improvements have provided urologists with a wide armamentarium of dilation devices for kidney access, with sizes ranging from 4.8 to 30 French (Fr) [2, 3, 4]. Miniaturization of instruments has impacted on indications, as smaller tracts theoretically reduce complications such as blood loss [5, 6]. To date, however, few studies have analyzed the possible renal trauma generated by PCNL tract dilation [7, 8, 20]. These investigations have been done mainly in animal models to assess the scar tissue after the procedure and the tract defect has rarely been described [9]. To our knowledge, no studies have evaluated the renal damage in human cadaveric kidneys (CK) with the most recent devices.

The purpose of this study was to evaluate and compare systematically the renal injury associated with all currently available PNCL dilation techniques in porcine kidney (PK) and CK models.

MATERIAL AND METHODS

Twelve dilation devices were tested: the 4.8 Fr MicroPerc® (Rocamed®); five dilators of the MIP: Minimally

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Invasive PCNL™ kit (Karl Storz®): 8.5/9.5 Fr, 11/12 Fr, 15/16 Fr, 16.5/17.5 and 21/22 Fr; two NephroMax™ (BostonScientific®) 20 ATM balloon dilators: 24 and 30 Fr; two X-Force® (Bard®) 30 ATM balloon dilators: 24 and 30 Fr; and the Alken (Karl Storz®) and Amplatz (Cook Medical®) sequential dilator sets. The dilations were performed in 11 PKs and in eight fresh human CKs in the upper, mid and lower poles, following Brodel's line and avoiding close dilations. The dilation sequence included a visually guided puncture with an 18-gauge Chiba needle into the collecting system through the renal papilla, with subsequent introduction of a PTFE-coated guidewire to guide the dilation device insertion. One-step dilations were performed with the MicroPerc®, the MIP™ kit, and the balloons. With the Amplatz kit over the PTFE catheter, sequential dilations to 24 Fr and 30 Fr were performed, as well as, two-step dilations using the 16 and 30 Fr instruments. The Alken set dilation was tested with sequential dilations up to 24 and 30 Fr. Each device was tested six times (three dilations in the PK and three in the CK).

Sequential photographs were taken of each specimen. Measurements of the longest diameter and the superficial area of the capsule and renal parenchyma edges surrounding the tract were done with the histologic analysis software Image J. Morphologic analyses of tract defects and comparisons of the different models were performed. A two-way ANOVA test was used to compare results. A p value <0.05 was considered significant.

RESULTS

Eleven PK bought at a local butchery and eight human CK from two females and two males with a mean age of 89 years (86–92 years) was used.

Forty-five dilations were performed for both PK and CK. The area of the dilation devices was calculated according to the manufacturer's information regarding the outer instrument diameter. All dilation devices had a circular shape and the areas ranged from 2.01 to 78.54 mm^2 (Table 1).

Morphologic evaluation

MicroPerc®: In both PK and CK, dilations were oval with clean edges and no parenchymal or capsule rupture.

MIP™: In PK, 8.5 to 16 Fr dilations resulted in an occasional renal fissure of <1 mm. Using the 16.5/17.5 Fr dilations, one 1.5-mm renal rupture appeared; this became more obvious with the 21/22 Fr instrument, and the oval shape was distorted into a V shape due to two or three renal fissures of 2–2.5 mm.

In CKs, dilations with the MIP™ had circular and oval shapes. The 8.5/9.5 to 16.5/17.5 Fr tracts showed 1-mm capsular retraction and fissures, while the 21/22 Fr tracts showed 1-mm renal rupture and capsular retraction.

Balloons: In PKs, dilations with the 24 and 30 Fr 20 ATM balloons were oval and mostly displayed clean edges but some 3- to 4.5-mm parenchymal fissures

Table 1. *Mean dilation areas and mean dilation diameters for each device in pig and cadaver kidneys*

Device (Fr)	Device Diameter (mm)	Device Area (mm^2)	Pig Dilation area Mean ±SD (mm^2)	Cadaver Dilation area Mean ±SD (mm^2)	Pig Dilation diameter Mean ±SD (mm)	Cadaver Dilation diameter Mean ±SD (mm)
MicroPerc (4.8)	1.6	2.01	0.52 ±0.16	1.05 ± 0.36	1.37 ±0.42	1.63 ±0.42
MIP-1 (8.5/9.5)	3.17	7.84	2.61 ±1.21	5.63 ± 0.93	2.71 ±0.89	3.18 ±0.73
MIP-2 (11/12)	4	12.57	7.05 ±1.06	5.61 ±0.46	4.60 ±0.19	3.24 ±0.26
MIP-3 (15/16)	5.3	22.06	11.52 ±3.73	8.90 ±3.43	6.28 ±1.29	4.44 ±0.64
MIP-4 (16.5/17.5)	5.8	26.42	12.97 ±3.26	13.20 ±2.03	6.05 ±1.07	5.51 ±0.94
MIP-5 (21/22)	7.3	42.2	27.89 ±24.97	23.98 ±6.26	10.58 ±1.14	8.54 ±1.28
Balloon 20 ATM-1 (24)	8	50.27	30.31 ±8.65	31.20 ±10.51	12.53 ±0.88	7.49 ±0.68
Balloon 20 ATM-2 (30)	10	78.54	34.23 ±13.81	47.60 ±1.54	14.58 ±0.65	10.80 ±1.03
Balloon 30 ATM-3 (24)	8	50.27	35.43 ±8.72	48.73 ±6.01	12.21 ±0.79	10.94 ±0.48
Balloon 30 ATM-4 (30)	10	78.54	80.97 ±16.82	57.13 ±12.80	16.31 ±1.05	12.82 ±0.94
Amplatz (sequential)-1 (24)	8	50.27	19.29 ±5.79	26.79 ±0.60	9.95 ±1.99	7.04 ±1.06
Amplatz (sequential)-2 (30)	10	78.54	38.71 ±11.02	38.83 ±6.98	13.66 ±2.39	11.45 ±1.51
Amplatz (two-step) (30)	10	78.54	62.08 ±7.17	49.99 ±11.48	15.80 ±3.56	11.62 ±3.58
ALKEN-1 (24)	8	50.27	32.73 ±11.63	30.18 ±2.78	10.17 ±1.13	9.17 ±1.36
ALKEN-2 (30)	10	78.54	48.81 ±7.54	50.78 ±4.35	11.70 ±1.83	10.54 ±0.80

appeared. The 24 and 30 Fr 30 ATM balloons yielded consistent results, with large parenchymal disruptions that became deep with the 30 Fr balloon.
In the CK, the 24 and 30 Fr 20 ATM balloon dilations were oval and irregular, and the capsules had 1- to 2.5-mm and 3- to 4-mm ruptures and retractions, respectively. The 24 and 30 Fr 30 ATM balloons yielded similar results to the 20 ATM balloons, but the edges were even more irregular and tortuous.
Amplatz set: In the PK, the sequential dilation showed mainly distorted oval shapes, with one <2 mm renal fissure for the 24 Fr dilation and fissures from 2 to 4 mm for the 30 Fr dilation. The two-step dilation produced deep renal ruptures of 2–4 mm in two specimens, while the third specimen had a V-shaped dilation due to two major deep fissures of 7 mm. In the CK, 24 and 30 Fr sequential dilations had clean edges. The 24 Fr dilation produced 1-mm ruptures and 2- to 3-mm capsule retractions, while the 30 Fr dilation resulted in a 4.4-mm capsule retraction and rupture. The two-step dilation showed a 3- to 4-mm capsule retraction with rupture at both edges of the oval.
Alken set: In PK and CK, 24 Fr dilations showed uneven edges and 1-mm fissures while 30 Fr tracts had oval shapes with 1- to 3-mm parenchymal fissures. One PK specimen showed a major shape distortion due to a large 5-mm fissure.
Examples of the dilations are shown in Figures 1 and 2.

Dilation areas and diameters

Mean dilation areas ranged from 0.52 to 80.9 mm^2 in the PK and from 0.35 to 12.8 mm^2 in the CK. The dilation diameters ranged from 1.37 to 16.31 mm in PK and 12.82 mm in CK (Table 1).
Comparison of device area with the PK and CK dilation tract areas (Figure 3) revealed major differences with the 20 ATM 30 Fr balloons ($p = 0.0001$ and 0.008 respectively), the sequential Amplatz dilation to 30 Fr ($p = 0.0005$ and 0.0006 respectively), and the Alken 30 Fr dilation ($p = 0.012$ and 0.02 respectively). The 30 Fr dilations were 32.76 mm^2 (mean) larger than the instruments themselves, while the ≤24 Fr dilations were 11.6 mm^2 (mean) larger than the instruments themselves. The Amplatz two-step dilation was significantly larger only in the CK and the Alken 24 Fr dilation was significantly larger only in the PK ($p = 0.0016$ and 0.008 respectively).
Upon comparison of the device diameters with the PK and CK dilation diameters (Figure 4), only the PK were found to have significantly larger injuries

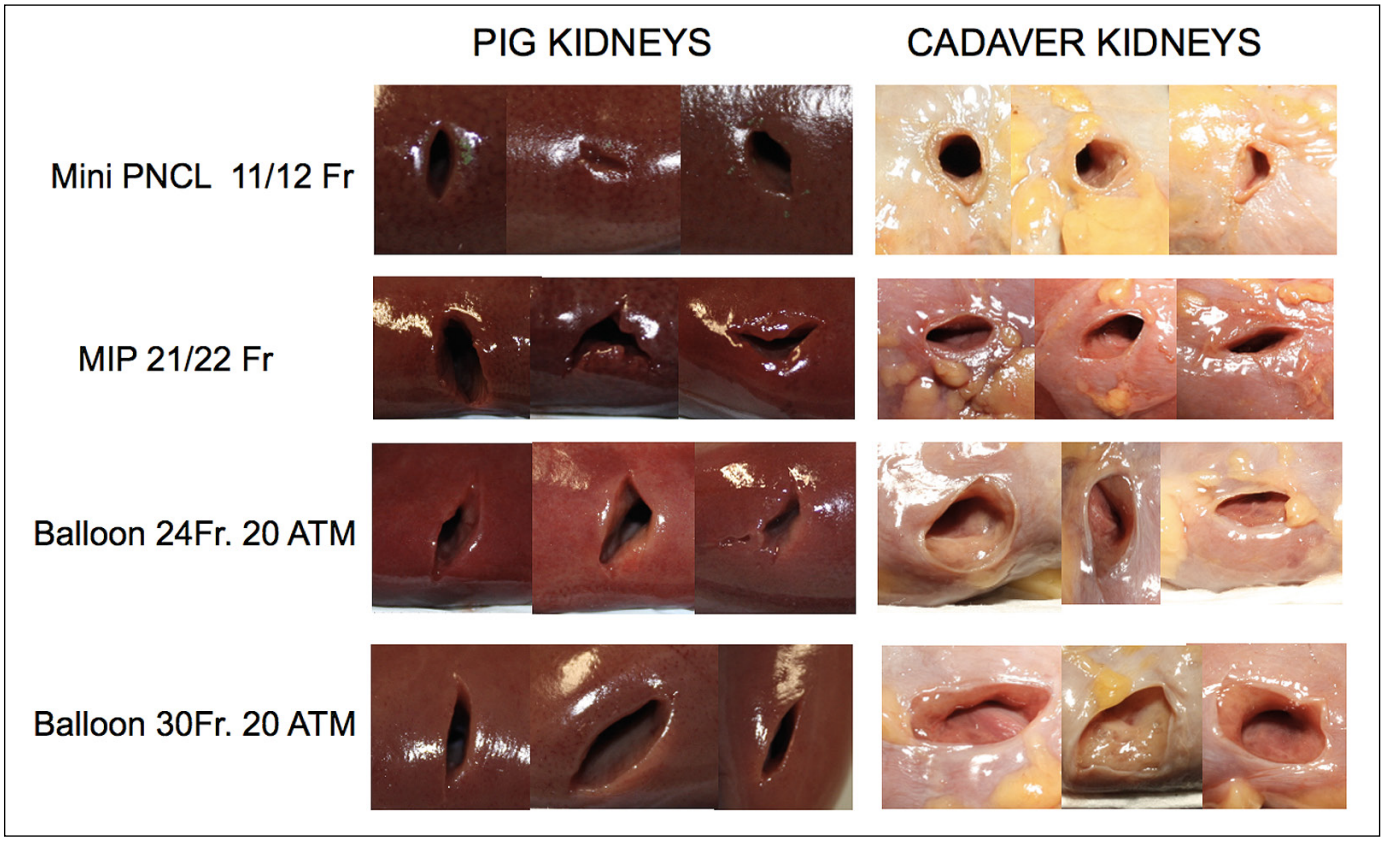

Figure 1. *Dilation morphology.*

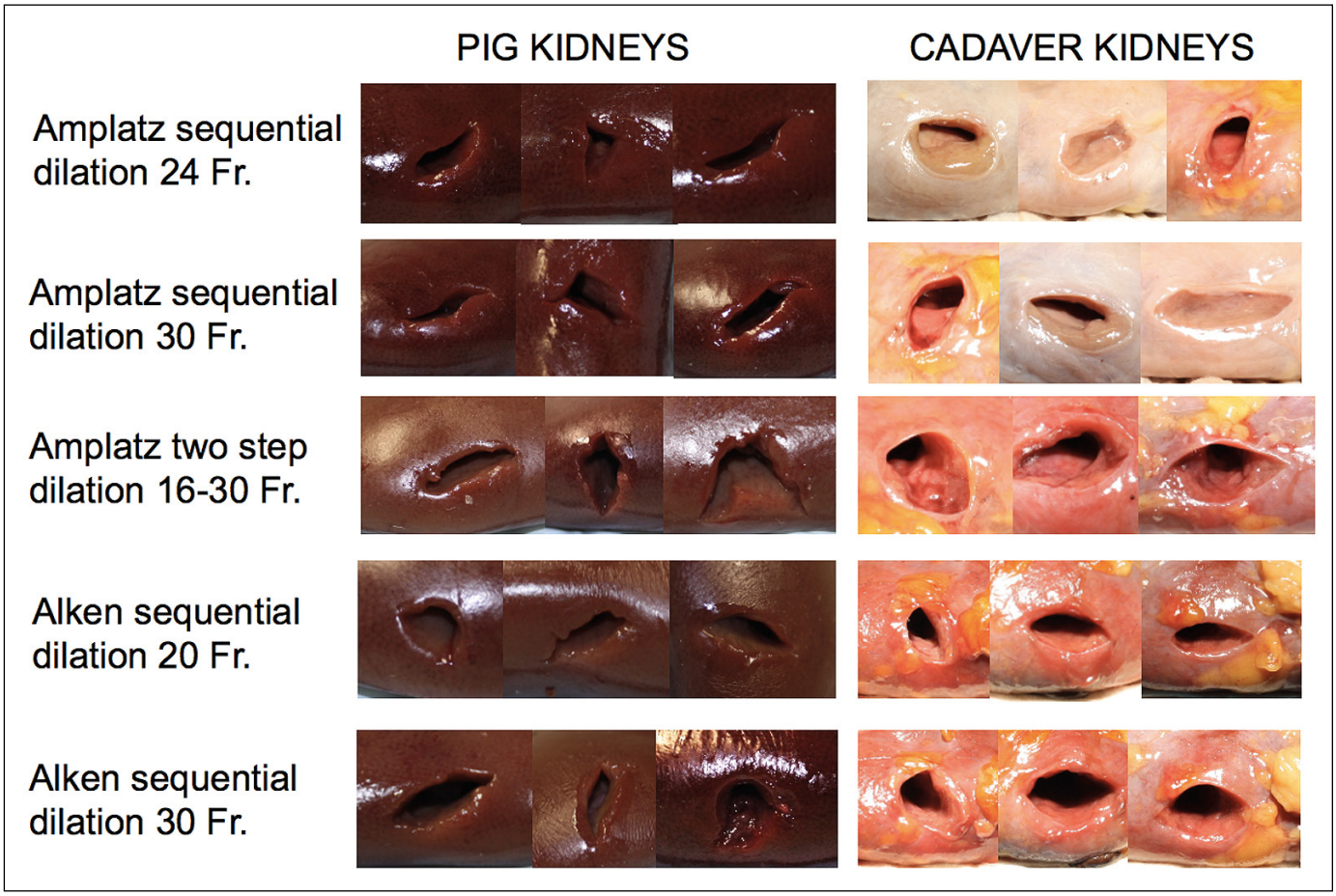

Figure 2. *Dilation morphology.*

with the balloons (especially the 30 ATM 30 Fr, p = 0.0008) and Amplatz two-step dilation (p = 0.002). When comparing the PK and CK tract diameters, significant differences were seen with the balloons (except in the 24 Fr 30 ATM device) and the Amplatz set when reaching 30 Fr with the two-step dilation and 24 Fr with the sequential dilation (p = 0.0017 and 0.03 respectively). Comparison of PK and CK areas revealed significant differences only with the 30 ATM 30 Fr balloon (p = 0.004).

DISCUSSION

A variety of dilator sizes have been described for PCNL access, ranging from standard 30 Fr through 'mini' dilators (13–24 Fr), more suitable for stones 1.5–2 cm in size, to 'ultramini' dilators (11–13 Fr) and the MicroPerc® (4.8 Fr), preferred for stone sizes <1.5 cm [5, 10]. In the current study, we tested all the sizes and materials currently available. Success rates of PCNL exceed 90% [5, 19], and major complications were accordingly uncommon. Overall complication rates may reach 83% [11], with the incidence of renal hemorrhage ranging from 0.6% to 1.4% and that of transfusion from 11.2% to 17.5% [12, 13].

Tract dilation techniques have been studied as possible factors influencing bleeding and morbidity in PCNL. It has been suggested that use of balloons over Alken metal dilators reduces transfusion rates from 25% to 10% [14], although this claim is not consistent with other literature [15]. The CROES study in a series of 5,537 patients found that balloon dilation produces significantly more bleeding than telescopic/serial dilation (9.4% *vs.* 6.7%, respectively; p <0.0001) and more transfusions (7.0% *vs.* 4.9%, respectively; p = 0.001) [16]. This can be explained by the increased laceration seen in this study, where balloon dilations produced increased blunt trauma, renal rupture, and tract irregularities than Alken and Amplatz dilators; this was especially evident with 30 Fr 30 ATM balloons. Similarly, an investigation by Al-Kandari et al. [9] showed, in a euthanized animal model, 25-mm V-shape fissured dilation tracts with 30 Fr balloons.

Tract size also has an impact on postoperative morbidity, influencing both pain and hospital stay

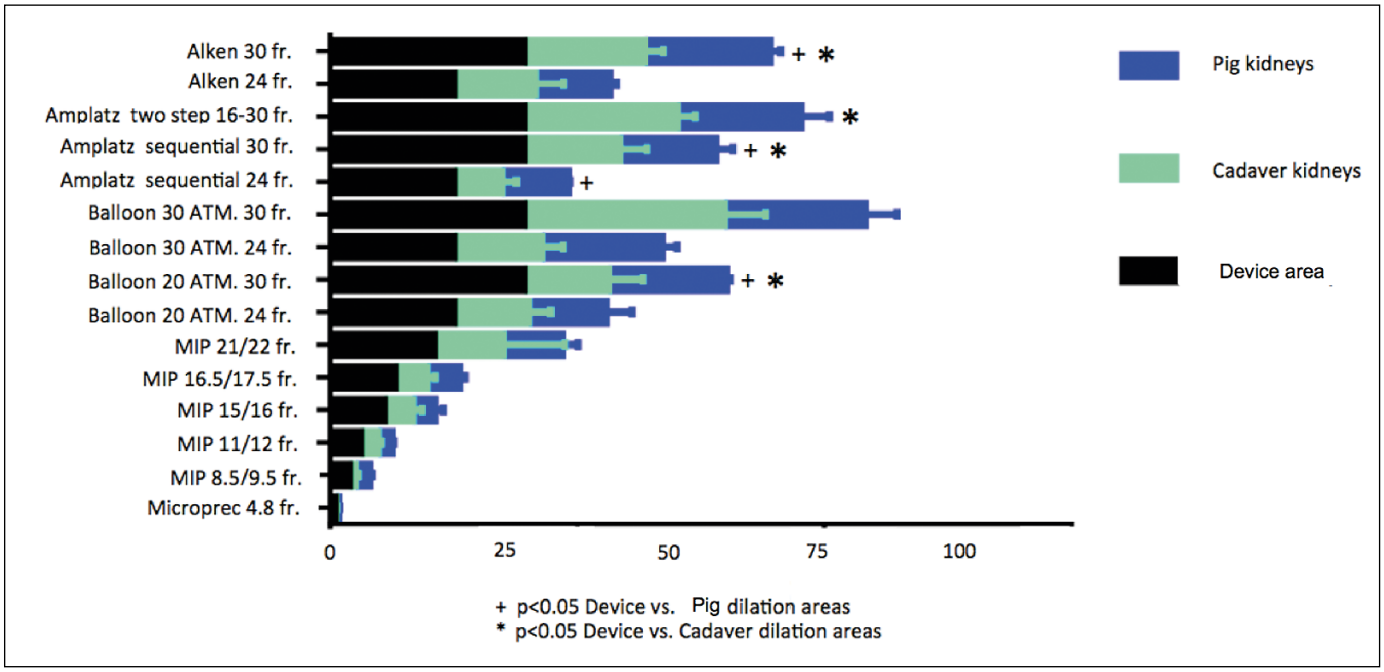

Figure 3. *Device area vs. mean pig kidneys (PK) and cadaveric kidney models (CK) dilation areas (mm²).*

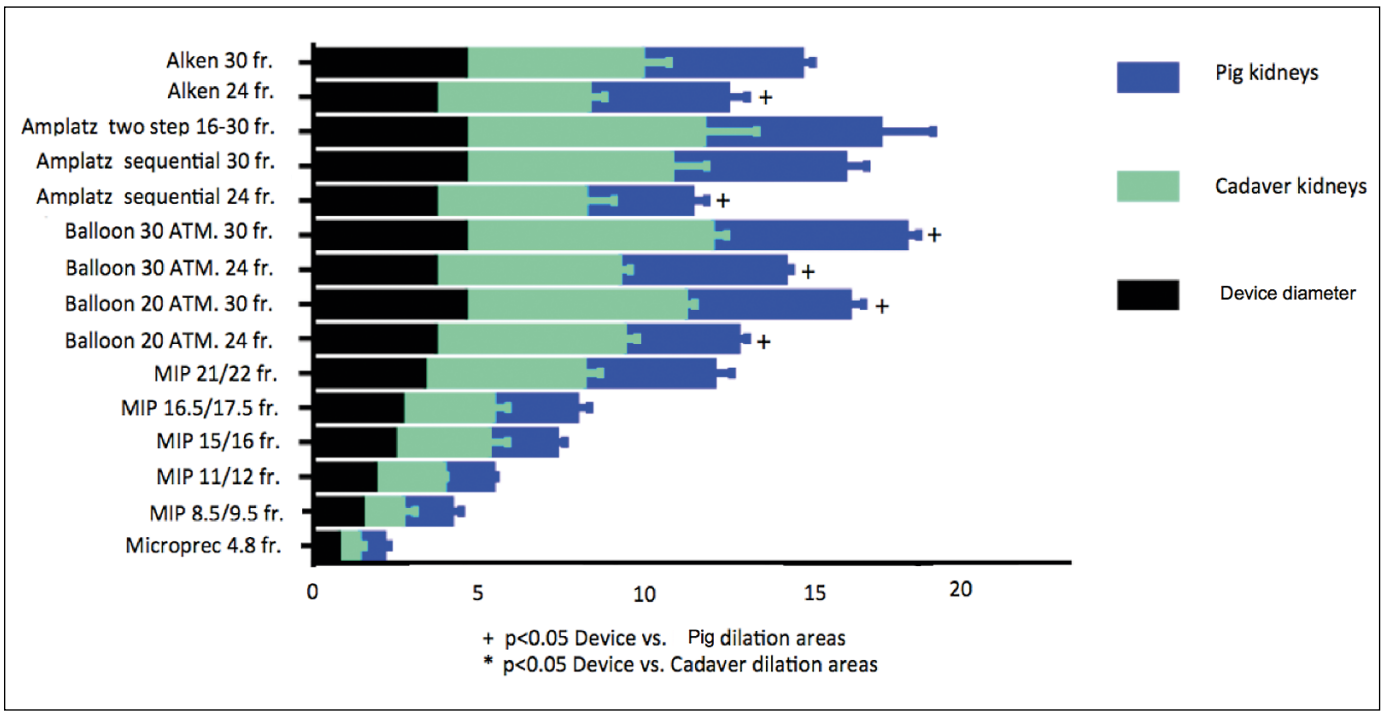

Figure 4. *Device diameter vs. mean pig kidneys (PK) and cadaveric kidney models (CK) diameters (mm).*

[6, 17]. Mishra et al. found a significantly reduced fall in hemoglobin with 15–20 Fr tracts compared with 24–30 Fr tracts: 0.8 ±0.9 g% *vs.* 1.3 ±0.4 g% (p = 0.01) [18]. The CROES study group also reported 1.1% transfusion rates for 18 Fr Amplatz sheath sizes *vs.* 5.9% for sheath sizes from 27 to 30 Fr [16].

These clinical findings correlate with the morphological findings of this study. Overall, significant CK laceration and capsule rupture (2–7 mm) could be seen in dilations above 24 Fr, and Amplatz two-step dilations were associated with more evident capsule fissures. One-step dilations below 22 Fr showed

minimal (<2 mm) parenchymal lesions and capsule retractions. Major significant differences in both PK and CK dilation tract areas, compared with device area, were seen with 20 ATM 30 Fr balloons, sequential Amplatz dilation, and Alken 30 Fr dilation; with Amplatz two-step dilation a significant difference was observed only in the CK.

Although reduced tract sizes have demonstrated good stone free rates of up to 86–96% for 13–18 Fr [17], longer operative times are seen [3, 18, 19].

To our knowledge, no previous studies have evaluated PNCL tract dilations in cadaveric models. We found that dilations were morphologically different in PK when compared with CK. Dilation diameters were larger in PK, with the exception of the two smallest devices; nevertheless, there were almost no significant differences when comparing the dilation areas. The reason for this result may be that human kidneys are stiffer and more rigid, so areas in PK collapsed more easily and fissures were larger. This could also explain why the PK started to show significant parenchymal fissures at dilations from 22 Fr while CK started to show this feature only when reaching 30 Fr. Comparing PK with CK dilation diameters, significant differences were seen with balloon dilators and Amplatz dilators when reaching 30 Fr. Also, PK had significantly larger dilation areas compared with the instrument areas when using the balloons and Amplatz two-step dilations, while CK did not show any difference. With balloon dilations, PK had larger renal fissures, but edges were cleaner than after CK tract expansion, which was associated with irregular edges; this was especially evident above 24 Fr. Dilation tracts with the Amplatz and Alken sets produced larger and more significant morphological damage in PK than in CK, particularly at 30 Fr. All these differences cast into doubt whether PK can be truly reliable when studying PCNL, and further evaluations may better consider the use of CK.

Nevertheless, no matter what the dilation size or the instrument used, studies have suggested that scarring is finally well achieved in all kidneys. Clayman et al. have shown in euthanized animal models that there is no significant difference in respect of renal damage between the semi-rigid 24 Fr and 36 Fr balloon dilations at 6 weeks [7]. These findings are similar to those reported in other animal models by Traxer et al., who found no differences in terms of scarring of the tracts with 28 Fr balloons and 11 Fr nephrostomy sheaths [20], and by Al-Kandari et al. after 30 Fr balloon and Amplatz sequential dilations [9]. Also, the volume used for <20 Fr PNCL is less than 1% of the renal volume [21] and medium- and long-term studies have shown no renal function damage [22, 23].

Based on the good outcomes of mini-PNCL [19], the trend toward fewer complications with smaller instruments [6, 17], and the results of this study, we consider that a reasonable recommendation would be to downsize standard PNCL dilations to tracts between 20 and 24 Fr.

One potential limitation of this study is the stiffness of kidneys. Living pig kidneys can be more solid and tense, which, we believe, may produce different parenchymal and capsule lesions than are found in cadaveric models. In addition, the use of living models permits evaluation of peri-renal bleeding.

CONCLUSIONS

In this study both porcine and cadaveric model dilation tracts up to 24 Fr had significantly smaller parenchymal fissures and reduced capsule rupture than when compared with 30 Fr tracts. In this respect, it is to be noted that dilation tract area exceeded device area by 11.6 mm^2 at dilations up to 24 Fr *vs.* 32.76 mm^2 with dilations of 30 Fr.

When comparing devices and tract areas, differences were significant at dilations above 24 Fr with all instruments, with one exception. Overall, morphologically PK had significantly larger injuries than the CK models. When comparing PK and CK tract diameters, significant differences were seen with the balloons and Amplatz dilators.

CONFLICTS OF INTEREST

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