Nationwide Provision of Radiologically-guided Interventional Measures for the Supportive Treatment of Tumor Diseases in Germany – An Analysis of the DeGIR Registry Data

Flächendeckende Versorgung mit radiologisch-interventionellen supportiven Maßnahmen bei Tumorerkrankungen und anderen Erkrankungen (DeGIR-Modul C) in Deutschland – Eine Analyse der DeGIR-Registerdaten

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Bibliography
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ABSTRACT

Purpose In addition to direct oncologic therapy, interventional radiology plays an important supportive role in oncologic therapy primarily guided by other disciplines. These supporting measures include diagnostic punctures, drainages, biliary interventions, central venous access including port implantations, osteoplasties, pain therapies etc.). This study investigated the extent to which these radiologically guided supportive measures are available in Germany.

Material and Methods All interventional procedures documented in the DeGIR-registry (excluding transhepatic portosystemic shunts) of the years 2018 and 2019 were recorded (DeGIR-module C). A breakdown of the documented interventions was performed based on federal states as well as 40 individual regions (administrative districts and former administrative districts).

Results A total of 136,328 procedures were recorded at 216 centers in DeGIR Module C in 2018 and 2019. On average, 389 cases were documented per hospital in 2018 and 394 cases in 2019; the increase per hospital from 2019 is not statistically significant but is relevant in the aggregate when new participating centers are included, with an overall increase of 10%
Introduction

In addition to vascular image-guided procedures, non-vascular minimally invasive interventional radiology procedures are an indispensable part of modern medicine. These include image-guided biopsies and drainage, port catheter implantation, pain management and osteoplastic procedures. The spectrum of diseases treated is very heterogeneous and includes mainly malignant diseases but also benign diseases such as osteoporosis or inflammatory bile duct stenosis. These procedures are classified as Module C by the German Society for Interventional Radiology and Minimally Invasive Therapy (DeGIR). There are numerous clinical cooperation partners for this type of surgery, such as visceral surgery, gastroenterology, gynecology, orthopedics, trauma surgery, neurosurgery, urology and many others.

Current oncological treatment concepts include not only causal therapy of the underlying disease, such as chemotherapy, ablation or surgical therapy, but also increasingly complex supportive measures in order to achieve an optimal outcome and improve the patient’s quality of life. Interventional radiology plays an increasingly important role in these supportive interventions pre-therapeutically, post-therapeutically, as well as the management of complications, and is therefore represented in various national (e.g., S3 guidelines) and international guidelines [1–5]. Supportive pre-therapeutic interventions of interventional radiology in the treatment of tumor diseases include, for example, biopsy of suspicious masses to confirm a diagnosis or marking of confirmed malignant tumors in preparation for therapy, such as prior to radiation, ablation or surgical removal. Pretherapeutic, biopptic intervention makes malignancy diagnosis and the resulting individualized therapy possible in the first place, as knowledge of tumor biology based on obtained tissue samples is critical. Benign findings can be detected early on in a minimally invasive and safe manner to avoid unnecessary treatments or major invasive diagnostic procedures. Bile duct interventions are another im-
important pillar of supportive, peritherapeutic measures in modern oncology. For example, stenoses and occlusions of the bile ducts in central liver tumors, bile duct malignancies, and pancreatic head carcinomas can be treated interventionaly. The lower morbidity and mortality of interventional procedures compared with open operative procedures is of high importance in mostly palliative situations [6]. Likewise, the implantation of port catheters is one of the important supportive measures in modern tumor therapy [7, 8]. Furthermore, pain that is difficult to control with medication can occur in the course of advanced tumor diseases. This can be successfully and safely treated by interventional, targeted deactivation of nerves, so that the quality of life of tumor patients can be enhanced [8]. These techniques are also used for pain patients with benign conditions (e.g., degenerative spine disease). In addition, osteolysis can occur during tumor diseases and eventually lead to fractures, which increases the morbidity as well as mortality of tumor patients. These osteolysis can be stabilized by radiologically-guided osteoplasty before a fracture occurs to improve patients’ quality of life [5].

Even in the case of oncologically successful treatment of a tumor, the underlying tumor tissue can become infected, allowing abscesses to develop, arising not only in the area of the treated tumor, but may also be triggered by certain therapeutic approaches, e.g., the risk of an intrahepatic abscess is increased by the placement of a biliodigestive anastomosis after pancreatic head resection [9–11]. In addition to malignancies, benign diseases also lead to abscesses or other fluid accumulation, thus interventional drainage techniques are also used in these cases. Abscesses can be treated minimally invasively by percutaneous drainage with very high level of patient safety [12]. In addition to abscess drainage, percutaneous creation of a nephrostomy as a complement to endoscopic retrograde procedures is also an important tool of interventional radiology [13]. In addition to the aforementioned techniques and indications, numerous other non-vascular interventions using similar techniques with image guidance have been established and often represent individually important clinical solutions for patients. All of the above procedures can be performed under local sedation and usually do not require general anesthesia, thus these therapies can be offered to a wide range of patients.

The German Society for Interventional Radiology and Minimally Invasive Therapy (DeGIR) has been recording vascular and non-vascular interventions for over 25 years as part of a quality assurance program based on a registry operated jointly with the German Society for Neuroradiology (DGNR). This Registry comprises the following modules: Module A (vasodilator and vascular reconstructive procedures); Module B (vaso-occlusive procedures); Module C (diagnostic punctures, drains, PTCD, TIPS, port implantations, osteoplasty, pain therapy, etc.). Module D (oncological procedures including primarily tumor-specific embolizations and ablations); Module E (vascular neuro-interventions), and Module F (neurovascular embolization treatments) [14].

The description of good, nationwide interventional radiological care for cerebral thrombectomy (Module E), revascularizing interventions (Module A) and emergency care for acute bleeding utilizing catheter embolization (Module B) has already been published based on DeGIR quality assurance data [14–17]. This current study presents the interventional supportive procedures of DeGIR Module C (excluding the placement of a transjugular intrahepatic portosystemic shunt [TIPS]).

The purpose of this study is to investigate whether interventional radiological therapy in Module C (excluding the installation of a TIPS) is available to patients in Germany on a nationwide basis. The interventions in DeGIR Module C are particularly challenging, as many different techniques are required to cover the sometimes very diverse approaches.

Materials and Methods

Data Collection

The study results of the current work are based on DeGIR Registry data from 2018 and 2019. The data was collected using software from Samedi (samedi GmbH). Module C (excluding the placement of a TIPS) was recorded as a proxy for those supportive interventions for tumor disease.

The number of centers meeting the criteria for DeGIR certification as a training center (at least 50 procedures per year) or already certified was recorded. Centers with more than 500 interventions per year were defined as “high volume”.

Analysis of Coverage

As described in the preliminary work on Modules B and E, the data breakdown was organized by German federal state. For a more detailed analysis of the area coverage, without making the data of individual clinics visible, the recorded Module C interventions were broken down into 40 smaller regions (government districts, former government districts and federal states [if there was never a division into government districts]: Arnsberg, Berlin, Brandenburg, Braunschweig, Bremen, Chemnitz, Darmstadt, Dessau, Detmold, Dresden, Düsseldorf, Freiburg, Gießen, Halle, Hamburg, Hanover, Karlsruhe, Kassel, Koblenz, Cologne, Leipzig, Lüneburg, Magdeburg, Mecklenburg-Vorpommern, Middle Franconia, Münster, Lower Bavaria, Upper Bavaria, Upper Franconia, Rhine-Hesse-Palatinate, Saarland, Schleswig-Holstein, Swabia, Stuttgart, Thuringia, Trier, Tübingen, Lower Franconia, Weser-Ems) [14, 18].

Analysis of selected Quality Parameters

As an example, as proxy parameters for a high quality of results from the registry database, quality parameters for diagnostic puncture, drainage and marking were analyzed, such as the indication in an interdisciplinary board, technical success and complications in the first 24 hours.

Statistics

A descriptive statistical analysis employed the R Statistics program (R version 3.5.3 (2019–03–11) – “Great Truth”) [19]. The accepted significance level was p < 0.05.

Creation of Graphics

Creation of the graphics was as previously described [14]. The following software was employed:

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Results

In 2018 and 2019, a total of 136,328 procedures at 216 centers were recorded in DeGIR Module C. In 2018, the number of documented procedures was 64,887 at 205 centers; 164 centers met certification requirements; 41 centers were considered high-volume centers with more than 500 documented procedures per year.

In 2019, the number of documented procedures was 71,441 at 216 centers; 179 centers met certification requirements; 44 centers identified as high-volume centers with more than 500 documented procedures per year.

On average, 389 cases were documented per hospital in 2018 and 394 cases in 2019; the increase per hospital in 2019 is not statistically significant but is relevant in the aggregate when new participating centers are included, with an overall increase of 10% (6554 more cases than the previous year). ▶ Table 1 shows a breakdown of the registered services for the years 2018 and 2019. ▶ Table 2 shows the anatomical regions of biopsies.

Coverage of Care

Normalized to one million inhabitants, an average of 781 interventions were performed across Germany in 2018 and 860 in 2019. Based on the calculations of the individual federal states from 2018 and 2019 together, this results in a mean of 1579 per million inhabitants (standard deviation = 943). The interquartile range (IRQ) is 1224–1784 interventions per million inhabitants; the minimum value is 7 in Bremen and the maximum value of 4,062 in Saarland. The median is 1500. ▶ Fig. 1 provides an overview of the registered services per million inhabitants for each federal state.

An analysis of the administrative districts or former administrative districts results in an average of 3408 interventions per year (calculated from 2018 and 2019) in 40 regions; the standard deviation is 2827. The median is 2892 procedures per year. There were no districts without procedures registered in Module C. ▶ Fig. 2 illustrates the absolute number of interventions by federal state and region as well as the related trend. ▶ Fig. 3 shows the combined number from 2018 and 2019 of interventions per million inhabitants for each federal state.

Trend between the Years 2018 and 2019.

There were no statistically significant changes in registered cases between 2018 and 2019, but there was an overall increase of just over 10%. Similar to Module B, some significant variations between individual districts and individual states occurred for Module C as well. ▶ Fig. 2D illustrates the trend between 2018 and 2019.

<table>
<thead>
<tr>
<th>Type of intervention</th>
<th>2018 (n = 68 971)</th>
<th>2019 (n = 75 890)</th>
<th>Year-on-year change (n = + 7183)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy</td>
<td>23 116 (34 %)</td>
<td>25 112 (33 %)</td>
<td>1996 (+ 8.6 %)</td>
</tr>
<tr>
<td>Drainage</td>
<td>8075 (12 %)</td>
<td>8958 (12 %)</td>
<td>883 (+ 10.9 %)</td>
</tr>
<tr>
<td>Marking</td>
<td>3367 (5 %)</td>
<td>4207 (6 %)</td>
<td>840 (+ 24.9 %)</td>
</tr>
<tr>
<td>Osteoplasty</td>
<td>874 (1 %)</td>
<td>819 (1 %)</td>
<td>−55 (−6.3 %)</td>
</tr>
<tr>
<td>Recanalization/reconstruction non-vascular</td>
<td>1516 (2 %)</td>
<td>1578 (2 %)</td>
<td>62 (+ 4.1 %)</td>
</tr>
<tr>
<td>Pain/infiltration treatment/neurolysis</td>
<td>20 866 (30 %)</td>
<td>22 327 (29 %)</td>
<td>1461 (+ 7.0 %)</td>
</tr>
<tr>
<td>Other procedures:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Port, PICC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Cava filter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Foreign body removal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Position correction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ PRG</td>
<td>11 103 (16 %)</td>
<td>12 889 (17 %)</td>
<td>1996 (+ 18.0 %)</td>
</tr>
</tbody>
</table>

Note: The sum of interventions in this table is larger than the study population for the geographic region analysis, as it also includes data from interventions without region assignment.
for each state. The increase at the state level averaged 13 % (IRQ: 0–19 %).

**Analysis of selected Quality Parameters**

The indication for Module C procedures was generally interdisciplinary. This was the case for drain placement in 84 %, marking in 75 %, and biopsy in 80 %. The quality of outcome was very high; for all three procedures, the technical success rate was 99 %, while the complication rate was significantly less than 1 %. ▶ **Table 3** provides a detailed breakdown of selected quality characteristics.

**Discussion**

Analysis from 2018 and 2019 DeGIR Registry data regarding nationwide coverage of interventional radiological procedures in

DeGIR Module C (excluding TIPS) shows sufficient availability exists for these procedures on a state-wide level; in addition, professional qualifications and experience regarding the required procedures are well distributed across the individual regions. Regions with comparatively lower numbers of procedures correspond to regions that have a low density of hospitals, see ▶ **Fig. 4**. At the district level, there is no region where this type of interventional radiology procedure is not available. The present results document not only the good availability of the above-mentioned interventions, but also a very high intervention quality.

Nonvascular interventional radiological procedures have an assured and increasing place in modern oncological concepts [20]. Interventional radiology performs both pre-therapeutic and post-therapeutic procedures under imaging guidance less radically than with surgical procedures. These include, for example, marking or biopsy as the basis for planning tumor therapy. Likewise, one of the modern pillars of tumor therapy is the placement of port catheters, as these allow safe administration of chemotherapy and other drugs; these catheters are also installed using interventional radiology. However, peri- and post-therapeutic measures are likewise offered, such as drainage placement or interventional pain therapy/neurolysis for affected nerves.

The above-mentioned procedures can contribute in various ways to enable and facilitate oncological therapy and to reduce the mortality and morbidity of patients, especially in palliative situations, and thus improve the overall outcome [21].

In addition to the quality and safety of therapies, ubiquitous availability plays the most important role in practical patient care. Therefore, this study investigated the availability of different supportive oncology and interventional radiology-guided nonvascular interventions in Germany.

DeGIR Registry data from 2018 and 2019 demonstrate a high level of nationwide availability at the state level, similar to the analysis for hemorrhage or stroke care. Numerous hospitals suitable for DeGIR training center certification or currently with certi-
Fig. 2 Comprehensive distribution and evolution of interventions. In Fig. 2 the numbers of interventions of 2018 and 2019 are illustrated for the states and regions. In A–C the absolute numbers are encoded in increasing green and the changes from 2018 and 2019 in increasing blue D. In A the absolute numbers of interventions in 2018 are shown for each state and in B those from 2019. C illustrates the summarized region associated numbers from 2018 and 2019. In D percentual changes of interventions between 2018 and 2019 on state level are illustrated; small changes and negative tendencies were encoded as white areas.
Fig. 3 Procedures in the different states per million inhabitants. Areal coverage of interventional supportive oncologic therapy (2018 and 2019) on state level per one million citizens in Germany.
fication are available in Germany for the training of young radiologists interested in interventional radiology. Although individual procedures from Module C are also provided by other disciplines, there is currently no published data on the exact number and area-wide distribution. Corresponding registry data from other professional societies are not currently available for these interventions. Due to the specialty definition of radiology as well as the special expertise in imaging procedures, many diagnostic and therapeutic measures from DeGIR Module C can only be provided by interventional radiologists, including, for example, CT-guided biopsy or marking. Of other supportive measures, only individual types of intervention are also covered by other specialist disciplines, e.g. ultrasound-guided breast biopsies in gynecology. The costs of an interventional radiological procedure are often lower with the same effectiveness; port implantation in the angiography unit, for example, is more cost-effective than surgical implantation with the same complication rate [22]. In addition, the interventional radiologist can be an important clinical partner in the overall treatment approach.

### Interpretation of Registry Data

Similar to prior studies, this analysis selected DeGIR data from Module C as a proxy for procedure distribution and experience for interventional radiology-guided, nonvascular procedures with a focus on diagnosis and treatment of tumor disease. Likewise, data provision was voluntary for the study years 2018 and 2019. There are also great regional fluctuations for Module C as previously shown in publications regarding the other individual modules B and E. Similarly, due to the voluntary nature of the registry documentation, a relevant but ultimately unknown number of missing entries (unreported numbers) can be assumed. As already discussed in the publications on Modules B and E, the scope and quality of the reported data are influenced by the motivation and activity of individuals in the clinics. City-states in particular are more affected by statistical fluctuations and the above-mentioned influences.

### Coverage of Care

The analysis of the DeGIR Module C (excluding TIPS) shows, analogous to the other modules, overall good nationwide coverage at federal state level with interventional-radiologically guided, nonvascular interventional measures. The normalized, mean average number of interventions at the federal state level from 2018 and 2019 corresponds to the value of the normalized total interventions in relation to the Federal Republic of Germany (1579 vs. 1641). Nevertheless, the number of interventions in each federal state varies significantly per million inhabitants (see [Fig. 3]). Individual regions such as Saxony-Anhalt, Bremen or Saarland deviate by more than one standard deviation from the mean. As discussed above and in previous studies, fluctuations in the scope of the documentation of the register data are responsible for this.

The above-mentioned favorable training situation in Germany could support the further training of more interventional radiologists and a more even distribution of these radiologists to less well-provided regions, thus allowing greater homogeneous area coverage in Germany in the future.

Overall, the data allow the statement that a comprehensive supply of radiologically-guided interventional measures for the supportive treatment of tumor diseases is assured in Germany; in addition, the training situation for prospective interventional radiologists is favorable.

### Table 3: Summary of selected quality parameters for biopsy, drainage and marking.

<table>
<thead>
<tr>
<th>Type of intervention</th>
<th>2018</th>
<th>%</th>
<th>2019</th>
<th>%</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drainage</td>
<td>8075</td>
<td>17 033</td>
<td>8958</td>
<td>14 340</td>
<td>16 820</td>
<td>98,7</td>
</tr>
<tr>
<td>Interdisciplinary indication</td>
<td>6388</td>
<td>79,1</td>
<td>7952</td>
<td>88,8</td>
<td>14 340</td>
<td>84,2</td>
</tr>
<tr>
<td>Technically successful</td>
<td>7957</td>
<td>98,5</td>
<td>8863</td>
<td>98,9</td>
<td>16 820</td>
<td>98,7</td>
</tr>
<tr>
<td>(target volume recorded or macroscopically representative or positive microbiology)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurrence of a complication in the first 24 h</td>
<td>21</td>
<td>0,3</td>
<td>16</td>
<td>0,2</td>
<td>37</td>
<td>0,2</td>
</tr>
<tr>
<td>Marking</td>
<td>3367</td>
<td>7574</td>
<td>4207</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interdisciplinary indication</td>
<td>1996</td>
<td>59,3</td>
<td>3654</td>
<td>86,9</td>
<td>5650</td>
<td>74,6</td>
</tr>
<tr>
<td>Technically successful</td>
<td>3344</td>
<td>99,3</td>
<td>4188</td>
<td>99,5</td>
<td>7532</td>
<td>99,4</td>
</tr>
<tr>
<td>(target area successfully marked)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurrence of a complication in the first 24 h</td>
<td>0</td>
<td>0,0</td>
<td>0</td>
<td>0,0</td>
<td>0</td>
<td>0,0</td>
</tr>
<tr>
<td>Biopsy</td>
<td>23 116</td>
<td>48 228</td>
<td>25 112</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interdisciplinary indication</td>
<td>17 085</td>
<td>79,5</td>
<td>21 242</td>
<td>84,6</td>
<td>38 327</td>
<td>79,5</td>
</tr>
<tr>
<td>Technically successful</td>
<td>22 837</td>
<td>98,8</td>
<td>24 808</td>
<td>98,8</td>
<td>47 645</td>
<td>98,8</td>
</tr>
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<td>(target volume recorded or macroscopically representative)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurrence of a complication in the first 24 h</td>
<td>29</td>
<td>0,1</td>
<td>24</td>
<td>0,1</td>
<td>53</td>
<td>0,1</td>
</tr>
</tbody>
</table>

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Conflict of Interest

The authors declare that they have no conflict of interest.

References
