# THE ESTABLISHMENT OF LOCAL DIAGNOSTIC REREFENCE LEVELS IN ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY – A PRACTICAL TOOL FOR THE OPTIMIZATION AND FOR QUALITY ASSURANCE MANAGEMENT

Short running title: ESTABLISHMENT OF LOCAL DRLS IN ERCP

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ABSTRACT

Fluoroscopic procedures are an area of special concern in relation to radiation protection. The aim of this study was to describe the current level of patient radiation doses in ERCP collected from a single center, as well as to establish and review local DRLs in ERCP. A total of 100 patients' radiation doses in ERCP were recorded and the third-quartile method was adopted to establish local DRLs for ERCP. The mean DAP was 2.05 Gy·cm2, fluoroscopy time 1.7 min and the number of images was 3. The proposed local DRLs for ERCP were 3.00 Gy·cm$^2$ and 3.0 min. Local DRLs were reviewed in a sample of 25 patients five years after they had been established. In reviewing data the averages DAP and FT were below the local DRLs. Local DRLs help in the optimization process of fluoroscopic procedures and guides to a good clinical practice.

## INTRODUCTION

In its publication 117 released in 2010, the International Commission on Radiological Protection (ICRP) expressed concern about the fact that the use of fluoroscopy outside the imaging departments has increased significantly and expanded to the larger clinical areas. There has been a general neglect and lack of training, knowledge and awareness regarding radiation protection among of those working with fluoroscopy outside the imaging departments. Gastroenterology is one of the specialties, which use fluoroscopy to aid endoscopic procedures, such as endoscopic retrograde cholangiopancreatography (ERCP). [(1)] It is a highly technical and demanding invasive procedure used as a gold standard in the treatment of the hepatobiliary disorders [(2-5)]. ERCP may be performed outside the imaging department, e.g. in operating theatre or endoscopy unit [(6)]. During ERCP, both patients and healthcare staff are exposed to ionizing radiation and this makes the ERCP undoubtedly an interventional radiological procedure. However, ERCP is not generally performed by a radiologist, but by a gastroenterologist or even by a general surgeon. [(5,7,8)]

In recent years, there has been a continuing and increasing interest in patient radiation dose particularly from the interventional radiology and cardiology, because of remarkable growth in frequency and complexity of procedures [(9-13)]. Several studies have been performed in response to growing interest in patient radiation dose from ERCP as well [(7,8,14-20)]. It is notable, that these interventional procedures may cause a high radiation dose to patients [(9)] and lead to the radiation-induced skin injuries [(21)]. Therefore, fluoroscopically guided interventional procedures are now an area of special concern in relation to radiation protection [(1, 22, 23)]. It has been recognized that application and use of diagnostic reference levels (DRLs) represents an efficient and substantial standard for radiation protection of patients and optimization of fluoroscopic procedures [(23-26)]. DRLs are defined as dose levels in diagnostic medical imaging or interventional radiology practices for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment' [(23)]. The DRL is not applied to individual patients, but it is used for a given medical imaging task or protocol. Basically, the objective of a DRL is to help avoid excessive radiation dose to the patient that does not commensurate with the clinical purpose. [(27,28)]

New Council Directive 2013/59/Euratom adopted in December 2013 obligates all Member States to ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures.  Member States of the European Union have to implement this comprehensive Directive into their national legislation by 6 February 2018. [(23)] Available information regarding DRLs for ERCP is unfortunately quite limited. Currently, there are no existing national DRLs for ERCP proposed by Radiation and Nuclear Safety Authority (STUK) in Finland, thus one study of patient doses in ERCP collected from 10 Finnish hospitals has been recently performed [(14)]. The United Kingdom (UK) and the Nordic Radiation Protection authorities have suggested DRLs of 50 $Gy \cdot cm^2$ and 20 $Gy \cdot cm^2$ for ERCP [(29,30)], respectively. According to the results of wide European survey on availability of national DRLs (Dose Datamed 2, DDM2), Austria and Switzerland have been established national DRLs of 45 Gy·cm$^2$ and 30 Gy·cm$^2$ for ERCP, respectively [(31)].

While the national levels are unavailable, it is recommended to establish local DRLs for specific procedure, which are based on local practice [(24)]. The local DRLs should be more stringent or equal compared to the national DRLs proposed by authority bodies [(31)]. Thus, the aim of the present study was to describe the current level of patient radiation doses during ERCP in a large university hospital in Finland and to establish local DRLs for optimization and for quality assurance management.

## MATERIALS AND METHODS

The study was carried out at the Medical Imaging Centre of Southwest Finland of Turku University Hospital, Finland. Patient exposure data were collected over a 4-month period in the year of 2010 by local personnel of radiological department. A total of 100 patients' radiation doses in ERCP were recorded consecutively without setting any restrictions on patient weight, sex or condition. For each procedure dose area product (DAP), fluoroscopy time (FT) and number of radiographic images were collected. Patient body characteristic, such as age, sex, height, weight and body mass index (BMI) were registered as well. No pediatric patients (< 18 years old) were imaged during the data collection.

The fluoroscopic system used in ERCP was a Philips MultiDiagnost Eleva, equipped with a multipurpose C-arm and with an image intensifier of 38 cm field size in diameter. Dose measuring device was integrated to the equipment. During ERCP pulsed fluoroscopy with lowest possible pulse rate of 1.5 fps was used and the x-ray beam was modified by collimating the field size to the region of interest. The total filtration was 4.0 mm Al + 0.1 mm Cu in normal fluoroscopy mode. The focal spot had a size of 0.6 mm. Magnification was rarely applied during the procedures. In ERCP an x-ray tube located under (“undercouch” system) the patient table and equipment was controlled by a radiographer. As a part of the quality assurance program, the equipment was serviced and calibrated regularly by its manufacturer or supplier. The dose-area-product (DAP) meter was calibrated in on the same occasion.

Statistical analysis was performed using the IBM SPSS Statistics for Windows, Version 22 (IBM Corp. 2013 Armonk, NY). DAP values measured in μGy·m$^2$ were converted to Gy·cm$^2$ and rounded to the nearest decimal point. Frequencies, percentages, mean, median and standard deviations were calculated for the data. In order to establish local DRLs for ERCP, the third-quartile method was adopted in this work [24]. In a first analysis, the 75th percentile of DAP was calculated from all recorded data and in the second one, a weight banding method was applied to reduce the dispersion in the data due to patient weight variation. Weight banding was performed by selecting the patients with weights between 55 and 85 kg (standard-sized patient 70 kg ± 15 kg). [20,24,32] As dosimetry data was not normally distributed, the DAP values were transformed with a log transformation for comparisons of both distributions. The possible statistical differences between variables were assessed using an independent two-tailed t-test and a level of significance ($p < 0.05$) was used in the test.

Consequently, the local DRLs for ERCP were established in terms of DAP and fluoroscopy time based on original dosimetry data, as they would be more representative of typical current practice. The proposed DRL values were then rounded up to the integer number. In the year of 2015, the local DRLs for ERCP were reviewed by collecting the similar data of 25 patients in a 55-85 kg weight class. The average DAP and fluoroscopy time were compared with the local DRLs established five years earlier.

Ethical issues were taken into account in this study. Institutional review board approval was obtained at the Turku University Hospital. According to the Finnish Medical Research Act [37] this type of study does not require the approval from local ethics committee. This study does not impair the quality of ERCP procedures or cannot harm the patient in any way. ERCP is always done for a specific clinical purpose aiming to improve the patients' condition. The collected data did not include patients’ personal information, which they could subsequently be identified. Verbal informed consent was obtained from all patients before the ERCP procedure. [38-39]

## RESULTS

In order to set up local DRLs for ERCP the dosimetry data of 100 patients’ was investigated in this study. Most of the ERCP procedures were therapeutic (96%) in nature. Approximately 53% of the patients who underwent ERCP were male and 47% female. The mean age for all patients was 65 years, ranging from 24 to 89 years. The average age of females were 64 years and males 66 years. The mean weight of all patients was 77 kg. The mean and range of BMI were 26.6 kg/m² and 18.3-37.7 kg/m², respectively. Males were heavier and taller than females in current data. Patients’ body characteristics are summarized in Table 1.

A large variation in radiation dose, fluoroscopy time and in the number of radiographic images was observed in original dosimetry data. During ERCP patients received on average 2.05 Gy·cm² radiation dose, while the highest DAP value recorded in this study was 9.30 Gy·cm². The mean FT was found to be 1.7 min, ranging from 0.4 to 7.8 min. A predetermined limit of 5 min of FT was exceeded only in two of the all ERCP procedures. The distributions of DAP and FT were asymmetric, with a large positive tail, as shown in Figure 1 and Figure 2. A positive linear correlation was found between the DAP and FT (Spearman's rho, $r=0.71$, $p<0.01$), as well as between the DAP and radiographic images ($r=0.61$, $p<0.01$). DAP correlated weakly with patient weight ($r=0.31$, $p=0.002$) or BMI ($r=0.27$, $p=0.007$). The number of radiographic images taken during ERCP varied from 0 to 9 images, and the mean number of images was 3.

Table 2 demonstrates the influence of weight banding method on the distribution of DAP for ERCP procedures. The mean weight (kg) and BMI ($kg/m^2$) for both patient groups are indicated as well. The distributions of DAP for original dosimetry data and for weight-selected data in logarithmic scale are illustrated in Figure 3. Although weight banding method reduce the sample size by factor of approximately 1.5, the both DAP distributions were found to be quite similar and the 75$^{th}$ percentile point of the two distributions are close to each other. An independent two-tailed t-test on the log-transformed data indicated that the means of DAP in the original dosimetry data (n=100, M=0.54, SD=0.60) and in weight-selected data (n=64, M=0.41 SD=0.51) were not significantly different at the 0.05 level, $t(162)=1.47$, $p=0.145$, $CI_{95}$ -0.05-0.31.

Based on original dosimetry data, the local DRLs were chosen as the rounded values of the 75$^{th}$ percentile of DAP and FT. Consequently, the proposed local DRLs for ERCP were 3.00 Gy·cm² and 3.0 min in this study. Local DRLs for ERCP were reviewed after five years they had been established. In the sample of 25 patients, the average DAP and FT were 2.50 Gy·cm² and 2.2 min, respectively. The mean number of radiographic images taken during ERCP was 3. The average weight, height and BMI for patients in reviewed data were 72 kg, 172 cm and 24.4 kg/m², respectively (table 3).

## DISCUSSION

This study presents the results of patient radiation doses in ERCP collected from a single center and describes the method of establishing and reviewing local diagnostic reference levels (DRLs) as a practical tool for dose optimization and for quality assurance management. Setting up local DRLs for dose-intensive fluoroscopically guided procedure such as ERCP was a challenge due to the large variation of patient radiation doses and fluoroscopy times. Distributions of DAP and FT in ERCP were skewed and asymmetrical with a main peak, a tail and a few extreme values as visualized in Figure 1 and Figure 2. Owing to the large variation of patient radiation doses, it is recommended to account for the relative complexity of the procedure besides the clinical and technical factors [(33)]. The difficulty level or over-all complexity of the ERCP procedures were not taken into consideration in this study, although this information could have been used to provide a more complete picture to the reasons behind the variation. Nonetheless, taking such information into account would considerably increase the data requirements.

Another challenge in establishment of local DRLs is associated with the difficulties in achieving sufficient sample sizes because of the lack of standard procedures and standard-size patients in fluoroscopically guided procedures [11,20]. Marshall et al. [20], Miller et al. [11] and Bleeser et al. [32] have tested weight banding method and size correction method introduced by Chapple et al. [34] for normalizing dose to patient body habitus. This normalization is not relevant for FT or the numbers of radiographic images, as these are not influenced by body size [11]. Marshall et al. [20] and Miller et al. [11] included in analysis the patients with weight between 60-80 kg and Bleeser et al. [32] between 65-80 kg. In general, weight banding seems to reduce the standard deviation of the data more effectively than size corrected method [20] and weight banding appears to had a little effect on the 75$^{th}$ percentile of distribution compared with the uncorrected values [11,32]. The size correction method is useful as well, however, it requires the experimental determination of the correction factor *k* and correction must be done for each patient separately [11]. Having considered time constraints and readily available resources as well as the appropriate phantom and measurement equipment, such an approach was deemed unfeasible for this study.

Established local DRLs in terms of DAP and FT for ERCP were 3.00 Gy·cm² and 3.0 min in this study. These values were considerably lower than those reported previously, inter alia, by Marshall et al. [20], Erskine et al. [35], Sulieman et al. [16], Saukko et al. [14] and Brambilla et al. [36]. Table 4 presents the comparison of this study with other published third quartiles of DAP and FT. Local DRLs were proposed based on original dosimetry data, as Miller et al. [11] acknowledged that for a single practice, it is sufficient to use reference levels that have not been corrected for patient body habitus. The effect of weight banding method on the 75$^{th}$ percentile of dose distribution was also tested in this study. Patients were selected from original dosimetry data with weight between 55 and 85 kg, so they would represent a standard-sized patient with average weight close to the 70 kg. All DAP values were log-transformed for the statistical analysis, as Marshall et al. [20] have already shown that logarithmic transformation of the DAP distributions for interventional procedures creates reasonably normal distribution. The two distributions of DAP were found to be quite similar and there were no statistically significant differences between the means obtained with weight banding and uncorrected values.

Local DRLs for ERCP were reviewed in 2015 by collecting the dosimetry data of 25 patients and compared the mean of DAP and FT with the reference levels. Radiation and Nuclear Safety Authority (STUK) in Finland recommends using a sample of ten average-sized patients (55-85kg) on a minimum in measuring a level of radiation exposure and in reviewing DRLs [40]. In reviewing data the average DAP and FT were below the local DRLs. Results showed that DAP was 17% and FT 27% lower than local DRLs established in 2010. The establishment of local DRLs should, in most circumstances, lead to a reduction of the radiation doses over the years [24]. However, in this situation, the reduction was not so significant and it follows that there is no current need to decrease local DRLs for ERCP. If reference levels are not exceeded, this does not automatically guarantee that the procedure has been performed optimally and optimized for radiation safety. It is still necessary to ensure that image quality is sufficient for a reliable clinical diagnosis. Local DRLs should be re-reviewed in the case of significant changes in protocol or in equipment or where they are consistently exceeded. [24]

## CONCLUSION

The increase in frequency and complexity of ERCP procedures indicates risk of an increase in radiation exposure to patients as well as to medical staff. The diagnostic reference levels (DRLs) play an essential role in the optimization process of fluoroscopic procedures and guides to a good clinical practice. Furthermore, DRLs help to identify the fluoroscopy equipment, protocols and practices that may be delivering unusually high radiation doses to the patient. For all those reasons, it is important to record routinely and regularly the patient radiation doses and compare them with the reference levels. If national DRLs do not exist, setting up local DRLs based on local practice is a viable option. The collection of such dosimetry data will increase the awareness of patient radiation doses and importance of radiation protection among the medical staff. The method described in this study of establishing and reviewing local diagnostic reference levels (DRLs) in ERCP may be useful to other institutions to provide a good safety culture in the medical use of radiation. The established and reported local DRL values for ERCP could be a tool for the daily follow-up of patient radiation doses or setting it as the alert threshold in a dose monitoring software. Accordingly, these local DRL values can be used in establishing national DRLs for ERCP, as they can be derived from the distribution of average radiation doses collected from several hospitals across the country.

## REFERENCES


1. International Commission on Radiological Protection. *Radiological protection in fluoroscopically guided procedures performed outside the imaging department.* ICRP Publication 117. Ann. ICRP **40** (2010).

2. Carr-Locke, D.L. *Overview of the role of ERCP in the management of diseases of the biliary tract and the pancreas.* Gastrointest. Endosc. **56**, S157-160 (2002).

3. Agarwal, J., Reddy, D.N., Talukdar, R., Lakhtakia, S., Ramchandani, M., Tandan, M., Gupta, R., Pratap, N. and Rao, G.V. *ERCP in the management of pancreatic diseases in children.* Gastrointest. Endosc. **79**, 271-278 (2014).

4. Grönroos J.M. *Clinical success of ERCP procedures in nonagenarian patients with bile duct stones.* Minim. Invasive Ther. Allied Technol. **20**, 146-149 (2011).

5. Boix, J. and Lorenzo-Zúniga, V. *Radiation dose to patients during endoscopic retrograde cholangiopancreatography.* World J. Gastrointest. Endosc. **3**, 140-144 (2011).

6. National Council on Radiation Protection and Measurements. *Radiation protection for procedures performed outside the radiology department.* NCRP Report 133. Bethesda, USA (2000).

7. Buls, N., Pages, J., Mana, F. and Osteaux, M. *Patient and staff exposure during endoscopic retrograde cholangiopancreatography.* Br. J. Radiol. **75**, 435-443 (2002).

8. Tsapaki, V., Paraskeva, K.D., Mathou, N., Andrikopoulos, E., Tentas, P., Triantopoulou, C. and Karagiannis, J.A. *Patient and endoscopist radiation doses during ERCP procedures.* Radiat. Prot. Dosim. **147**, 111-113 (2011).

9. Bartal, G., Vano, E., Paulo, G. and Miller D.L. *Management of patient and staff radiation dose in interventional radiology: current concepts.* Cardiovasc. Intervent. Radiol. **37**, 289-298 (2014).

10. Brnić, Z., Krpan, T., Faj, D., Kubelka, D., Popić Ramać, J., Posedel, D., Steiner, R., Vidjak, V., Brnić, V., Višković, K. et al. *Patient radiation doses in the most common interventional cardiology procedures in Croatia: first results.* Radiat. Protec. Dosimetry **138**, 180-186 (2010).

11. Miller, D.L., Hilohi, C.M. and. Spelic, D.C. *Patient radiation doses in interventional cardiology in the U.S.: advisory data sets and possible initial values for U.S. reference levels.* Med. Phys. **39**, 6276-6286 (2012).

12. Zotova, R., Vassileva, J., Hristova, J., Pirinen, M. and Järvinen, H. *A national patient dose survey and setting of reference levels for interventional radiology in Bulgaria.* Eur. Radiol. **22**, 1240–1249 (2012).

13. Kloeckner, R., Bersch, A., Pinto dos Santos, D., Schneider, J., Düber, C. and Pitton, M.B. *Radiation exposure in nonvascular fluoroscopy-guided interventional procedures.* Cardiovasc. Intervent. Radiol. **35**, 613-620 (2012).

14. Saukko, E., Henner, A. and Ahonen, S-M. *Radiation exposure to patients during endoscopic retrograde cholangiopancreatography: A multicentre study in Finland.* Radiography **21**, 131-135 (2015).

15. Alzimami, K., Sulieman, A., Paroutoglou, G., Potamianos, S., Vlychou, M. and Theodorou, K. *Optimisation of radiation exposure to gastroenterologists and patients during therapeutic ERCP.* Gastroenterol. Res. Pract. **2013**, 1-7 (2013).

16. Sulieman, A., Paroutoglou, G., Kapsoritakis, A., Kapatenakis, A., Potamianos, S., Vlychou, M. and Theodorou, K. *Reduction of radiation doses to patients and staff during endoscopic retrograde cholangiopancreatography.* Saudi J. Gastroenterol. **17**, 23-29 (2011).

17. Olgar, T., Bor, D., Berkmen, G. and Yazar, T. *Patient and staff doses for some complex X-ray examinations.* J. Radiol. Prot. **29**, 393-407 (2009).

18. Tsalafoutas, I.A., Paraskeva, K.D., Yakoumakis, E.N., Vassilaki, A.E., Maniatis, P.N., Karagiannis, J.A. and Koulentianos, E.D. *Radiation doses to patients from endoscopic retrograde cholangiopancreatography examinations and image quality considerations.* Radiat. Prot. Dosim. **106**, 241-246 (2003).

19. Larkin, C., Workman, A., Wright, R. and Tham, T. *Radiation doses to patients during ERCP.* Gastrointest. Endosc. **53**, 161-164 (2001).

20. Marshall, N.W., Chapple, C-L. and Kotre C.J. Diagnostic reference levels in interventional radiology. Phys. Med. Biol. 45, 3833-3846 (2000).

21. Balter, S., Hopewell, J., Miller, D., Wagner, L. and Zelefsky, M. *Fluoroscopically guided interventional procedures: a review of radiation effects on patients' skin and hair.* Radiology **254**, 326-341 (2010).

22. International Commission on Radiological Protection. *Avoidance of radiation injuries from medical interventional procedures.* ICRP Publication 85. Ann. ICRP **30** (2000).

23. European Union. *Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.* Off. J. Eur. Union **57**, L013 (2014).

24. European commission. *Guidance on diagnostic reference levels (DRLs) for medical exposures.* Radiation protection 109 (Luxembourg: Office for Official Publications of the European Communities) (1999).

25. International Commission on Radiological Protection. *The 2007 Recommendations of the International Commission on Radiological Protection.* ICRP Publication 103. Ann. ICRP **37** (2007).

26. International Atomic Energy Agency. *Radiation protection and safety of radiation sources: international basic safety standards. IAEA Safety Standards for protecting people and the environment.* Series No. GSR Part 3 (2014).

27. International Commission on Radiological Protection. *Diagnostic reference levels in medical imaging: review and additional advice.* Ann. ICRP **31**, 33-52 (2001).

28. Rosenstein, M. *Diagnostic reference levels for medical exposure of patients: ICRP guidance and related ICRU quantities.* Health Phys. **95**, 528-534 (2008).

29. Hart, D., Hillier, M.C. and Wall, B.F. *National reference doses for common radiographic, fluoroscopic and dental X-ray examinations in the UK.* Br. J. Radiol. **82**, 1-12 (2009).

30. Widmark, A., Fosmark, H., Einarsson, G., Gundtoft, P., Hjardemaal, O., Leitz, W. and Pukkila, O. *Guidance levels in the Nordic countries: a preliminary report for selected interventional procedures.* Radiat. Prot. Dosim. **94**, 133-135 (2001).

31. European commission. *Diagnostic reference levels in thirty-six European Countries. Part 2/2. Radiation Protection N° 180.* (Luxembourg: Publications Office of the European Union) (2014).

32. Bleeser, F., Hoornaert, M.-T., Smans, K., Struelens, L., Buls, N., Berus, D., Clerinx, P., Hambach, L., Malchair, F. and Bosmans, H. *Diagnostic reference levels in angiography and interventional radiology: A Belgian multi-centre study.* Radiat. Prot. Dosim. **129**, 50-55 (2008).

33. International Commission on Radiological Protection. *Radiological protection in medicine.* ICRP Publication 105. Ann. ICRP **37** (2007).

34. Chapple, C.-L., Broadhead, D.A. and Faulkner, K. *A phantom based method for deriving typical patient doses from measurements of dose-area product on populations of patients.* Br. J. Radiol. **68**, 1083-1086 (1995).

35. Erskine, B.J., Brady, Z. and Marshall, E.M. *Local diagnostic reference levels for angiographic and fluoroscopic procedures: Australian practice.* Australas. Phys. Eng. Sci. Med. **37**, 75-82 (2014).

36. Brambilla, M., Marano, G., Dominietto, M., Cotroneo, A.R. and Carriero, A. *Patient radiation doses and references levels in interventional radiology.* La. Radiol. Med. **107**,408-418 (2004).

37. Ministry of Social Affairs and Health, Finland. *Medical Research Act No. 488/1999.* Original text in Finnish. Available from: https://www.finlex.fi/fi/laki/ajantasa/1999/19990488 [accessed 26.8.15].

38. Muthuswamy, V. *Ethical Issues in Clinical Research.* Perspect. Clin. Res. **4**, 9-13 (2013).

39. Nerenz, D.R. Ethical issues in using data from quality management programs. Eur. Spine. J. 18, 321-330 (2009).

40. The Radiation and Nuclear Safety Authority (STUK), Finland. *The national diagnostic reference levels for conventional X-ray examinations of adults.*9/3020/2014. Original text in Finnish. Available from: http://www.stuk.fi/documents/12547/476916/paatos-9-3020-2014-potilaan-sateilyaltistuksen-vertailutasot-aikuisten-tavanomaisissa-rontgentutkimuksissa.pdf/5ca5353d-8bdf-48da-9123-c82f52629fb2 [accessed 1.9.15].

**Table 1. Patients' body characteristics including age, weight, height and BMI in original dosimetry data (n=100).**

| | Age (year) | Weight (kg) | Height (cm) | BMI (kg/m$^2$) |
|---|---|---|---|---|
| Min | 24 | 44 | 146.0 | 18.3 |
| Max | 89 | 115 | 190.0 | 37.7 |
| Mean | 65.1 | 77.0 | 169.8 | 26.6 |
| Median | 68.0 | 76.0 | 171.0 | 26.5 |
| Std. Deviation | 15.7 | 15.5 | 10.4 | 4.2 |

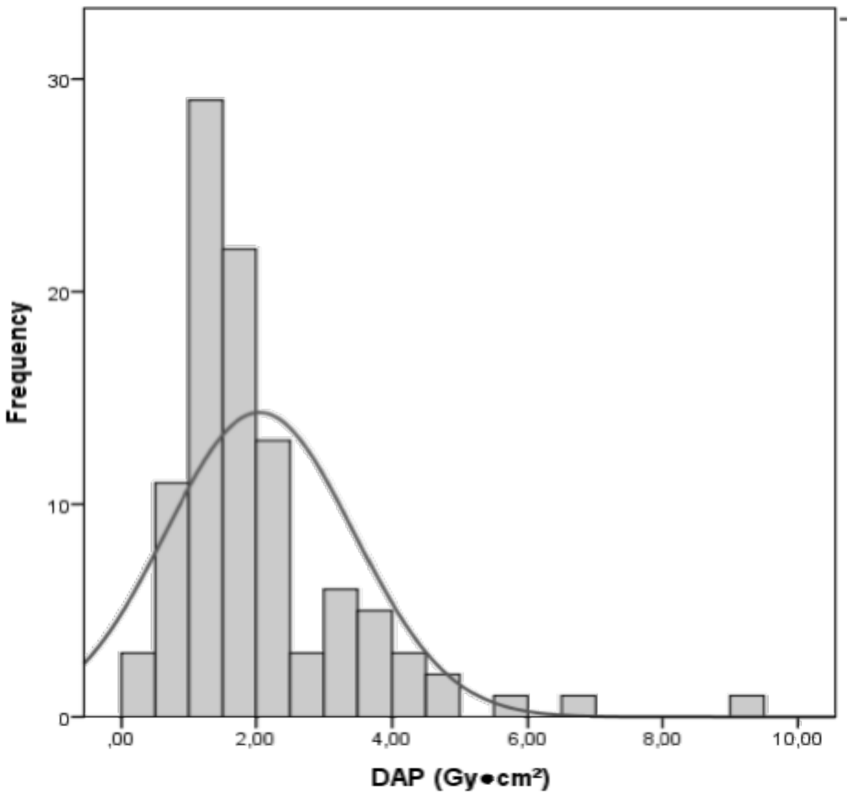


**Figure 1. Histogram of total DAP values for ERCP in original dosimetry data (n=100).**

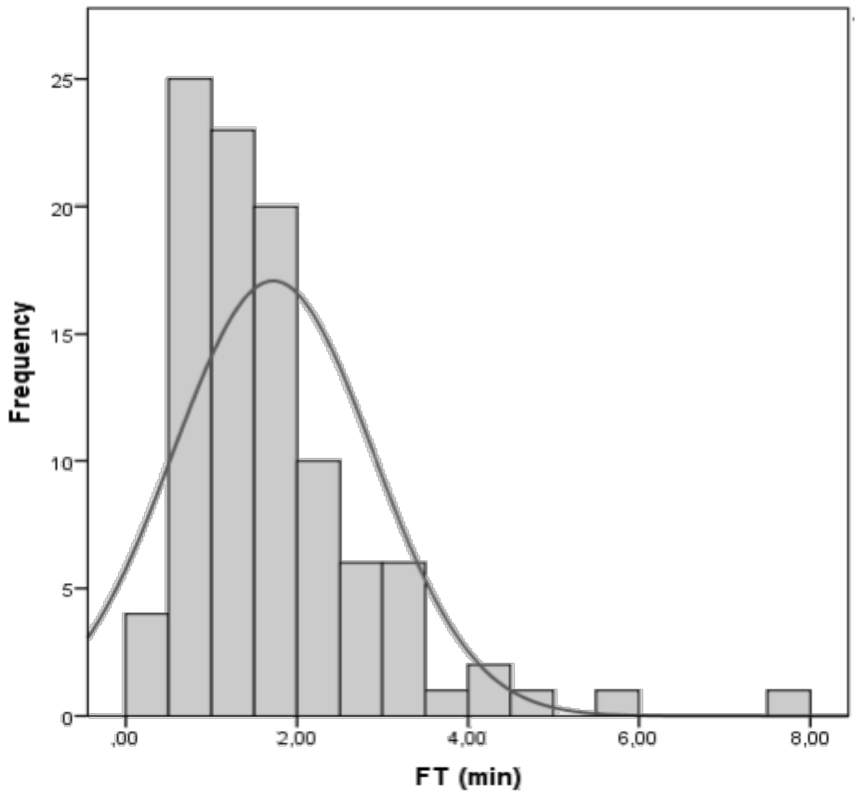


**Figure 2. Histogram of fluoroscopy times for ERCP in original dosimetry data (n=100).**

**Table 2. Comparison of original dosimetry data and weight-selected (55-85 kg) data in ERCP.**

| | Original data | Weight-selected data |
|---|---|---|
| Sample size | 100 | 64 |
| Mean of DAP (Gy·cm²) | 2.05 | 1.70 |
| Median of DAP (Gy·cm²) | 1.62 | 1.48 |
| Std. Deviation of DAP (Gy·cm²) | 1.40 | 0.87 |
| 25$^{th}$ percentile of DAP (Gy·cm²) | 1.21 | 1.14 |
| 75$^{th}$ percentile of DAP (Gy·cm²) | 2.36 | 2.13 |
| Mean of weight (kg) | 77.0 | 70.3 |
| Mean of BMI (kg/m²) | 26.6 | 25.3 |

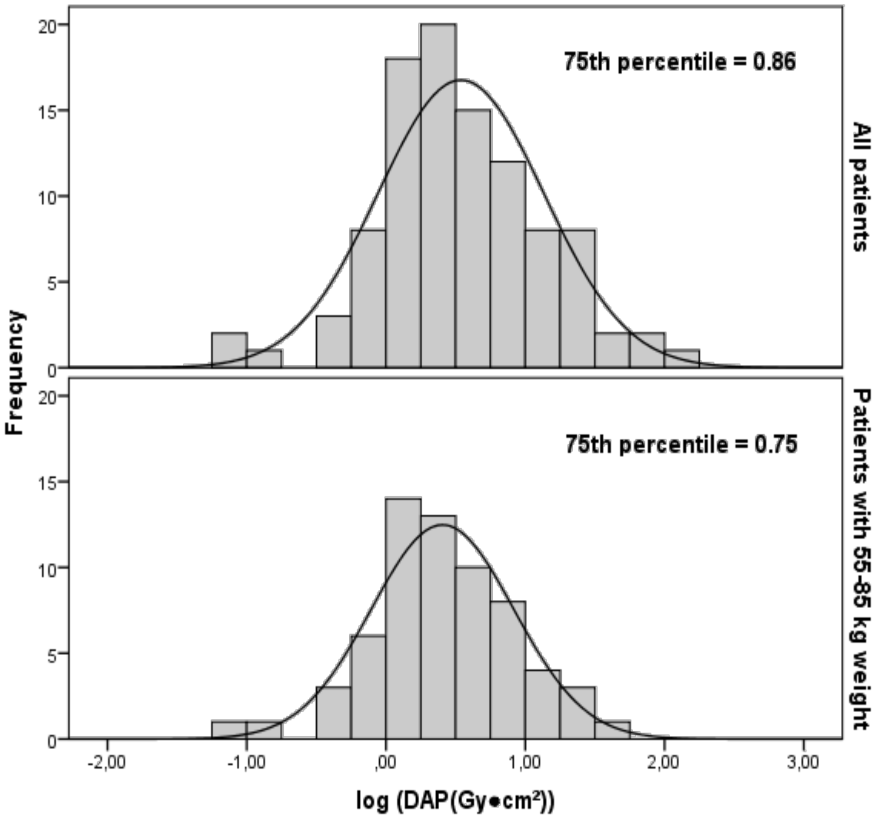


**Figure 3. The distributions of log-transformed DAP values in original dosimetry data (n=100) versus weight-selected data (n=64) in ERCP.**

**Table 3. Dosimetric measurements and patients demographics in original dosimetry data (n=100) and in reviewed data (n=25).**

| | Original data | Reviewed data |
|---|---|---|
| Sample size | 100 | 25 |
| Mean of weight (kg) | 77.0 | 72.1 |
| Mean of height (cm) | 169.8 | 171.8 |
| Mean of BMI ($kg/m^2$) | 26.6 | 24.4 |
| DAP ($Gy \cdot cm^2$) | 3.00 * | 2.50 # |
| Fluoroscopy time (min) | 3.0 * | 2.2 # |
| Mean number of images | 3 | 3 |

* Local DRLs in ERCP
# Mean

**Table 4. DAP (Gy·cm²) and FT (min) third quartiles in ERCP in different studies.**

| | Sample size | DAP (Gy·cm²) | FT (min) |
|---|---|---|---|
| Original dosimetry data | 100 | 2.36 | 2.2 |
| *local DRLs* | | *3.00* | *3.0* |
| Erskine et al. [35] | 400+ | 17.5 | 2.75 * |
| Marshall et al. [20] | 1736 | 16.4 | |
| Sulieman et al. [16] | 57 | | 3.5 |
| Buls et al. [7] | 54 | 60.3 | 8.3 |
| Tsalafoutas et al. [18] | 21 | 48.9 | 7.1 |
| Brambilla et al. [36] | 383 | 33.0 | |
| Saukko et al. [14] | 227 | 5.83 | 2.7 |

* Median.