

# 1 **Contemporary radiation doses in interventional cardiology: A**

## 2 **nationwide study of Patient Doses in Finland**

3

4 Jukka Järvinen<sup>1,2,3</sup>, MP, Lic. Phil, Joanna Sierpowska<sup>4</sup>, PhD, MP, Teemu Siiskonen<sup>5</sup>, PhD, Hannu Järvinen<sup>5</sup>,  
5 MSc(Eng), Tuomas Kiviniemi<sup>1</sup>, MD, PhD, FESC, Tuomas T Rissanen<sup>4</sup>, MD, Hanna Matikka<sup>6</sup>, MP, PhD,  
6 Eini Niskanen<sup>7</sup>, MP, PhD, Saija Hurme<sup>8</sup>, MSc, Heli R S Larjava<sup>9</sup>, MP, Timo J Mäkelä<sup>10</sup>, MP, PhD, Satu  
7 Strengell<sup>11</sup>, MP, PhD, Markku Eskola<sup>12</sup>, MD, PhD, Teuvo Parviainen<sup>5</sup>, PhD, Elina Hallinen<sup>5</sup>, PhD, Markku  
8 Pirinen<sup>5</sup>, PhD, Antti Kivelä<sup>6</sup>, MD, Mika Teräs<sup>3,13</sup>, MP, PhD.

9

10 <sup>1</sup> Turku Heart Centre, Turku University Hospital and University of Turku, Turku, Finland

11 <sup>2</sup> The Medical Imaging Centre of Southwest Finland, Turku University Hospital, Turku, Finland

12 <sup>3</sup> Department of Medical physics, Turku University Hospital, Turku, Finland

13 <sup>4</sup> Central Hospital of Northern Karelia, Joensuu, Finland

14 <sup>5</sup> Radiation and Nuclear Safety Authority, Helsinki, Finland

15 <sup>6</sup> Imaging Centre, Kuopio University Hospital, Kuopio, Finland

16 <sup>7</sup> Department of Radiology, Vaasa Central Hospital, Vaasa, Finland

17 <sup>8</sup> Department of Biostatistics, University of Turku

18 <sup>9</sup> Department of Medical Imaging, Central Finland Health Care District, Jyväskylä, Finland

19 <sup>10</sup> Division of Cardiology, Department of Internal Medicine, Oulu University Hospital, Oulu, Finland

20 <sup>11</sup> Cardiology division, Heart and lung center, Helsinki University Hospital, Helsinki, Finland

21 <sup>12</sup> Heart Hospital, Department of Cardiology, Tampere University Hospital, Tampere, Finland and  
22 Faculty of Medicine and Life Sciences, University of Tampere, Finland

23 <sup>13</sup> Institute of Biomedicine, University of Turku, Turku, Finland

24

25 Word count: 4806

26 Corresponding author: Jukka Järvinen, [jukka.jarvinen@tyks.fi](mailto:jukka.jarvinen@tyks.fi), +358408322137, Fax: +35823139017

27 Running title: Cardiological radiation doses in Finland

## 28 ABSTRACT

29 The amount of interventional procedures such as percutaneous coronary intervention, transcatheter aortic  
30 valve implantation, pacemaker implantation and ablations has increased within the previous decade.  
31 Simultaneously, novel fluoroscopy mainframes enable lower radiation doses for patients and operators.  
32 Therefore, there is a need to update the existing DRLs and propose new ones for common or recently  
33 introduced procedures. We sought to assess patient radiation doses in interventional cardiology in a large  
34 sample from seven hospitals across Finland between 2014 and 2016. Data was used to set updated national  
35 diagnostic reference levels for coronary angiographies (KAP 30 Gy $\text{cm}^2$ ) and percutaneous coronary  
36 interventions (KAP 75  $\text{cm}^2$ ), and novel levels for pacemaker implantations (KAP 3.5 Gy $\text{cm}^2$ ), atrial  
37 fibrillation ablation procedures (KAP 25 Gy $\text{cm}^2$ ) and transcatheter aortic valve implantations (TAVI, KAP  
38 90 Gy $\text{cm}^2$ ). Tentative KAP values were set for implantations of cardiac resynchronization therapy devices  
39 (CRT, KAP 22 Gy $\text{cm}^2$ ), electrophysiological treatment of atrioventricular nodal reentry tachycardia (6  
40 Gy $\text{cm}^2$ ) and atrial flutter procedures (KAP 16 Gy $\text{cm}^2$ ). The values for TAVI and cardiac resynchronization  
41 therapy device implantation are published for the first time on national level. Dose from image acquisition  
42 (cine) constitutes the major part of the total dose in coronary and atrial fibrillation ablation procedures. For  
43 TAVI, patient weight is a good predictor of patient dose.

44

45 Word count: 209

46

## 47 INTRODUCTION

48 Fluoroscopic methods do not only play an integral role in contemporary cardiology [1,2,3], but their use has  
49 also been steadily growing over the past years. Mainly, this is due to the fact that new technologies have  
50 been developed and replaced the need for open surgery [1], the availability of medical aiding devices (such  
51 as catheters and stents) has increased, and the robustness of fluoroscopic systems has improved. All of the  
52 above have led to the fact that patients' advanced age or present comorbidities, such as previous cardiac  
53 surgery or renal disease, do not necessarily constitute contraindications for conducting procedures [1]. As a  
54 consequence, the increasingly complex and time-consuming procedures in interventional cardiology (IC)  
55 may increase the radiation exposure of patients, even though the technological advances, such as improved  
56 image quality or reduced frame rates, have partly compensated for this increase. Moreover, the procedures  
57 are often performed by cardiologists, whose knowledge on radiation protection, physics and technology  
58 might not be as profound as that of specialized radiologists.

59

60 Diagnostic reference levels (DRLs) are an essential tool for procedure optimization and controlling the dose.  
61 Their importance has been emphasized recently by the International Commission on Radiological Protection  
62 (ICRP) dedicating an entire issue to the use of DRLs [4]. The application of DRLs in IC is challenging,  
63 because many factors, the complexity of the procedure being the most important one, affect the dose  
64 significantly. At the same time, the parameters that describe the complexity, such as lesion characteristics or  
65 disease severity, are often difficult to collect unambiguously [5]. The ICRP proposes to tackle this problem  
66 by performing dose audits [4]. In this method, a large amount of data from a given procedure are pooled  
67 together and the full distribution of the doses can be analyzed, not just medians or third quartiles as is the  
68 case in customary DRL analysis [6].

69

70 The ICRP proposes to set DRLs on both regional (international) and national levels. The importance of the  
71 latter is emphasized when new techniques with potentially high exposure are implemented into clinical  
72 practice. Transcatheter aortic valve implantation (TAVI) can serve as a good example. After the first  
73 implantation in year 2008 [7], it is now performed routinely worldwide. Further, the technique has been

74 recommended for patients in high-risk surgical groups [8]. As an increasing number of hospitals are  
75 implementing this potentially high-dose procedure, the DRLs on a national level provide an important  
76 optimization tool and a reference of what can be achieved when good practice is followed.

77

78 Finland has a long history of setting DRLs on a national level. In particular, DRLs for cardiological  
79 procedures had already been published in 2005 [9]. However, with technological advances and new  
80 techniques implemented into daily routines, they have become outdated. In addition, the ICRP urges  
81 updating DRLs on a regular basis [4], in order to account for new methods and encompass new procedure  
82 types. In Finland, DRLs for TAVI, pacemaker implantation and electrophysiological procedures have not  
83 been published earlier. These procedures however have now become part of the clinical routine and have the  
84 potential to result in relatively high patient dose.

85

86 The main goal of the study was to update the existing DRLs and propose new ones for common or recently  
87 introduced IC procedures. Additional parameters, related to patient anatomy, equipment or performed  
88 procedure were used to study variation between hospitals and to investigate the contribution of these  
89 parameters to the total dose. Procedures were further categorized – when possible – into subcategories or, in  
90 the case of percutaneous coronary intervention (PCI), classified according to the American College of  
91 Cardiology/American Heart Association (ACC/AHA) grading to account for differences in procedure  
92 complexity.

93

## 94 MATERIALS AND METHODS

### 95 **Collection of Data**

96 The data was collected from 5 Finnish university hospitals (UH) and 2 central hospitals (CH): Turku  
97 (TYKS), Helsinki (HUS), Tampere (TAYS), Oulu (OYS) and Kuopio (KYS) university hospitals and Vaasa  
98 (VKS) and Joensuu (PKSSK) central hospitals. At the time of data collection, electrophysiological and TAVI  
99 procedures were performed only in the university hospitals. The hospitals were chosen based on the amount  
100 of procedures performed. The data collection period was from February 2014 to March 2016 and focused on

101 obtaining 10 procedures per category from each site. Not all hospitals were able to provide data on all  
102 requested parameters, such as fluoroscopy or cine kerma-air product (KAP) or fluoroscopy time (FT) or total  
103 imaging time.

104

105 Procedure categorization, covering 4 procedures divided to subcategories, is presented in **Table I**. Initially,  
106 transfemoral, transaortic and transapical access routes were distinguished for TAVI, but due to lack of data  
107 for transaortic and transapical routes, TAVI procedures had to be pooled. Angiographic systems and their  
108 installation years are presented in **Table II**. Their KAP-meter display accuracies as provided by regular  
109 maintenance were accounted for, and all the collected KAP-values were corrected accordingly. In general,  
110 these errors were less than 15 %.

111

## 112 **Statistical Analysis**

113 DRLs were calculated from the third quartiles of the hospitals' median values in accordance with the ICRP  
114 135 recommendations [4]. Mainly, the amount of data was also in accordance with the recommendations. No  
115 data imputation was carried out. For the cases where complete data was available, impact of various  
116 parameters on patient dose in the four procedure categories was estimated using Spearman correlation  
117 coefficients with 95% confidence intervals (95% CI) calculated using Fisher's z transformation. For binary  
118 variables (patient gender, previous bypass surgery and cardiologist fellow or trainee), a Kruskal-Wallis test  
119 was performed to test the differences between the groups. AHA classification [10, 11, 12] was treated as an  
120 ordinal variable ranging from a low to high difficulty and from a low to high radiation dose.

121

122 Two tailed tests of significance (95% CI) were performed to assess the dose level differences between  
123 hospitals and how much they deviated from the national median. For these tests, the dose data was  
124 transformed with natural logarithm and normality was checked with histograms. After the transformation,  
125 several procedures performed in UH2 (Coronary angiographies (CA), PCI, and pacemaker implantation (PI))  
126 were conspicuous as having anomalously high numbers of low doses, but generally the data was deemed

127 sufficiently normal. Dose level differences between different procedures or between hospitals were tested  
128 with t-tests for independent samples.

129

130 The analysis methods were selected based on the amount of obtained data and the observed variance.  
131 Statistical power was not calculated before data collection. Statistical analyses were performed by an  
132 experienced statistician using SAS System for Windows, Version 9.4 (SAS Institute Inc., Cary, NC) and  
133 only some obvious typos were removed from the data.

134

## 135 RESULTS

136 Dose data from 21 278 procedures was collected. Most of the data was for coronary procedures (n=18 296).  
137 For comparison, according to the Finnish Cardiovascular Diseases Register and Finnish Cardiac Society  
138 chief physician survey 2015 [1,13], the total amount of collected dose data corresponded to roughly 44 % of  
139 procedures performed annually in Finland.

140

141 The main result of the study are the new DRLs, tentative KAP and FT values, calculated as third quartiles of  
142 the hospitals' median values and presented in **Tables III** and **IV**. The tables highlight the novelty of many of  
143 the new DRLs. Compared to other results, the new Finnish DRLs are mainly lower.

144

145 Comparison of doses between the procedure types has been shown in **Figure 1**. Compared to other  
146 procedures, PCI and TAVI stand out with relatively high dose level and large variance. **Figure 2** shows  
147 boxplots of the total KAP values in different hospitals and the numbers of procedures performed. Because of  
148 the low number of procedures combined with the deviating results, the following hospitals were excluded  
149 from the DRL calculations: UH4 for PCI and CH1 for PI. For the same reasons, actual DRLs were not set for  
150 implantation of cardiac resynchronization device (CRT), electrophysiological treatment of atrioventricular  
151 nodal reentry tachycardia (AVNRT) and atrial flutter, and tentative KAP values calculated in the same way  
152 as DRLs were used instead. With good statistics in the t-tests, many hospitals deviated significantly from the  
153 total data median in CA procedures. Likewise, UH1 deviated significantly from the total data median in

154 TAVI procedures. **Figure 3** shows how radiation doses in TAVI procedures have decreased in Finland  
155 during the period of data collection (Spearman correlation -0.082, P=0.151).

156

157 In **Table V**, relevant statistics for the collected parameters for the cases where complete data was available  
158 are presented. As can be seen, the percentage contribution of fluoroscopy and acquisition varies between  
159 procedure types. The high standard deviation in PI procedures is due to procedures performed in CH1 being  
160 carried out with an older C-arm.

161

162 **Table VI** shows the Spearman correlations of the collected parameters for the total KAP and their total  
163 amounts for the cases where complete data was available. The correlation of weight to the total KAP is  
164 substantial in the TAVI procedure. Furthermore, cine acquisitions correlate strongly with total KAP in all  
165 high dose procedures. In addition, low correlation of AHA-score in CA procedures, low correlation of  
166 angiosystem age and negative correlation of patient age in PI procedures are noteworthy.

167

168 Male patient gender was an influential and significant factor for total dose in all procedure types ( $\chi^2 = 68.56$   
169 with  $p < 0.001$  for coronary procedures,  $\chi^2 = 13.33$  with  $p < 0.001$  for pacemaker implantations,  $\chi^2 = 4.72$  with  
170  $p < 0.05$  for electrophysiological procedures and  $\chi^2 = 7.08$  with  $p < 0.01$  for TAVI). In addition, patient's  
171 previous bypass surgery had a significant but minor effect on dose in coronary procedures ( $\chi^2 = 6.81$  with  
172  $p < 0.01$ ). A cardiologist fellow or trainee performing the procedure had no significant effect on total radiation  
173 dose. This was the case for all procedure types.

174

## 175 DISCUSSION

176 In this study, diagnostic reference levels, in terms of a cumulative KAP as well as FT, were set for several  
177 cardiological procedures. The suggested DRLs can be applied in current clinical practice. Some of the new  
178 DRL values replace the previous Finnish DRLs set in 2005. The DRLs for TAVI and CRT were set for the  
179 first time.

180

## 181 **Diagnostic reference levels**

182 The DRLs were calculated as third quartile values of the hospitals' medians for the quantity in question, in  
183 line with ICRP recommendations [4] and methodology of the Finnish authority (STUK) for the new DRLs  
184 [14]. Traditionally, DRLs have been published as either third quartiles of the whole data or as third quartiles  
185 of the hospital medians and this methodology is not always accurately reported [15]. Compared to dose  
186 levels calculated as third quartiles of the whole data, on average the new Finnish DRLs (medians of hospital  
187 third quartiles) are 30 % lower. This difference, due to the methodology, is in line with results published by  
188 Georges et al [15].

189

190 For TAVI procedures, the DRLs are among the first DRLs in the world. TAVI is a relatively new procedure  
191 in many hospitals and the DRL is an essential optimization tool at the onset of the procedure, when extensive  
192 local dose data are not yet available. In this study, different TAVI access routes (i.e. transfemoral, transaortic  
193 or transapical) were not distinguished, even though they are known to affect the dose [29]. This was due to  
194 an insufficient number of cases in each access route subcategory and accordingly the data had to be pooled  
195 together. The most common access route in Finland - transfemoral- does not render the highest nor the  
196 lowest doses. The DRL for TAVI is the highest amongst the investigated procedures.

197

198 In addition, the tentative KAP value for CRT procedures is among the first published values in the world.  
199 Often CRT is categorized as a pacemaker implantation and, thus, the DRL for PI are applied to CRT as well.  
200 In this study, the two procedures have been separated since CRT procedures result in significantly higher  
201 doses than other pacemaker implantations. Further, for the installation of a peacemaker with one or two  
202 leads, the observed dose levels were similar and thus only one DRL is given.

203

204 Only a few DRLs for electrophysiological procedures have been published so far [24]. However, since these  
205 procedures have become an important part of cardiological routine [30], the DRLs are important to help in  
206 the optimization of the procedure. In this study, the subcategories of EF procedures were investigated, unlike  
207 most other studies where these procedures are pooled together [24]. Significant variation across the  
208 subcategories was observed and, accordingly, the DRLs were set for each subcategory.



209

## 210 **Variation between hospitals**

211 Variation of total KAP values between the hospitals is shown in **Figure 2**. The variation is largest in CA and  
212 PCI procedures, in particular in university hospitals, where there are more patients and cardiologists  
213 performing procedures. Both of these contribute to the observed higher variation. Regarding equipment age,  
214 with the exception of PM in CH1 where procedures were partly performed with a mobile C-arm from 2001,  
215 equipment age had no significant correlation to patient dose.

216

217 Except for CA and PCI, the inter-hospital variation in doses is reasonably small making the DRL setting  
218 straightforward. This might be due to the fact that cardiologists in Finland obtain extensive radiation  
219 protection training in which patient protection and dose optimization are continuously emphasized resulting  
220 in a consistent approach across the country. Additionally, medical physicists often work together with  
221 clinical practitioners in optimization processes in cardiology clinics.

222

223 Protocol optimization plays an integral role in patients' radiation exposure level. Poorly optimized  
224 equipment might force users to increase the dose to unnecessarily high level (i.e. excessive use of cine) in  
225 order to obtain an acceptable image quality. A previous study that investigated 18 fluoroscopy systems from  
226 13 medical facilities within one city, found that dose rates and image quality vary widely between systems  
227 and the difference in image quality was considerable [31]. Moreover, inappropriate use of zoom or position  
228 of the x-ray tube and the detector can have a large influence on patient exposure.

229

## 230 **Comparison to other studies**

231 DRLs for certain cardiological procedures have been published earlier (**Table III**). Most commonly the  
232 DRLs have been set for CA and PCI procedures. The DRL for CA and PCI presented here are at the same  
233 level as DRLs from the studies published after 2010 (Australia's DRL [27] being an exception). As  
234 compared to previous Finnish national DRLs from 2005 [9] and to RAD-IR DRLs in the US from 2003 it  
235 can clearly be seen that in these 15 years the doses have decreased significantly [17,18,19]. Particularly, the

236 difference between the new and old Finnish CA DRLs (50%) emphasizes the need for regular updates of  
237 DRLs as suggested by the ICRP [4]. The decrease can possibly be explained by the technological advances,  
238 such as improvements in x-ray tubes, detectors and post-processing, and highlights the importance of  
239 embracing new technology. This observed decrease in dose, however, does not guarantee that the collective  
240 dose to all patients (and thus the dose to the staff) is reduced, because the decrease can readily be  
241 counterbalanced by the increasing number of procedures performed on the aging population.

242

243 The DRLs for the PI, AVNRT, atrial flutter and AF were significantly lower in the present study than in  
244 previous studies (**Table III**). A part of this difference can be explained by the different procedure definitions.  
245 For example, in Greek DRLs from 2013 [24] no distinction was made between atrial flutter and AF, and  
246 DRLs for radiofrequency cardiac ablation were reported instead.

247

248 The DRL for TAVI (90 Gy $\text{cm}^2$ ) has been set in this study for the first time in Finland but some comparison  
249 can be found for the median value presented in **Table IV**. The median KAP value in this study (76.7 Gy $\text{cm}^2$ )  
250 was lower than most previously reported median KAP values, which vary between 75-186 Gy $\text{cm}^2$   
251 [32,33,34,35]. Interestingly, the value found in the present study was at the same level as Sharma et al. [34]  
252 reported for the “modified image acquisition setting”, a protocol that reduces the dose. This emphasizes the  
253 importance of careful dose optimization. Further, for TAVI, a technique that is relatively complex, a learning  
254 curve is present (**Figure 3**). It is apparent that immediately after implementing the technique the doses are  
255 higher; however, as the performing staff acquire more experience and with possible protocol adjustments, the  
256 dose decreases and stabilizes. This has also been observed previously [29].

257

258 Similar to TAVI, a tentative KAP value for CRT has not been published before in Finland. The value for the  
259 median dose in CRT implantation, 13.4 Gy $\text{cm}^2$ , was lower than that published earlier, 26 Gy $\text{cm}^2$  [36]. The  
260 dose for CRT is significantly higher than for other investigated PI procedures.

261

262 In this study, DRLs for FT were not set because its use as a surrogate for patient doses is not encouraged [4].  
263 However, typical FT values are given in **Table IV**, calculated in the same way as the DRLs. No significant

264 differences in FT are observable when comparing the results from this and previous studies. One noticeable  
265 fact is that although TAVI and CA are higher-dose procedures than CRT, they have shorter FT. This is also  
266 visible in **Table VI**, where FT (or total imaging time) is an inferior predictor of total KAP than the number  
267 of cine series or images. Accordingly, FT cannot be the only factor used to assess the patient's dose. Further,  
268 the alert levels for preventing radiation induced skin damage that are based solely on FT may be misleading.

269

### 270 **Factors associated with changes in Kerma-area product**

271 Factors associated with increased KAP are presented in **Table VI**. In CA procedures, use of acquisition (i.e.  
272 cine) is an important factor explaining the total KAP. In EF procedures, use of cine is even more pronounced  
273 considering the 3D imaging performed in some EF procedures. As such, despite all the technological  
274 advances, minimizing the use of cine in IC is still an effective way to decrease patient (and staff) doses.

275

276 DRLs are conventionally set for patients within a predetermined weight range. The ICRP urges normalizing  
277 the data by compensating for differences in patient body habitus and weight [4]. The results from the present  
278 study show that, with the exception of TAVI, weight is a poor determinant of the total dose: the correlations  
279 were significant but weak. We have also investigated whether the body mass index (BMI) would improve the  
280 correlation. However, the BMI transpired to be an even poorer determinant of total KAP. In TAVI  
281 procedures, unlike in the others, patient's weight is a relatively strong predictor of the total dose, a finding  
282 that is in line with previous studies [32]. However, this may be influenced by the limited number of available  
283 cases in the statistical analysis as suggested by the result that the number of acquisition images and FT are  
284 not significant predictors of the TAVI dose (**Table VI**). Patient gender had a reasonably big influence on  
285 patient dose in all procedure types. This can be mostly attributed to gender correlating strongly with patient  
286 size.

287

288 The result that the AHA-score has a low correlation to the radiation dose means that alone it is not sufficient  
289 to estimate the difficulty of a procedure from the perspective of using radiation. The result that a cardiologist  
290 fellow performing a procedure does not correlate with higher or lower doses in any procedures can be due to

291 inter-hospital variation as to who performs what procedures and inter-fellow variation. In addition,  
292 angiosystem age correlating very little can be interpreted to highlight the importance of the other factors.  
293 Lastly, the result that patient age has a negative correlation in PI procedures can be assumed to be mostly due  
294 to the type of pacemaker implanted.

295

## 296 CONCLUSION

297 In this study, a comprehensive analysis of patient doses in contemporary interventional cardiology in Finland  
298 has been presented. The data was used to update the existing national DRLs for CA and PCI with lower ones  
299 that better reflect contemporary practice and to set new DRLs for pacemaker implantation,  
300 electrophysiological procedures and TAVI procedures. In addition, tentative KAP values were presented for  
301 CRT, AVNRT and atrial flutter procedures. Both the TAVI DRL and the CRT tentative KAP value are  
302 among the first to be published. The results show that even though technical advances have helped to reduce  
303 the radiation burden of patients and staff, the careful optimization of the procedure (e.g. amount of cine used)  
304 is still an essential part of dose optimization.

305

## 306 ACKNOWLEDGEMENTS

307 The authors wish to express our sincere thanks to the following people for their help in collection of the data:  
308 Veli-Pekka Poutanen, Anniina Lampinen and Kirsi Vinni-Lappalainen.

309

## 310 REFERENCES

- 311 [1] Kiviniemi, T.O., Pietilä, A., Gunn, J.M., Aittokallio, J.M., Mähönen, M.S.,  
312 Salomaa, V.V. and Niiranen, T.J. Trends in rates, patient selection and  
313 prognosis of coronary revascularisations in Finland between 1994 and 2013:  
314 the CVDR. Eurointervention 12, 1117-1125 (2016).
- 315 [2] Blackledge, H.M. and Squire, I.B. Improving long-term outcomes following  
316 coronary artery bypass graft or percutaneous coronary revascularisation: results

- 317 from a large, population-based cohort with first intervention 1995-2004. Heart  
318 95, 304-11 (2009).
- 319 [3] Fokkema, M.L., James, S.K., Albertsson, P., Akerblom, A., Calais, F.,  
320 Eriksson, P., Jensen, J., Nilsson, T., de Smet, B.J., Sjögren, I., Thorvinger, B.  
321 and Lagerqvist, B. Population trends in percutaneous coronary intervention:  
322 20-year results from the SCAAR (Swedish Coronary Angiography and  
323 Angioplasty Registry). J. Am. Coll. Cardiol. 61, 1222–30 (2013)
- 324 [4] ICRP, 2017. Diagnostic reference levels in medical imaging. ICRP Publication  
325 135. Ann. ICRP 46(1).
- 326 [5] Balter, S. et al Patient radiation dose audits for fluoroscopically guided  
327 interventional procedures; Med. Phys. 2011 38, 1611–1618
- 328 [6] Padovani, R., Quai, E. Patient dosimetry approaches in interventional  
329 cardiology and literature dose data review. Radiat. Prot. Dosim. 2005 117,  
330 217–221.
- 331 [7] German Heart Surgery Report 2016: The Annual Updated Registry of the  
332 German Society for Thoracic and Cardiovascular Surgery ; DOI  
333 <https://doi.org/10.1055/s-0037-1606603>.
- 334 [8] Transcatheter Aortic Valve Implantation – History, Current Guidelines and  
335 Implications for the Future. Med Monatsschr Pharm. 2017 May;40(5):205-8.
- 336 [9] STUK Päätös 27/310/05. Potilaan säteilyaltistuksen vertailutasot  
337 kardiologisessa radiologiassa. Helsinki (2005).
- 338 [10] Ryan, T.J., Faxon, D.P., Gunnar, R.M., Kennedy, J.W., King, S.B. III, Loop,  
339 F.D., Peterson, K.L., Reeves, T.J., Williams, D.O. and Winters, W.L. Jr.  
340 Guidelines for percutaneous transluminal coronary angioplasty. A report of the  
341 American College of Cardiology/American Heart Association Task Force on  
342 Assessment of Diagnostic and Therapeutic Cardiovascular Procedures  
343 (Subcommittee on Percutaneous Transluminal Coronary Angioplasty).  
344 Circulation 78, 486–502 (1988).

- 345 [11] Ellis, S.G., Roubin, G.S., King, S.B., Douglas, J.S., Weintraub, W.S., Thomas,  
346 R.G. and Cox, W.R. Angiographic and clinical predictors of acute closure after  
347 native vessel coronary angioplasty. *Circulation* 77(2), 372-9 (1988).
- 348 [12] Ellis, S.G., Vandormael, M.G., Cowley, M.J., DiSciascio, G., Deligonul, U.,  
349 Topol, E.J. and Bulle, T.M. Coronary morphologic and clinical determinants of  
350 procedural outcome with angioplasty for multivessel coronary disease.  
351 Implications for patient selection. Multivessel Angioplasty Prognosis Study  
352 Group. *Circulation* 82, 1193–1202 (1990).
- 353 [13] Raatikainen, P., Mäkynen, H., Hedman, A., Vikman, S., Hartikainen, J. and  
354 Airaksinen, J. Ylilääkärikysely 2006-2015. Finnish Cardiac Society (2016).
- 355 [14] STUK Päätos 15/3020/2016. Potilaan säteilyaltistuksen vertailutasot  
356 kardiologisessa radiologiassa. Helsinki (2016).
- 357 [15] Georges J.L., Belle L., Etard C., Azowa J.B., Albert F., Pansieri M., Monsegu  
358 J., Barbou F., Trouillet C., Leddet P., Livarek B., Marcaggi X., Hanssen M.,  
359 Cattan S., The Ray'act-Investigators. Radiation Doses to Patients in  
360 Interventional Coronary Procedures-Estimation of Updated National Reference  
361 Levels by Dose Audit. *Radiat. Prot. Dosim.* 175(1), 17-25 (2017).
- 362 [16] Padovani, R., Vano, E., Trianni, A., Bokou, C., Bosmans, H., Bor, D.,  
363 Jankowski, J., Torbica, P., Kepler, K., Dowling, A., Milu, C., Tsapaki, V.,  
364 Salat, D., Vassileva, J. and Faulkner, K. Reference levels at European level for  
365 cardiac interventional procedures. *Radiat. Prot. Dosim.* 129(1-3), 104-7 (2008).
- 366 [17] Miller, D.L., Balter, S., Cole, P.E., Lu, H.T., Schueler, B.A., Geisinger, M.,  
367 Berenstein, A., Albert, R., Georgia, J.D., Noonan, P.T., Cardella, J.F., St  
368 George, J., Russell, E.J., Malisch, T.W., Vogelzang, R.L., Miller, G.L. 3<sup>rd</sup> and  
369 Anderson, J. Radiation Doses in Interventional Radiology Procedures: the  
370 RAD-IR Study: Part I: Overall Measures of Dose. *J. Vasc. Interv. Radiol.*  
371 14(6), 711-27 (2003).

- 372 [18] Miller D.L., Balter, S., Cole, P.E., Lu, H.T., Berenstein, A., Albert, R.,  
373 Schueler, B.A., Georgia, J.D., Noonan, P.T., Russell, E.J., Malisch, T.W.,  
374 Vogelzang, R.L., Geisinger, M., Cardella, J.F., George, J.S., Miller, G.L. 3<sup>rd</sup>  
375 and Anderson, J. Radiation Doses in Interventional Radiology Procedures: the  
376 RAD-IR Study: Part II: Skin Dose. *J. Vasc. Interv. Radiol.* 14, 977-990 (2003).
- 377 [19] Miller, D.L., Hilohi, C.M. and Spelic, D.C. Patient radiation doses in  
378 interventional cardiology in the U.S.: Advisory data sets and possible initial  
379 values for U.S. reference levels. *Med. Phys.* 39(10), 6276 (2012).
- 380 [20] Wegleitung R-06-05 Diagnostische Referenzwerte (DRW) für interventionelle  
381 radiologische Anwendungen. Bundesamt für Gesundheit BAG (2018).
- 382 [21] D’Helft, C., McGee, A., Rainford, L., McFadden, S., Winder, J., Hughes, C.  
383 and Brennan, P.C. Proposed preliminary diagnostic reference levels for three  
384 common interventional cardiology procedures in Ireland. *Radiat. Prot. Dosim.*  
385 129(1-3), 63-6 (2008).
- 386 [22] Brnic, Z., Krpan, T., Faj, D., Kubelka, D., Ramac, J.P., Posedel, D., Steiner, R.,  
387 Vidjak, V., Brnić, V., Visković, K. and Baraban, V. Patient radiation doses in  
388 the most common interventional cardiology procedures in Croatia: first results.  
389 *Radiat. Prot. Dosim.* 138(2), 180-186 (2009).
- 390 [23] Zotova, R., Vassileva, J., Hristova, J., Pirinen, M. and Järvinen, H. A national  
391 patient dose survey and setting of reference levels for interventional radiology  
392 in Bulgaria. *Eur. Radiol.* 22, 1240-1249 (2012).
- 393 [24] Simantirakis, G., Koukorava, C., Kalathaki, M., Pafilis, C., Kaisas, I.,  
394 Economides, S., Hourdakis, C.J., Kamenopoulou, V. and Georgiou, E.  
395 Reference levels and patient doses in interventional cardiology procedures in  
396 Greece. *Eur. Radiol.* 23, 2324-2332 (2013).
- 397 [25] Pantos, I., Pataloukas, G., Katritsis, D.G. and Efstathopoulos, E. Patient  
398 Radiation Doses in Interventional Cardiology Procedures. *Curr. Cardiol. Rev.*  
399 5(1), 1-11 (2009).

- 400 [26] Statens strålevern Norwegian Radiation Protection Authority. ISSN 0806-895x.  
401 <http://www.nrpa.no/filer/d49db9aeb1.pdf> (2010).
- 402 [27] Crowhurst, J.A., Whitby, M., Thiele, D., Halligan, T., Westerink, A., Crown, S.  
403 and Milne, J. Radiation dose in coronary angiography and intervention: initial  
404 results from the establishment of a multi-centre diagnostic reference level in  
405 Queensland public hospitals. *J. Med. Radiat. Sci.* 61, 135-141 (2014).
- 406 [28] Hart, D., Hillier, M.C., Wall, B.F. National reference doses for common  
407 radiographic, fluoroscopic and dental X-ray examinations in the UK. *Br. J.*  
408 *Radiol.* 82(973), 1-12 (2009).
- 409 [29] Simard, T. et al. Impact of center experience on patient radiation exposure  
410 during transradial coronary angiography and percutaneous intervention: A  
411 patient-level, international, collaborative multi-center analysis. *J Am Heart*  
412 *Assoc.* 5(6), (2016).
- 413 [30] Faxon, D.P. and Williams, D.O. The Changing Face of Interventional  
414 Cardiology. *Circulation: Cardiovasc Interv.* 5, 325-327 (2012).
- 415 [31] Yohei Inaba, et al A cross-sectional study of the radiation dose and image  
416 quality of X-ray equipment used in IVR. *J Appl Clin Med Phys.* 17(4), (2016).
- 417 [32] Crowhurst J. Establishing radiation dose levels during TAVI procedures for the  
418 patient and the multidisciplinary Heart Team. *EuroPCR Abstract Book.* 2015.
- 419 [33] Goldsweig AM et al Predictors of patient radiation exposure during  
420 transcatheter aortic valve replacement. *Catheter Cardiovasc Interv.* 27, (2017).  
421 doi: 10.1002/ccd.27452
- 422 [34] Sharma D Reducing radiation exposure during transcatheter aortic valve  
423 implantation (TAVI). *Catheter Cardiovasc Interv* 85(7), 1256-61 (2015). doi:  
424 10.1002/ccd.25363.
- 425 [35] Benoit Daneault et al; Radiation exposure during transcatheter aortic valve  
426 implantation (TAVI) procedures. *JACC.* 57(15), (2011).



- 427 [36] Thibault B et al Reducing radiation exposure during CRT implant procedures:  
428 early experience with a sensor-based navigation system. *Pacing Clin*  
429 *Electrophysiol.* 38(1), 63-70 (2015). doi: 10.1111/pace.12522.
- 430 [37] IAEA, 2009. International Atomic Energy Agency annual report 2009. IAEA.
- 431 [38] Padovani, R., Bernardi, G., Malisan, M.R., Vañó, E., Morocutti, G. and  
432 Fioretti, P.M. Patient dose related to the complexity of interventional  
433 cardiology procedures. *Radiat. Prot. Dosim.* 94(1-2), 189-92 (2001).  
434

435 **Table I. Used procedure categorization.**

436

<b>Coronary procedures</b>		
<b>Type 1:</b> Coronary angiography (CA)		<b>Type 2:</b> Percutaneous coronary angioplasty (PCI)
<b>Pacemaker implantations (PI)</b>		
<b>Type 1:</b> Single chamber (1C) or dual chamber (2C)		<b>Type 2:</b> Cardiac resynchronization therapy (CRT)
<b>Electrophysiological procedures (EF)</b>		
<b>Type 1:</b> Atrioventricular Nodal Reentrant Tachycardia (AVNRT)	<b>Type 2:</b> Atrial flutter	<b>Type 3:</b> Atrial fibrillation (AF)
<b>Transcatheter aortic valve implantations (TAVI) – procedure types combined</b>		

437

438

439

440 **Table II. Angiography systems and their installation years in different hospitals.**

441

	System	Installation year
<b>Coronary procedures</b>		
UH1	Siemens Artis Zee	2013
UH2	Siemens Artis Zee	2005
UH3	GE Innova 2100 IQ	2006
UH4	Siemens Axiom Artis	2006
UH5	Siemens Artis Q Zen	2014
CH1	Philips Velara 100	2005
CH2	Siemens Artis Zee	2011
CH3	Philips Allura Xper	2010
<b>Pacemaker Implantations</b>		
UH1	Siemens Artis Zee	2012
UH2	Siemens Artis Zee	2011
UH3	Philips Allura Xper	2009
UH4	Siemens Artis Zee	2009
UH5	Philips Allura Xper	2010
CH1	GE Innova 4100 IQ pro/Ziehm Exposcop 8000 (Mobile C-arm)	2009/2001
CH2	Siemens Axiom Artis	2007
CH3	GE Innova IGS 520	2013
<b>Electrophysiological procedures</b>		
UH1	Siemens Artis Zee	2013
UH2	Siemens Artis Zee	2012
UH3	Philips Allura Xper	2009
UH4	Siemens Artis Zee	2010
UH5	Philips Allura Xper	2010
<b>TAVI procedures</b>		
UH1	Siemens Artis Zee Ceiling	2012
UH2	Siemens Artis Zeego	2014
UH3	Siemens Innova 2100 IQ	2006
UH4	Siemens Axiom Artis dFA	2006
UH5	Siemens Artis Q zen	2014

442

443

444

445 **Table III. Published DRLs and published results of patient KAP values (Gycm<sup>2</sup>) in interventional**  
 446 **cardiology. Calculation method may vary between national and international DRLs.**

Publication / Procedure and parameter	CA KAP	PCI KAP	PI KAP	CRT KAP	AVNRT KAP	Atrial flutter KAP	AF KAP	TAVI KAP
This study and Finnish national DRLs and tentative 3rd quartile values calculated similarly to DRLs [14] (2016)	30	75	3.5	22*	6*	16*	25	90
Finnish national DRLs [9] (2005)	60	100	NA	NA	NA	NA	NA	NA
Sentinel EU, DRLs [16] (2008)	45	85	NA	NA	NA	NA	35	NA
RAD-IR, USA, DRLs [17,18,19] (2003)	83	193	NA	NA	NA	NA	NA	NA
Switzerland DRLs [20] (2018)	50	100	5	NA	EF 20	RFA 30		100
Ireland KAP DRLs and mean FT's [21] (2008)	46.5	106.5	16.9	NA	NA	NA	NA	NA
Croatia DRLs [22] (2009)	32	NA	NA	NA	NA	NA	NA	NA
Bulgaria KAP DRLs and mean FT's [23] (2012)	40	NA	NA	NA	NA	NA	NA	NA
Greece 75 <sup>th</sup> percentiles [24] (2013)	53	129	36	NA	NA	NA	RFA 146	NA
Pantos et al (averages) [25] (2009)	39.9	78.3	NA	NA	EF 14.5	RFA 54.6		NA
Norwegian DRL [26] (2010)	21	NA	NA	NA	NA	NA	NA	NA
Queensland, Australia DRL [27] (2014)	58.6	129	NA	NA	NA	NA	NA	NA
2 <sup>nd</sup> RAY'ACT study, France [14] (2017)	26	60	NA	NA	NA	NA	NA	NA
UK [28] (2009)	29	NA	NA	NA	NA	NA	NA	NA

447 CA = coronary angiography. PCI = percutaneous coronary angioplasty. PI = pacemaker installation. EF = electrophysiological study. RFA =  
 448 radiofrequency ablation.

449

450

451

452

453 **Table IV. Published fluoroscopy times (FT, min) in interventional cardiology.**

Publication / Procedure and parameter	CA FT	PCI FT	PI FT	CRT FT	AVNRT FT	Atrial flutter FT	AF FT	TAVI FT
Present study 3rd quartile values calculated similarly to DRLs	6.0	18.4	6.7	20.5	13.3	23.1	14.0	21.5
Finnish national DRLs [9] (2005)	8	20	NA	NA	NA	NA	NA	NA
Sentinel EU, DRLs [16] (2008)	6.5	15.5	NA	NA	NA	NA	21	NA
RAD-IR, USA, DRLs [17,18,19] (2003)	5.4	18.5	NA	NA	NA	NA	NA	NA
Switzerland DRLs [20] (2018)	8	20	5	NA	EF 10	RFA 9		30
Ireland mean FT's [21] (2008)	4.3	14.5	6.6	NA	NA	NA	NA	NA
Croatia DRLs [22] (2009)	6.6	NA	NA	NA	NA	NA	NA	NA
Bulgaria mean FT's [23] (2012)	5.1	NA	NA	NA	NA	NA	NA	NA
Pantos et al (mean values) [25] (2009)	4.7	15	NA	NA	EF 9	RFA 45.8		NA
2 <sup>nd</sup> RAY <sup>2</sup> ACT study, France DRLs [14] (2017)	4	11	NA	NA	NA	NA	NA	NA
UK DRLs [28] (2009)	4.5	13	8.2	NA	NA	NA	NA	NA

454 CA = coronary angiography. PCI = percutaneous coronary angioplasty. PI = pacemaker installation. EF = electrophysiological study. RFA =

455 radiofrequency ablation.

456

457 **Table V. Analyzed relevant statistics of the collected data. Due to non-normality, KAP and imaging**458 **time values are presented as medians, whereas others are presented as means or percentages.**

Procedure type and total amount of collected data	CA n=364	PCI n=290	PI n=166	CRT n=31	AVNRT n=54	Atrial flutter n=13	AF n=45	TAVI n=38
Age (y)	67.2	67.4	73.7	65.4	49.9	61.1	57.8	82.0
Male gender	59.1%	72.4%	54.4%	71.6%	41.0%	72.0%	70.8%	52.0%
Weight (kg)	81.9	82.7	81.1	85.0	77.0	88.6	87.6	75.0
Height (cm)	169.8	170.6	169.5	172.0	169.0	174.2	175.8	165.9
Previous bypass surgery	3.3%	4.8%	3.0%	3.2%	0	0	0	0
Cardiologist fellow/trainee	11.8%	6.9%	7.2%	3.2%	0%	0%	0%	0%
AHA/ACC classification [12,13,14]	NA	A: 11.0% B: 32.8% C: 23.4%	NA	NA	NA	NA	NA	NA
Fluoroscopy time (min)	3.2	11.2	4.4	15.5	8.0	17.3	7.9	20.8
Total radiation time (min)	4.2	12.4	2.8	20.1	6.8	NA	12.3	15.3
Fluoroscopy KAP (Gycm <sup>2</sup> ) (% of total KAP)	2.0 (11.0 %)	10.9 (27.2 %)	3.3 (100 %)	8.2 (51.2 %)	3.4 (100 %)	12.8 (62.7 %)	5.8 (21.1 %)	35.8 (50.9 %)
Acquisition KAP (Gycm <sup>2</sup> ) (% of total KAP)	16.2 (89.0 %)	29.2 (72.8 %)	0	7.8 (48.8 %)	0	7.6 (37.3 %)	21.7 (78.3 %)	34.5 (49.1 %)
Number of acquisitions	24.0	27.7	0	5.7	0	1.2	3.8	13.2
KAP per acquisition (Gycm <sup>2</sup> )	0.68	1.05	NA	1.37	NA	6.33	5.71	2.61
Number of acquisition images	771.8	1270.2	74.8	225.0	4.6	0	181.2	521.8
Total KAP (Gycm <sup>2</sup> )	20.3	46.1	3.2	22.8	3.1	15.4	24.6	83.0
TOTAL KAP Standard deviation*	37.3	63.6	17.9	41.7	18.5	37.2	23.4	48.4
Air kerma (mGy)	409.0	1187.4	55.4	426.9	85.0	194.7	367.0	1068.4

459 CA = Coronary Angiography, PCI = Percutaneous Coronary Angioplasty, PI = Pacemaker Implantation, CRT = Cardiac Resynchronization Therapy,

460 AVNRT = Atrioventricular Nodal Reentrant Tachycardia, AF = Atrial Fibrillation, TAVI = Transcatheter aortic valve implantations.

461 \* Standard deviation calculated with outliers.

462

463

464 **Table VI. Statistically significant ( $p < 0.05$ ) factors affecting total dose in the different procedure**  
 465 **categories. Presented values are Spearman correlations. Values in parenthesis are total amounts of**  
 466 **data specific to the parameter.**

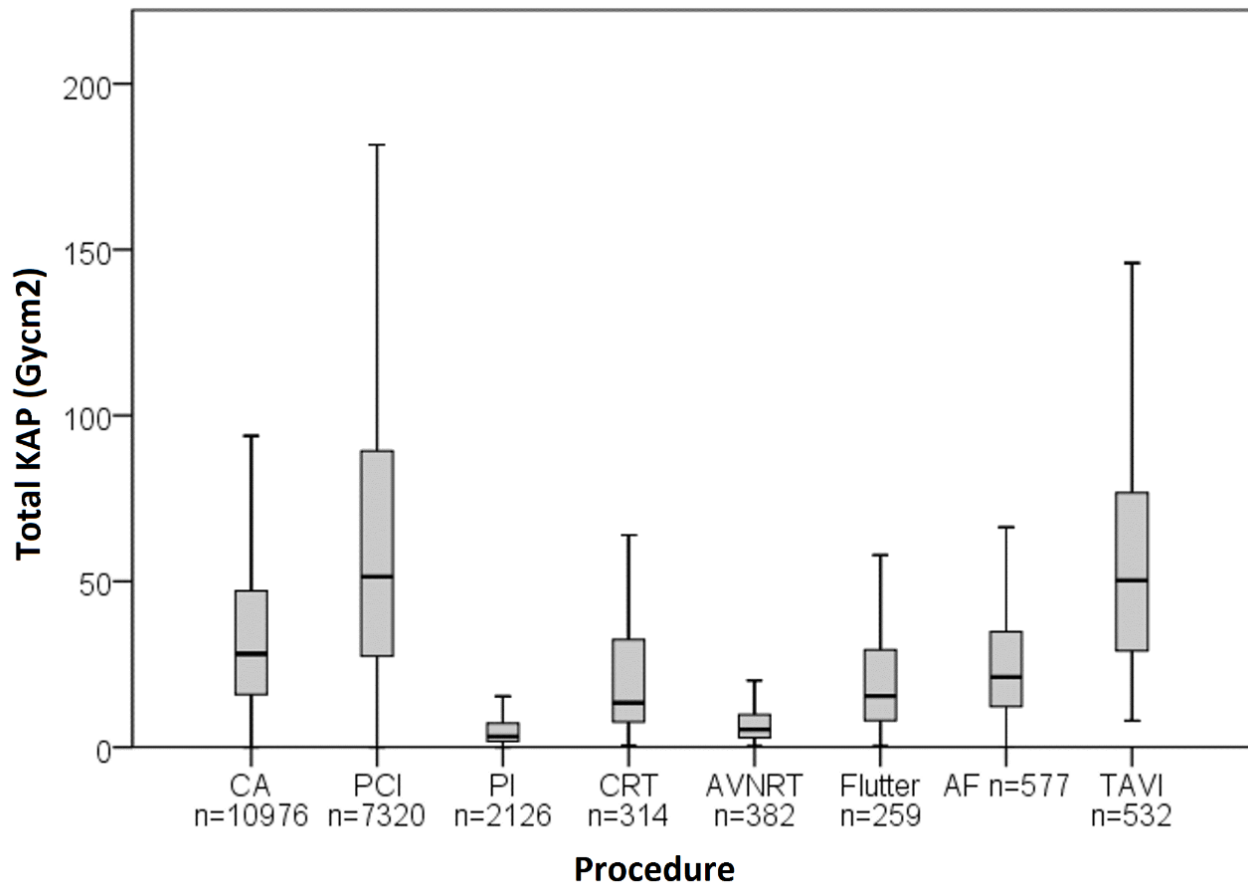
467

Factor	Coronary procedures	Confidence intervals	Pacemaker implantations	Confidence intervals	Electrophysiological procedures	Confidence intervals	TAVI procedures	Confidence intervals
Fluoroscopy KAP (n)	0.856 (526)	0.831-0.877	0.905 (90)	0.859-0.937	0.720 (72)	0.586-0.816	0.820 (22)	0.608-0.922
Acquisition KAP (n)	0.835 (521)	0.807-0.859	0.431 (90)	0.245-0.586	0.598 (72)	0.425-0.729	0.784 (22)	0.541-0.906
Air kerma (n)	0.830 (646)	0.805-0.853	0.974 (154)	0.964-0.981	0.931 (101)	0.899-0.953	0.765 (37)	0.587-0.873
Amount of acquisition images (n)	0.613 (104)	0.476-0.720	Not significant		0.864 (17)	0.655-0.950	Not significant	
Fluoroscopy time (n)	0.626 (493)	0.569-0.677	0.788 (120)	0.709-0.848	0.358 (73)	0.139-0.543	Not significant	
Amount of acquisition series (n)	0.636 (540)	0.582-0.683	0.470 (100)	0.301-0.610	0.414 (77)	0.209-0.584	Not significant	
Total imaging time (n)	0.560 (234)	0.465-0.642	0.723 (75)	0.594-0.816	0.319 (43)	0.020-0.565	Not significant	
Weight (n)	0.335 (650)	0.265-0.402	0.261 (195)	0.125-0.387	0.527 (112)	0.378-0.649	0.759 (37)	0.577-0.869
AHA-classification (n)	0.261 (654)	0.188-0.331	NA		NA		NA	
Height (n)	0.253 (647)	0.179-0.324	0.162 (193)	0.021-0.296	0.309 (111)	0.130-0.468	0.555(37)	0.281-0.745
BMI* (n)	0.257 (646)	0.184-0.328	0.249 (193)	0.111-0.377	0.430 (111)	0.265-0.571	0.525 (37)	0.243-0.726
Angiosystem age (n)	0.111 (654)	0.034-0.186	0.190 (197)	0.051-0.321	Not significant		Not significant	
Patient Age (n)	Not significant		-0.204 (182)	-0.339 – -0.060	Not significant		Not significant	

468 \* Body Mass Index

469

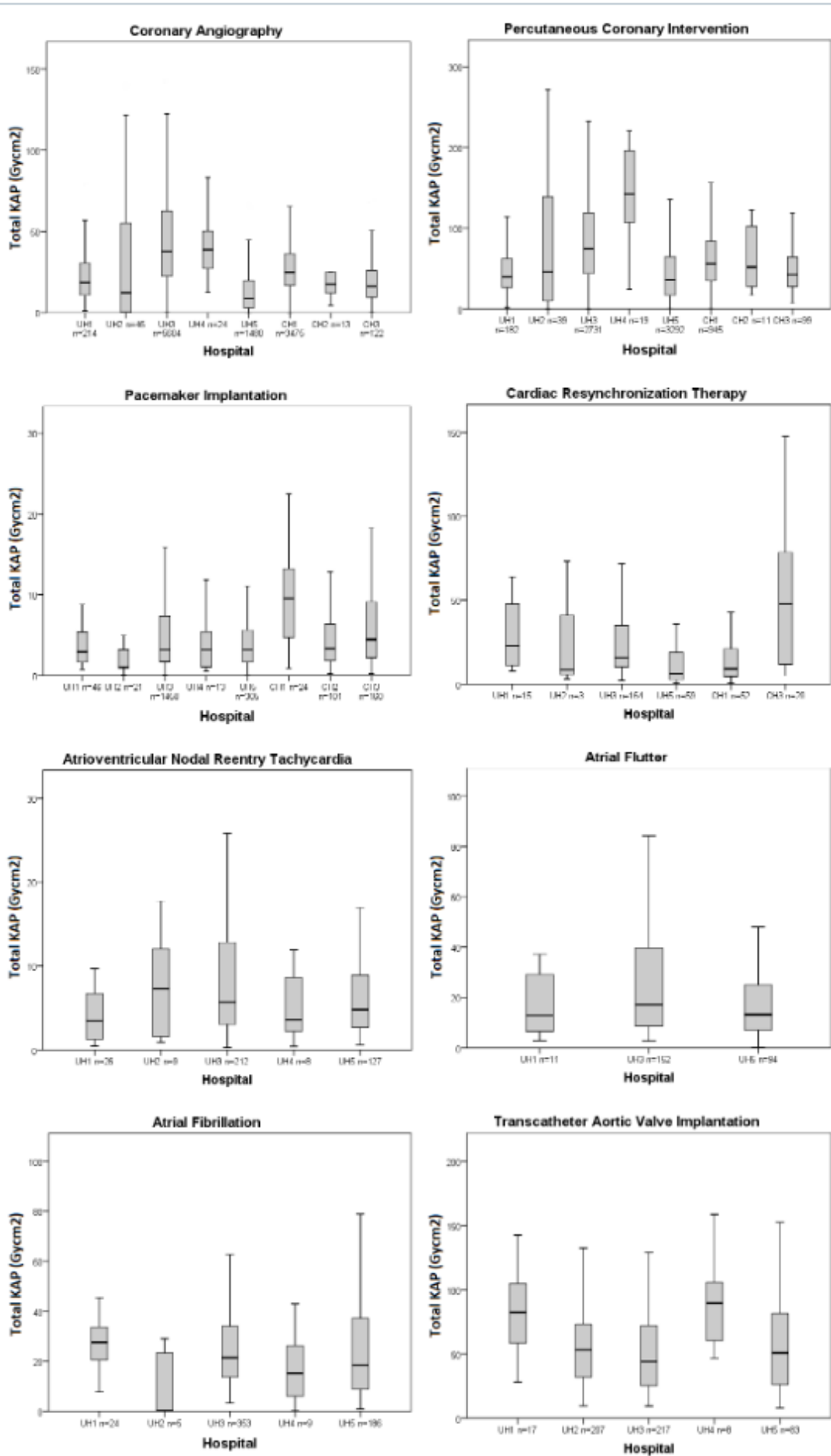
470 **Figure 1. Comparison of patient doses in cardiological procedures from all the hospitals. CA =**  
 471 **Coronary Angiography, PCI = Percutaneous Coronary Angioplasty, PI = Pacemaker Implantation,**  
 472 **CRT = Cardiac Resynchronization Therapy, AVNRT = Atrioventricular Nodal Reentrant**  
 473 **Tachycardia, AF = Atrial Fibrillation, TAVI = Transcatheter aortic valve implantations. The boxes**  
 474 **show 25<sup>th</sup>, 50<sup>th</sup> and 75<sup>th</sup> percentiles and the tails show the minimum and maximum of the data. Far out**  
 475 **and extreme outliers of the data as analyzed by SPSS have been omitted from the figure. These data**  
 476 **points ranged from several Gycm<sup>2</sup> for most procedure types to above 1 000 Gycm<sup>2</sup> for some**  
 477 **retrospective data in CA and PCI.**



478

479

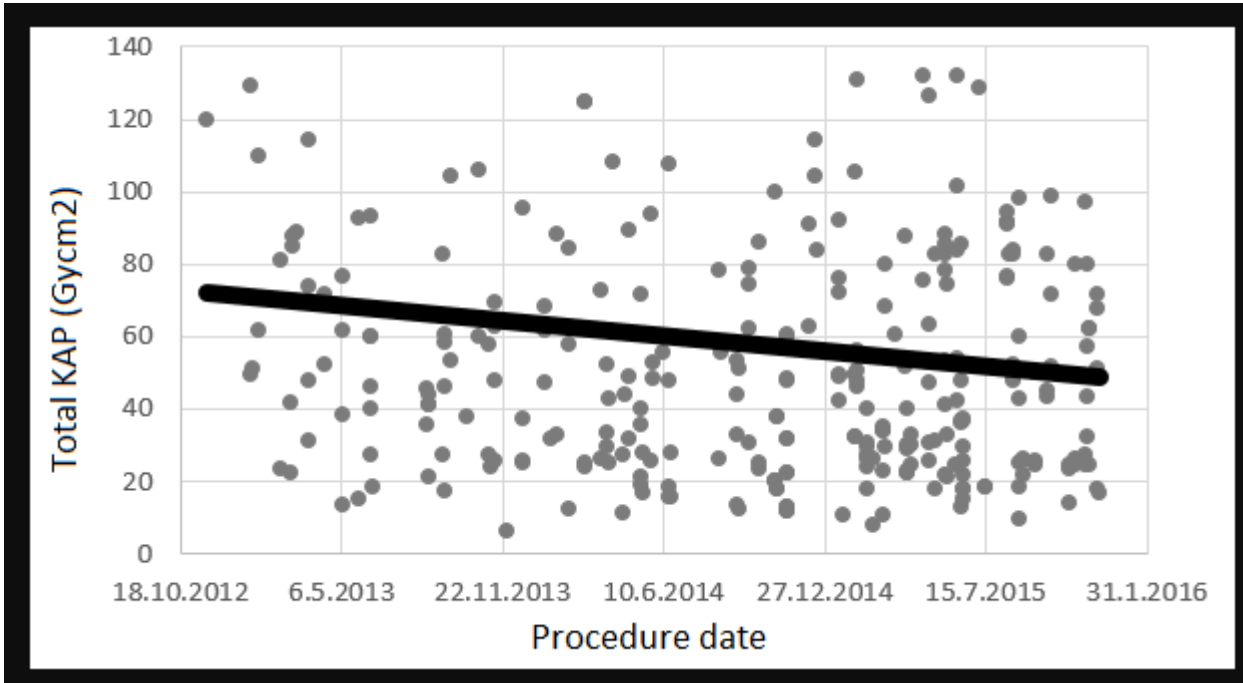
480 **Figure 2. Total KAP values in different hospitals. The boxes show the 25<sup>th</sup>, 50<sup>th</sup> and 75<sup>th</sup> percentiles**  
 481 **and the tails show the minimum and maximum data. Far out and extreme outliers of the data as**  
 482 **analyzed by SPSS have been omitted from the figure. UH = university hospital, CH = central hospital.**  
 483 **Asterisks denote hospitals whose medians deviate significantly ( $P < 0.05$ ) from that of the aggregate**  
 484 **data.**



486

487

488 **Figure 3. TAVI KAP as function of procedure date.**



489

490