Preliminary Diagnostic Reference Levels for Endoscopic Retrograde Cholangio-Pancreatography in Greece

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Abstract

Purpose

The main objective of this study was to determine the preliminary Diagnostic Reference Levels (DRLs) in terms of Kerma Area Product (KAP) and fluoroscopy time (Tf) during Endoscopic Retrograde Cholangio-Pancreatography (ERCP) procedures. Additionally, an investigation was conducted to explore the statistical relation between KAP and Tf.

Material - Methods

Data from a set of 200 randomly selected patients treated in 4 large hospitals in Greece (50 patients per hospital) were analyzed in order to obtain preliminary Diagnostic Reference Levels (DRLs) for KAP and Tf during therapeutic ERCP procedures. Non-parametric statistic tests were performed in order to determine a statistically significant relation between KAP and Tf.

Results

The resulting third quartiles for KAP and Tf for hospitals (A, B, C and D) were found as followed: KAP_A=10.7 Gy·cm^2, Tf_A=4.9 min ; KAP_B=7.5 Gy·cm^2, Tf_B=5.0 min ; KAP_C=19.0 Gy·cm^2, Tf_C=7.3 min ; KAP_D=52.4 Gy·cm^2 , Tf_D=15.8 min. The third quartiles, calculated for the total 200 cases sample, are: KAP=18.8 Gy·cm^2 and Tf=8.2 min. For 3 out of 4 hospitals and for the total sample, p-values of statistical indices (correlation of KAP and Tf) are less than 0.001, while for the Hospital A p-values are ranging from 0.07 to 0.09. Using curve fitting, we finally determine that the relation of Tf and KAP is deriving from a power equation ($KAP=Tf^{1.282}$) with R^2=0.85.

Conclusion

The suggested Preliminary DRLs (deriving from the third quartiles of the total sample) for Greece are: **KAP=19 Gy·cm^2** and **Tf=8 min**, while the relation between KAP and Tf is efficiently described by a power equation.

Introduction

Endoscopic Retrograde Cholangio-Pancreatography (ERCP) is a commonly used procedure, which enables physicians to examine the pancreatic and bile ducts. An endoscope is inserted through mouth into patient's stomach and first part of duodenum. In the duodenum a small opening is located and through the endoscope, a secondary tube is passed into that opening. Contrast material is injected and images are acquired by the use of x-rays, in order to study ducts of pancreas and liver [1].

The steadily increasing use of fluoroscopy in ERCP technique has often raised concerns regarding the potential risks from the radiation exposure of patients [1-9]. That is mainly due to the fact that ERCP is often performed outside radiological departments by operators with questionable knowledge and training on radiation protection and procedure optimization [10]. Diagnostic reference levels (DRLs) have been recommended by the Internal Commission of Radiological Protection (ICRP) as an advisory measure to improve optimization of patient protection, by identifying high or low patient dose levels which might not be justified on the basis of image quality requirements [11]. There is limited data on ERCP DRL in Europe [1-7,9] and and absence of national ERCP DRLs in Greece.

The new Basic Safety Standards Directive (Council Directive 2013/59/Euratom) on the safe use of radiation in Europe underlines the immense importance of setting national DRLs especially in complex interventional procedures including ERCP. The main aim of the current study was to measure Kerma Area Product (KAP) and fluoroscopy time (Tf) in representative centers in Greece performing ERCP and determine national preliminary DRLs for ERCP. The secondary target was to investigate possible statistically significant relation between the measured KAP and Tf and if so, to determine which is the best equation to describe it.

Materials and Methods

Patient data were randomly collected from 4 large hospitals performing therapeutic ERCP procedures for a variety of both benign and malignant hepatobiliary and pancreatic diseases. Written informed consent was obtained from all patients in accordance with guidelines set forth by the institutional boards of the hospitals. All patients were sedated and positioned on the X-ray unit table in a semi-prone position that was kept fixed throughout the whole procedure. Therefore, the typical exposed anatomical area (given that the patients have deviations in height, weight, BMI etc.) was maintained for the total sample.

Technical data collected for each patient included patient radiation dose expressed in terms Kerma Area Product (KAP measured in $Gy \cdot cm^2$) and fluoroscopy time (Tf measured in minutes). Data were collected for a total number of 200 ERCPs (50 cases for each hospital in order to have statistically balanced sets of data), performed by gastroenterologists with more than 10 years of experience in ERCP procedures. All endoscopists shared similar competence, efficiency and expertise in the field. There was no digression from standard unit practice in terms of the procedures performed. The X-ray machines were controlled by the radiographer according to the indications of the endoscopist.

Different equipment was used in each hospital for ERCP procedures (Table 1). In Hospital A, a conventional radiology unit with over-couch X-ray tube (OC) was used.

In Hospital B, a conventional radiology unit but with under-couch X-ray tube (UC) was used. In Hospitals C and D, a C-arm unit (CA) and a digital angiography unit (AG) were used respectively. All X-ray machines had a KAP meter installed in the X-ray tube housing. The meter was calibrated according to the method summarized in the 'national protocol for patient dose measurements in diagnostic radiology' developed by the National Radiological Protection Board [12].

For each hospital the following statistics were calculated for KAP and Tf: a) Average, b) Median, c) Standard Deviation (SD), d) Coefficient of Variation (SD/Average), e) First Quartile and f) Third Quartile. Then the above statistics were calculated again for the total of 200-patients sample. These results were compared with the recent international literature for further investigation.

To extract the suggested national preliminary DRLs all 200 cases were considered as one sample. For this set of data the third quartiles for KAP and Tf were extracted and considered as DLRs.

Using non-parametric statistic indices (Spearman and Kendall's tau B p-values in 2-tailed correlation) a possible statistically significant relation between KAP and Tf for each hospital and for the total sample was investigated. Investigating that relation, a benchmark of fit was performed for a total of 10 different types of equations (linear, Logarithmic, Inverse, Quadratic, Cubic, Compound, Power, S, Growth and Exponential). The fit that would present the highest value of R^2 was considered to be the most appropriate to describe the relation between KAP and Tf.

Results

The resulting statistics (Average, Standard Deviation, Median, Range, Coefficient of Variation, First Quartile and Third Quartile) for KAP and Tf, both for each hospital independently and for the total sample, are stored in Table 2. Since data were not following the normal distribution, non parametric methods were used.

The resulting third quartiles for KAP and Tf for each one of the hospitals (stored in Table 2 as Third Quartiles) are as follows: KAP_A=10.7 Gy·cm^2 , Tf_A=4.9 min ; KAP_B=7.5 Gy·cm^2 , Tf_B=5.0 min ; KAP_C=19.0 Gy·cm^2 , Tf_C=7.3 min ; KAP_D=52.4 Gy·cm^2 , Tf_D=15.8 min. Regarding the 200 cases as one sample the third quartiles for KAP and Tf (Table 2), which will provide the national suggested preliminary DRLs for Greece, are: KAP=18.8 Gy·cm^2 and Tf=8.2 min.

Furthermore, for the 3 out of 4 hospitals Spearman and Kendall's tau B p-values are less than 0.001 while for the Hospital A p-values are ranging from 0.07 to 0.09 (data along with the correlation coefficients stored in Table 4). As for the total sample of 200 cases, both Spearman and Kendall's tau B p-values are less than 0.001, stating we are sure at 99% significance level that there is a relation between KAP and Tf. For the determination of the most proper equation to describe that relation, a series of benchmarks were used and the possible fit curves are presented in figure 1. In contrast to what expected, the linear equation does not provide the best fit (R^2=0.608); instead the best fit is derived from a power equation: $KAP=Tf^{1.282}$ (R^2=0.845).

Discussion

This is an initial study for the description of preliminary DRLs for ERCP procedures in general. For that reason, we used 50 therapeutic ERCPs cases from each of 4 participant hospitals. In order to provide a credible comparison, we chose to benchmark our results with studies based on sufficient number of cases (10 cases or more). Statistical values of KAP and Tf chosen to be used for comparison are: Average, Median and Third Quartile, because they are the mostly commonly used in current literature. The comparison data are shown in Table 3.

Diagnostic ERCPs (diag) of current literature [3,4] show that average values for KAP and Tf are approximately 20 Gy·cm^2 and 2 min respectively. For therapeutic ERCPs (ther) average values for KAP and Tf are approximately 44 Gy·cm^2 and 4.2 min respectively [2,5,10]. The above results confirm that therapeutic ERCPs average fluoroscopy time and KAP are two times greater than the respective values for diagnostic ERCPs. The average values for KAP and Tf of this work (therapeutic cases) are 15.5 Gy·cm^2 and 6.4 min respectively, significantly lower for KAP in comparison even with the purely diagnostic studies. NRPB –W14 [9] is the only study big study that involves a mixture of diagnostic and therapeutic ERCPs (mixed). NRPB –W14 states that for a mixed cases sample greater than 4500 patients, the average values for KAP and Tf are 15.5 Gy·cm^2 and 4.4 min - exactly the same average KAP with the one of our study. The comparison for the average values of KAP and Tf is visualized in figure 2.

The average of median values for KAP and Tf in therapeutic ERCPs [2,5,10] are 25.45 Gy·cm^2 and 3.5 min, while in our study are 7.8 Gy·cm^2 and 4.4 min respectively. In comparison with the respective median values from NRPB –W14 (14.1 Gy·cm^2 and 4.2 min), this work produces the half value of median KAP in approximately the same median time. The comparison for the median values of KAP and Tf is visualized in figure 3.

Finally, therapeutic ERCPs [2,5] approximately produce values for third quartiles for KAP=54.6 Gy·cm^2 and Tf=7.7 min, while in mixed cases scenario (NRPB –W14) the respective values are KAP=19 Gy·cm^2 and Tf=5.3 min. For the current study, the third quartiles of the total sample are KAP=18.8 Gy·cm^2 and Tf=8.2 min. The above confirms that in term of KAP third quartile for the total sample, this study produces nearly identical results with NRPB–W14, while the Tf third quartile value is higher for Greece. The comparison for the third quartiles of KAP and Tf is visualized in figure 4.

Regarding the description of the KAP and Tf correlation by a power equation rather than a linear one, we must recall that the data set includes the deviation of different equipment and methods applied in each of the 4 hospitals, and is limited to 200 cases. Even the most recent studies [13] state that the relation of KAP and Tf is described by a linear equation, given that all cases were treated with unchanged machinery. Since DRLs should not be related with specific method, equipment or patient, the relation of KAP and Tf is possible to derive from a power equation. The huge difference in the R^2 for the linear and power equation models is mainly caused by the equipment used in each hospital (refer to medians of KAP and Tf for each hospital in Table 2).

Any benchmark relating the equipment used in the 4 participating hospitals, KAP, Tf, patient characteristics and image quality is out of the scope of this study. DRLs, as already mentioned in the introduction, are advisory measures to improve optimization of patient protection and should be highly considered by hospitals in Greece performing therapeutic ERCPs with parameters above the suggested levels.

Conclusion

This study is a first approach for national DLRs for therapeutic ERCP procedures. The suggested preliminary DRLs by this work (summarizing Table 5) are: **KAP=19 Gy·cm^2 and Tf=8 min** (calculated for KAP and Tf of the total sample). Adding to the above and according to our sample we can be confident that there is a relation between KAP and Tf, which is most appropriately described by a power equation.

Table 1

Hospital	*X-ray machine*	*Type*	*X-ray tube above/under table*
A	Philips Essenta	Conventional	up
B	Philips Easy Diagnost	Conventional	down
C	Philips BV Pulsera	C-arm	down
D	Siemens Axiom Artis	Angiography	down

Table 1 - Equipment used in each of the 4 participant hospitals for ERCP procedures

Table 2

	Tf_A *(min)*	KAP_A *(Gy·cm²)*	Tf_B *(min)*	KAP_B *(Gy·cm²)*	Tf_C *(min)*	KAP_C *(Gy·cm²)*	Tf_D *(min)*	KAP_D *(Gy·cm²)*	*Tf (min)*	*KAP (Gy·cm²)*
Average	4.4	8.5	4.2	6.1	6.4	13.2	10.5	34.3	6.4	15.5
SD	4.2	15.4	4.4	6.1	6.2	8.7	7.3	28.5	6.2	20.4
Median	3.3	3.1	3.1	4.6	4.9	9.3	9.2	25.7	4.4	7.8
Range	(0.2-18)	(0.4-104.3)	(0.5-26.8)	(1.0-41.3)	(0.1-41.7)	(1.7-49.0)	(1-32.7)	(2.3-130.0)	(0.1-41.7)	(0.4-130.2)
Coefficient of Variation	95%	182%	106%	100%	98%	66%	70%	83%	98%	131%
First Quartile	1.7	2.0	1.7	3.1	3.4	6.6	4.8	15.5	2.3	3.7
Third Quartile	4.9	10.7	5.0	7.5	7.3	19.0	15.8	52.4	8.2	18.8

Table 2 - Statistical Analysis for each hospital (A, B, C and D) and total sample for ERCP procedures

Table 3

	Larkin et Al. [3] (diag)		**Olgar et Al. [4] (diag)**		**Tsalafoutas et Al. [2] (ther)**	
	Tf (min)	*KAP (Gy·cm²)*	*Tf (min)*	*KAP (Gy·cm²)*	*Tf (min)*	*KAP (Gy·cm²)*
Average	2.3	13.5	1.9	26.2	6.0	41.8
Median					4	27.9
Third Quartile					7.1	48,9
	IAEA 1641 Part.E [10] (ther)		**IAEA 1641 Part.F [10] (ther)**		**NRPB W14 [9] (Mixed)**	
	Tf (min)	*KAP (Gy·cm²)*	*Tf (min)*	*KAP (Gy·cm²)*	*Tf (min)*	*KAP (Gy·cm²)*
Average	6.0	20.0	3.7	65.3	4.4	15.5
Median	3.3	11.1	1.7	23.6	4.2	14.1
Third Quartile					5.3	19.0
	Buls et Al. [5] (ther)		**Averages of 4 Hospitals**		**Total Sample**	
	Tf (min)	*KAP (Gy·cm²)*	*Tf (min)*	*KAP (Gy·cm²)*	*Tf (min)*	*KAP (Gy·cm²)*
Average	6	49.9	6.4	15.5	6.4	15.5
Median	5.2	39	5.1	10.7	4.4	7.8
Third Quartile	8.3	60.3	8.3	22.4	8.2	18.8

Table 3 - Results comparison with diagnostic, therapeutic and mixed cases data of the current literature on ERCP procedures

Table 4

	P-value Spearman	*Correlation Coefficient ρ*	*P-value Kendall*	*Correlation Coefficient τ*
Hospital A	0.068	0.260	0.077	0.174
Hospital B	0.000	0.922	0.000	0.778
Hospital C	0.000	0.788	0.000	0.588
Hospital D	0.000	0.654	0.000	0.508
Total Sample	0.000	0.692	0.000	0.533

Table 4 - Spearman and Kendall correlation p-values for KAP and Tf for ERCP procedures

Table 5

	KAP (Gy·cm^2)	*Tf (min)*
Preliminary DRL	19	8
Average	16	6
SD	20	6
Median	8	4
Range	0 - 42	0 - 130

Table 5 - ERCP DRLs for KAP and Tf for 200 ERCP procedures in Greece

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Figure 1 - Possible Fit Curves describing the relation KAP-Tf
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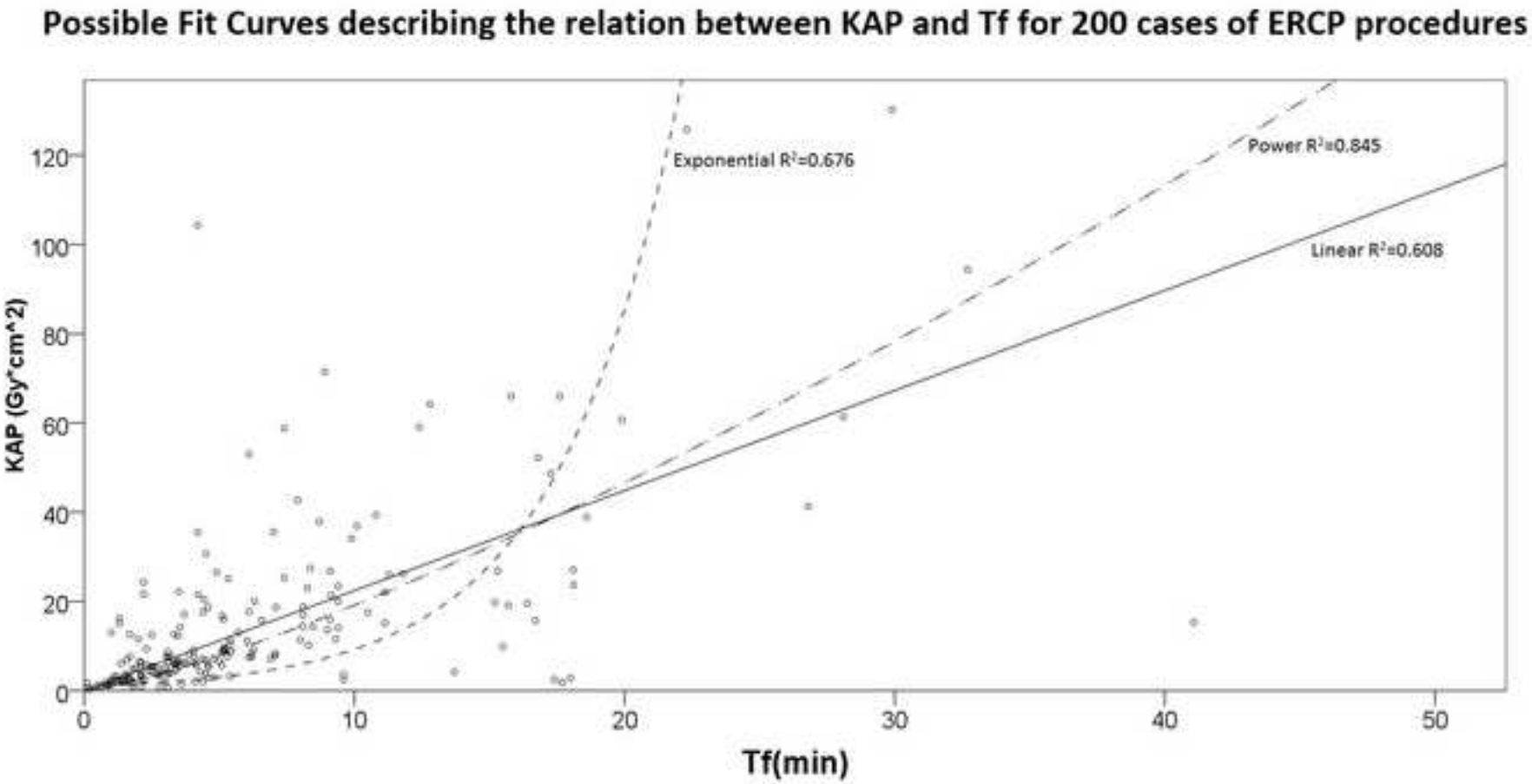

Figure 1 - Possible Fit Curves describing the relation between KAP and Tf in 200 cases of ERCP procedures

Figure 2 - Comparison for Averages of Tf and KAP
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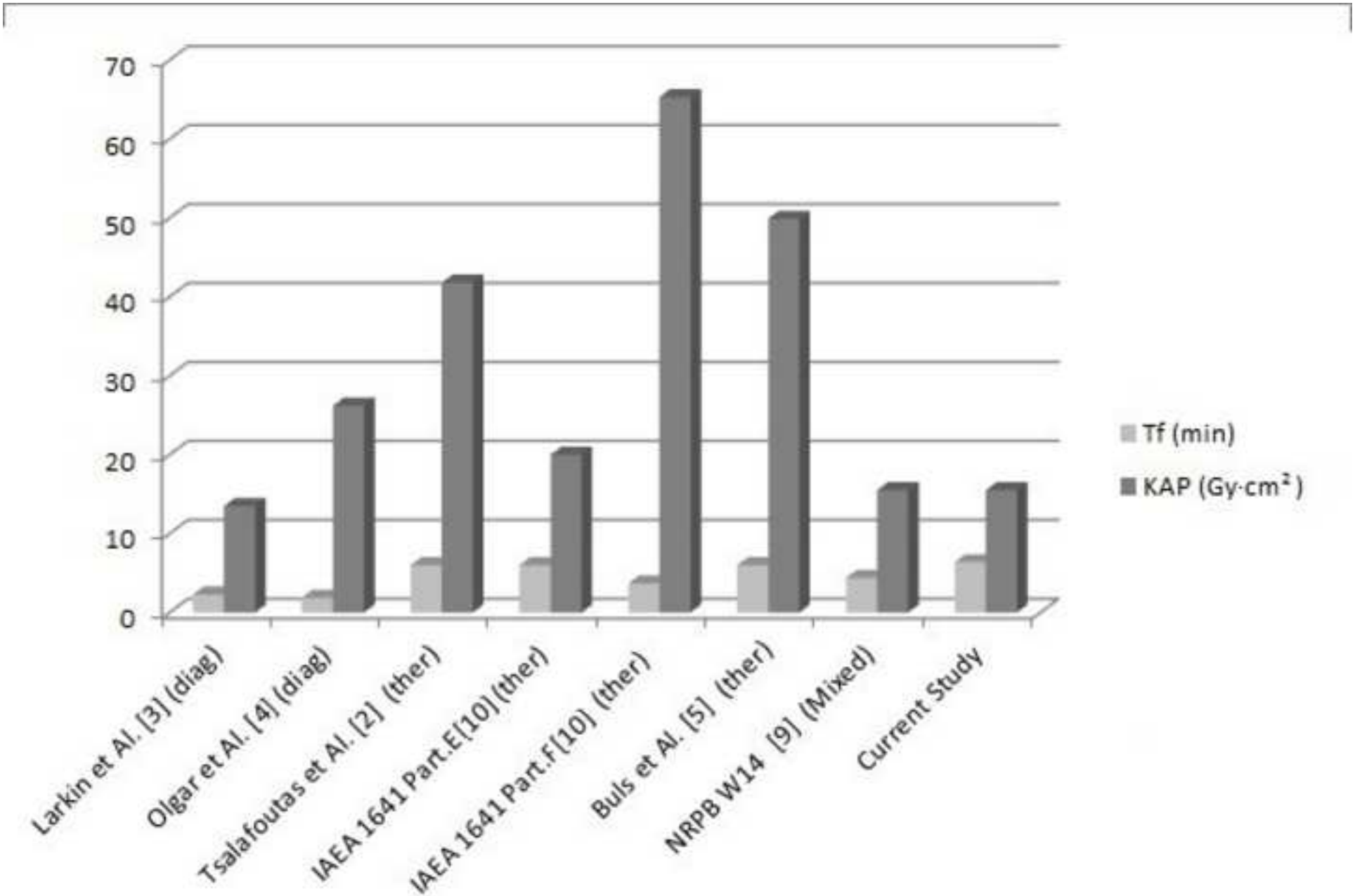

Figure 2 - Comparison for Averages of KAP and Tf for ERCP procedures

Figure 3 - Comparison of Medians for Tf and KAP
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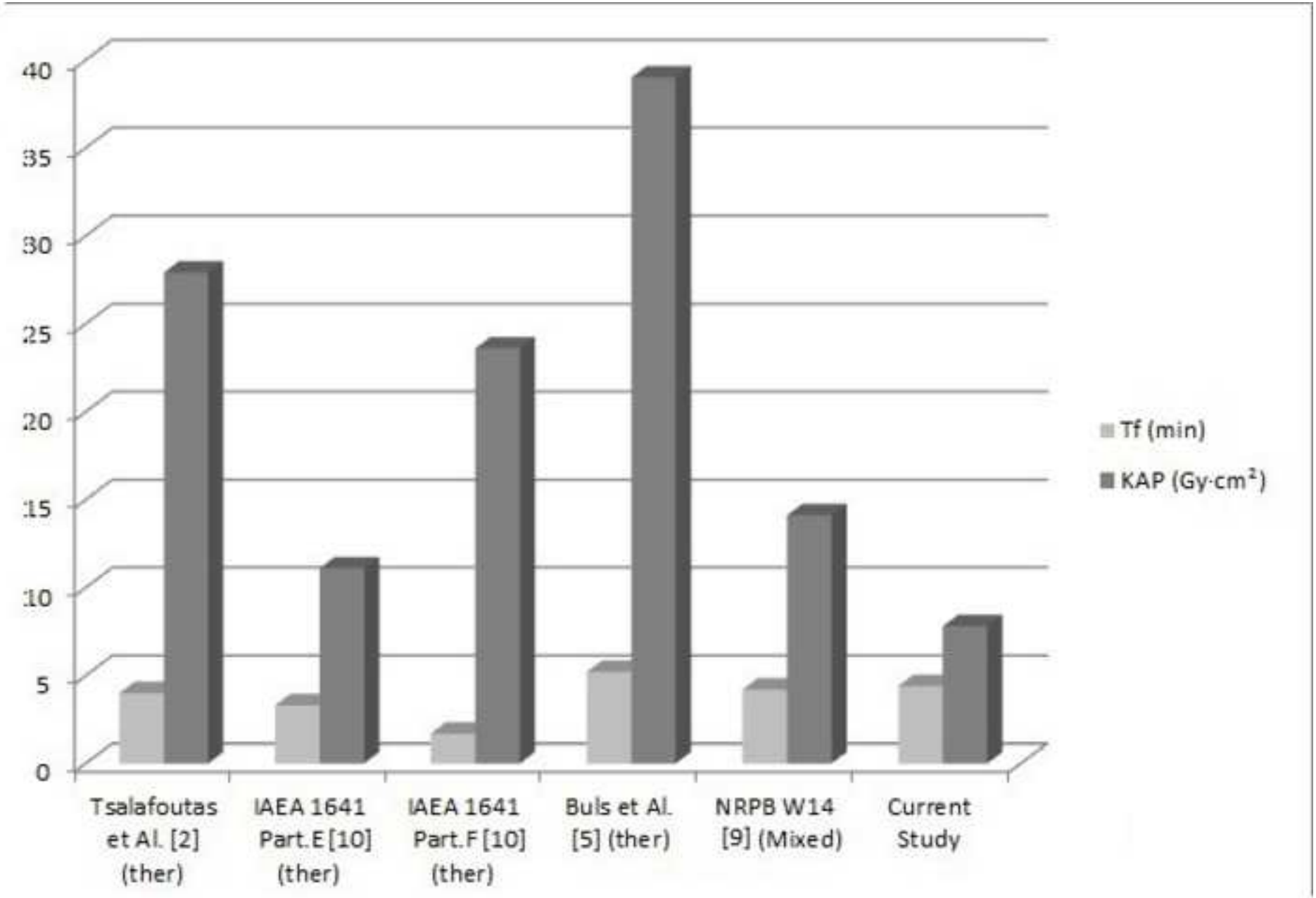

Figure 3 - Comparison of Medians for KAP and Tf for ERCP procedures

Figure 4 - Comparison of 3rd Quartiles for Tf and KAP
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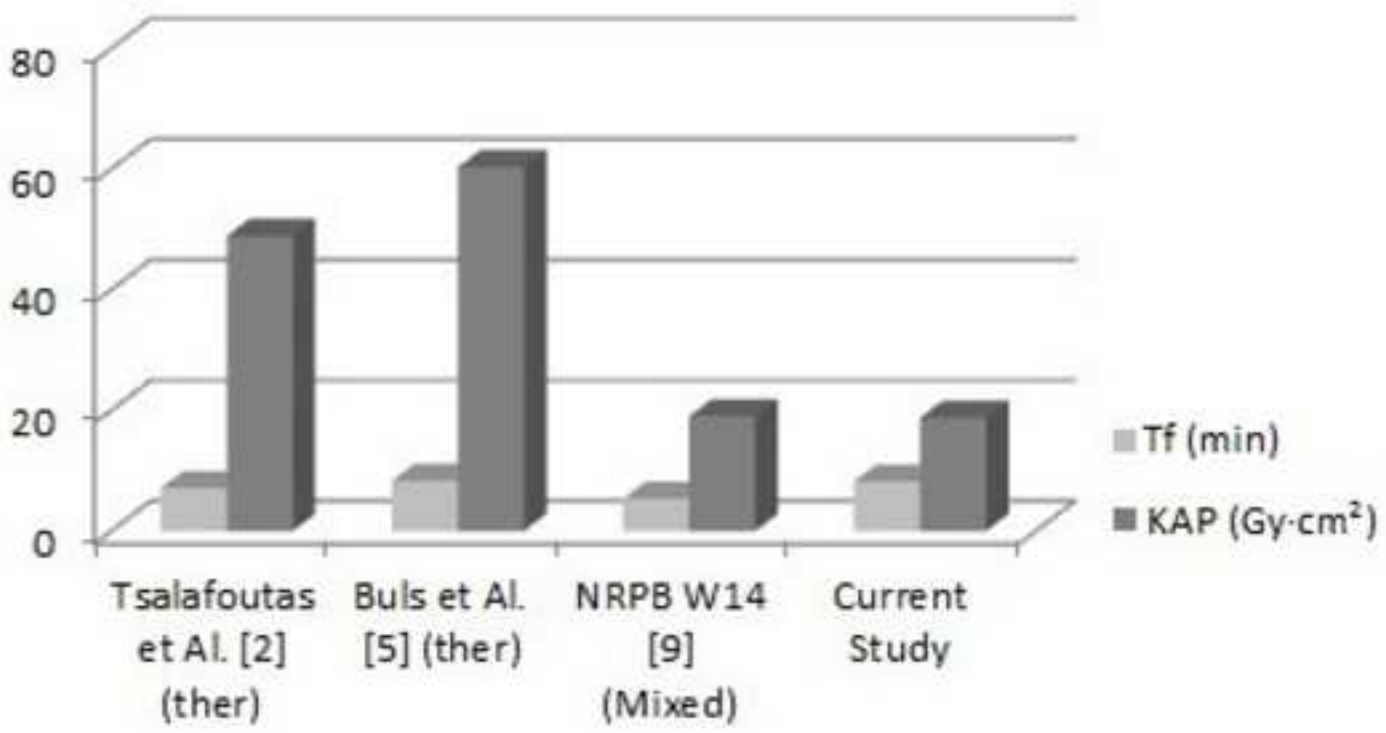

Figure 4 - Comparison of Third Quartiles of KAP and Tf for ERCP procedures