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I. List of Abbreviations

ABBREVIATION	English	German
BI-RADS	<i>Breast Imaging Reporting and Data System</i>	Mamma Bildgebungsbericht und Daten System
CAD-RADS	<i>Coronary artery Disease-Reporting and Data System</i>	Koronare Herzkrankheit-Bericht und Datensystem
CT	<i>computed tomography</i>	Computertomographie
CTA	<i>computed tomography angiography</i>	Computertomographie Angiographie
CTPA	<i>computed tomography pulmonary angiography</i>	Computertomographie - Pulmonalisangiographie
LI-RADS	<i>Liver Imaging Reporting and Data System</i>	Leber Bildgebungsbericht und Daten System
LV	<i>left ventricle</i>	linker Ventrikel
PACS	<i>Picture Archiving and Communication System</i>	Bilder archivierendes Kommunikationssystem
PAD	<i>peripheral arterial disease</i>	periphere arterielle Verschlusskrankheit
PE	<i>pulmonary embolism</i>	Lungenembolie
PI-RADS	<i>Prostate Image Reporting and Data System</i>	Prostata Bildgebungsbericht und Daten System
RSNA	<i>Radiological Society of North America</i>	Radiologische Gesellschaft von Nordamerika
RV	<i>right ventricle</i>	rechter Ventrikel

1. List of Scholarly Publications from this Thesis

Results from this thesis have been published in the following journal articles:

Sabel BO*, **Plum JL***, Kneidinger N, Leuschner G, Koletzko L, Raziorrouh B, Schinner R, Kunz WG, Schoeppe F, Thierfelder KM, Sommer WH, Meinel FG:

Structured Reporting of CT Examinations in Acute Pulmonary Embolism.

J Cardiovasc Comput Tomogr. 2017 May - Jun;11(3):188-195.

(2016 Journal Impact Factor: 3.185)

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Sabel BO, **Plum JL**, Czihal M, Lottspeich C, Schoenleben F, Gaebel G, Schinner R, Schoeppe F, Meinel FG:

Structured Reporting of Run-off CT Angiography Examinations of the Lower Extremities.

Eur J Vasc Endovasc Surgery 2018 May;55(5):679-687.

(2016 Journal Impact Factor: 4.061)

2. Authors' Confirmation

All authors have confirmed their participation in the above studies. It has also been confirmed, that publications resulting from these studies have not and will not be used in another dissertation. This has been confirmed by the doctoral candidate and all other authors.

3. Introduction – Structured Reporting

3.1 Background

3.1.1 Historical Background

Throughout the past decades a discrepancy has emerged in radiology. While investigation techniques and image modalities become more and more advanced, radiology reports remain in their classic form. A conventional radiology report usually includes a narrative description of the evaluated structures, which is then completed by a brief interpretation of the findings and an overall impression section [1]. However a checklist of what to include is usually not provided, which results in a higher variability and likely source of error [2-5].

To some extent the need for structured reporting has already been discussed for various decades in the literature. Sierra et al. have found that the linguistic complexity and therefore the readability of conventional radiology reports vastly vary between different radiologists and also between different image modalities [6].

But even though structured reporting seems to be the easy solution for a difficult problem its general implementation remains difficult. In the literature it is often celebrated as more complete, accurate, standardized, comprehensible and correct, but if it is not implemented correctly and in an easy usable manner, it can also lead to a decrease in accuracy and completeness [7;8].

Therefore the Radiological Society of North America (RSNA) has assembled an ever growing list of templates in order to provide structural guidance for radiology reports. Their recognized aim is to increase the comprehensibility, standardization, data analyzability, structured terminology and communication of reports [9].

3.1.2 Forms of Structured Reporting

When the term “structured reporting” is used, it usually implies the report is more structured than a conventional radiology report, but it does not reveal to what extent it is organized. In reality the term “structured reporting” can refer to a number of different levels of structure.

One of the more basic forms of structured reporting is the division of the report into paragraphs with subheadings. It compartmentalizes the text into theme-based sections, which in themselves are not structured.

Structured reports, which were created along the lines of a checklist, take the organization of a radiology report one step further. Basically all the structures, which

are supposed to be evaluated, are given and have to be commented on. This checklist-like approach may lead to a very complete and accurate but also rigid form of report [4;5].

The furthest degree of structure provides a defined, and for its semantic content classified terminology. In addition to their templates, the RSNA has also created the RadLex project. RadLex is a database that currently includes 75 000 medical terms/synonyms and was designed to create a standardized terminology for radiological reporting, data mining and registries [10;11].

Those three levels of structure can be implemented into other forms of structured reporting.

The Image Reporting and Data Systems are very valued on a clinical level. Those systems use structured reporting in combination with scientifically evaluated scales and specific diagnostic parameters in order to provide a management recommendation and in some cases treatment suggestions. Further diagnostic and treatment decisions are at least partly based on different radiological prognosis impacting criteria and the stage of the disease itself [12-21].

Another report form with clinical value and great teaching opportunities is the multimedia report. Again all levels of structure can be implemented into such a report. Additionally images or videos can be linked to the key pathologies and features of the report [22].

3.1.3 Current Status of Implementation

With the tools provided by the RSNA, the American College of Radiology has already successfully developed and implemented many structured reporting systems into the clinical routine. For example the Breast Imaging Reporting and Data System (BI-RADS), which has been implemented into breast cancer diagnostic guidelines [12;21]. The BI-RADS may also contribute to predict breast cancer reoccurrence risk [13]. Liver Imaging (LI-RADS) [14] and Prostate Imaging Reporting and Data Systems (PI-RADS) [15;19] have also found their way into the clinical routine.

Various organizations also support the implementation of structured reporting into cardiac imaging. Coronary Artery Disease - Reporting and Data System (CAD-RADS) has proven its clinical value. This system enables a high interobserver agreement for the reporting of coronary artery disease (computed tomography angiography (CTA) images) [16]. Additionally it provides the radiologist not only with a classification for coronary artery disease, which successfully identifies patients at risk for an adverse event [17], but also provides information on a stage adapted course of therapy [18]. Systematic databases with CAD-RADS results also harbor big data mining and

technological possibilities.

3.1.4 Possibilities and Concerns

It is realistic to assume that in the future we will have more and more electronic patient data. The data of a radiology report becomes inaccessible to an electronic health care record, or Picture Archiving and Communication System (PACS), or other systems if it doesn't use an accessible format. A universal format is easily designed for a structured reporting system; hence these data become not only analyzable but also integratable into other software which makes a structured approach just about imperative [23;24]. Also it enables the exchange of high quality templates [24].

Despite the fact that many radiological institutions experiment with structured reporting and have come to recognize its potential, there are still a lot of concerns about its limitations and value, with two of the main concerns being work flow efficiency and report rigidity [7;25;26].

Consequently it remains to be seen, whether there can be an absolute and general definition of/ system for a standardized radiology report, which can be utilized by every specialty, or whether structured reports will need to be customized for different fields and inquiries.

3.2 Advantages

3.2.1 Standardized High Quality Reports

The development and implementation of structured reporting into the clinical routine has great potential and could lead to substantial improvement.

Conventional reports have a high degree of variability which is created by different modalities, inconsistencies between radiologists with varying degrees of experience and inconsistent ambiguous terminology that is being used [6]. Furthermore the lack of structure and standardization makes it easy to overlook key points. This can elude the key question and is a further source of error [2-4].

This being said, studies have shown a well implemented structure can reduce those sources of potential errors, which supplies structured reports with the same or a better quality and correctness than conventional reports [2;27].

The specifically planned design of standardized reports forces the radiologist to evaluate normal structures, which results in a better completeness and consistency of radiology reports [3].

Among other reasons the thorough evaluation of pathological and not pathological structures results also in greater clarity and content [28-30].

Text presentation can also lead to an increase of conciseness and clarity, because it has been shown that clinicians prefer brief, detailed itemized reports to prose. It seems to make the extraction of measurements and relevant information easier, while a radiologist's comment at the end of the report is still appreciated [25;29-31]. Additionally the standardized terminology of RadLex, which is often used by structured reporting systems and templates, also leads to a greater comprehensibility and standardization of the reports [10;11;32].

3.2.2 Communication

Generally a standardized language and an itemized structure can be implemented into a structured reporting template more easily and they can both lead to a better communication of the findings [28].

The radiology report is ultimately one of the major means to communicate results to different specialists and patients. Therefore it is sensible to adapt a report to the specific needs of the specialty it is meant for [25;31;33].

In structured reporting, templates can be specifically developed for rare inquiries, creating a very important gateway between radiology and other specialties. For example a template can be developed specifically to guide decisions on the management of various types of cancers (e.g. rectal or pancreatic cancer). Such a template, developed together with the corresponding surgeons and oncologists, addresses the specific details they need in order to determine the further course of therapy, such as a very detailed staging. Tarulli et al. have found that this strategy "[...] ensures the essential information affecting resectability and prognosis are communicated to physicians in a concise, consistent, and complete manner" [34-36]. This may also result in a different outcome [36].

3.2.3 Teaching Opportunities

Tremendous advantages of structured reporting are the various teaching opportunities for residents in radiology. The templates with their checklist-like structure ensure that all features are evaluated resulting in a better completeness and can provide inexperienced radiologists with a structured approach at the

beginning of their training. For example Collard et al. proved that a structured reporting curriculum, with a three step approach and different modules dealing with the structure and content of a report itself, can improve the report quality of radiology residents throughout their training [37].

The teaching opportunities are not only limited to checklists and a systematic evaluation, but also provide the opportunity to increase the image evaluation skills of the reader. Especially in sonography and echocardiography images are usually not attached to the conventional reports. With a structured approach, in which every pathological feature of the checklist is linked to a correlating image, inexperienced radiologists can hone their skills and increase their confidence, so information can be better communicated to other colleagues [22].

New software developments create the possibility to monitor the exact progression of specific pathological findings like cancer with lesion tracking tools [38]. The results could also be one day automatically integrated into a structured report.

Those possibilities enable patients and doctors to get digital second opinions or consultations from colleagues farther away.

3.2.4 Data Mining and Statistical Analyzability

Different forms of data mining become increasingly important in an environment that doubles their per-capita capacity to store digital data approximately every 40 months since the 1980's [39;40]. Hence, digital communication, documentation and data analysis become more and more fundamental. In this context, structured reporting becomes a resource for systematic data analysis. It is possible to collect semantic information from radiology reports through a natural language recognition software and analyze its content statistically [41;42]. It could be argued that with RadLex and its standardized language and the new technological developments a statistical analysis of structured radiology reports becomes even more easy and accurate. A structured report with clickable decision trees would probably further support such a development and supply analyzable complete data concerning various areas (violent crimes, health structure of the population etc. [42]).

Flexible databases of structured radiological findings can enable computers to analyze thousands of reports accurately in order to improve cancer detection and screening algorithms [43]. Consequently they harbor great research and teaching opportunities [22]. With big data, a simplified data collection process and an easy way of sharing information become imperative. Structured reporting could be a step into that direction [23;24;44].

3.2.5 Influence on Patient Care

Templates can also be adapted to ensure compliance with radiology practice guidelines, which are mostly developed by expert committees and ultimately approved by scientific societies [45].

Another possibility or example for this could be the implementation of a radiation dose measuring tool into a template or program. Such a tool can provide additional information, because additive radiation exposure through repetitive radiological examinations is usually not mentioned in conventional reports. A structured reporting template could be, with additional software, designed to provide the cumulative radiation dose automatically at the beginning of the report and hence ensuring patients' safety [46].

Many structured imaging reporting and data systems have already been implemented into the clinical routine. The literature shows that image scoring systems provide benefits for patient management, be it in their prediction of cancer reoccurrence risks [13] (BI-RADS) or their strong positive predictive value of prostate cancer [47] or hepatocellular carcinoma [48](PI-RADS, LI-RADS).

One of the most imperative consequences of structured reporting however is its direct influence on patient care. Brook et al. presented its potential effect on the staging and surgical planning of pancreatic cancer. Surgeons found it easier to estimate the resectability of the cancer with structured reports, which, in a clinical setting, influences surgical planning and the course of therapy [36]. Similar observations have also been described for structured magnetic resonance imaging reports of rectal cancer [49]. These are good examples for how structured reporting may also influence the outcome of certain diseases.

3.3 Limitations

3.3.1 Timeliness

One of the most frequent points made against the implementation of structured reporting is reduced work flow efficiency, report rigidity and a time consuming reporting process [7;8;25]. Despite this concern, studies have shown that structured reporting can be as fast as conventional reporting [27;50].

Many of the radiological findings are dictated in the clinical routine. Hence it is not correct to compare dictation time vs. the time you need to create a structured report, because the audio file still needs to be transcribed. Therefore the creation of

a structured report might take the radiologist longer than free dictation itself, but the overall time to create a report can be comparable or even shorter[50] ensuring a timeliness of the report. However speech recognition software is more and more implemented into the clinical routine, which leads to a better report turnaround time [51]. Even though speech recognition software is still associated with more errors [52-54] it is constantly progressing [55]. To some extent it could also be implemented into a structured reporting process, but this matter should be further investigated in the future.

Another aspect might be the better communication of results to clinicians through structured reports and therefore a potential increase of efficiency or time reduction, through shorter reading time and no necessity for additional explanations [28;31].

3.3.2 Work Flow Efficiency and Report Rigidity

The matter of work flow efficiency is a serious concern and depends vastly on the individual and the implementation of structured reporting itself.

Especially older radiologists might find it difficult to adapt to new systems, when this disrupts their work flow, which has been established over many years. It is a process and a matter of leadership and organization to help people adapt to a new system [25;56;57]. Aside from the individual factors there is also the matter of the design of the reporting system, which can also influence work flow efficiency and productivity. Technological setbacks are a struggle with structured reporting and its implementation. The interface has to be user-friendly, while at the same time the software has to interact with various other programs (PACS, search engines etc.) in order to realize its full potential [23;56-59].

Despite the fact that structured reporting holds a great promise of reproducibility and order, there are various different structured reporting systems, templates and software platforms. Each of them is varying in contents, software usability and degree of structure [7;60]. Therefore it is safe to assume those different options also hold varying degrees of quality. For example, if a template is too rigid for the radiologist to express the image findings accurately, this may lead not only to frustration and incompliance, but also to a drop in quality of accuracy, clarity and content of the report [7;8]. It is no surprise; a too rigid template with too simplified a language and options is a major concern of structured reporting [61]. Especially the development of structured systems for complex pathologies is considered difficult [7;8].

3.3.3 Eye Dwell vs. Satisfaction of Search

A too rigid template, especially one in a checklist style, also encourages a phenomenon called “eye dwell problem”. This effect can be observed, when radiologists miss pathologies or reduce their productivity by focusing more on the report template than the actual image [62].

The “eye dwell problem” stands in contrast to the “satisfaction of search” effect. When a pathology is found, which is considered to be the likely source of the symptoms that are being investigated, it tempts radiologists to stop looking for a further source. In such cases this can lead to the overlooking of the actual cause. Especially the checklist style templates that are used by structured reports could help to minimize this error [63].

3.3.4 Implementation Strategy

Considering the points made above, the implementation of structured reporting depends vastly on the software and the template that is being used and the indication it is used for. Larson et al. describe how a structured reporting system was developed and implemented successfully into a department. The mostly favorable feedback of the affected radiologists can probably be explained through their close involvement into the development of the report itself. Everybody could vet and make suggestions to the reports beforehand [64]. Even if this might be impractical on a national scale, it can be argued that a system which was vetted by many different specialists probably has already been cleared of many issues and therefore can be implemented on a wider scale.

3.4 Clinical Consequences and Future Implications

The clinical consequences of a well developed and implemented structured reporting system could be a decline in secondary testing, because of its high standard of completeness and clarity [28]. Such a system seems to be especially advantageous concerning specific inquiries such as surgical planning. There a possible change of therapy with a potential impact on the outcome can be noted [36;49].

Both assumptions should be further investigated in future studies.

Even though the impact on work flow efficiency remains questionable, structured reporting leads to a better and clearer communication of the findings [28].

However considering the possibilities of structured reporting, it has not yet reached its full potential. With increasingly more software and hardware developments, options arise, which would not have been imaginable a few decades ago.

One example of this is the Merit-based Incentive Payment System, which can be used for reimbursement. The incentive behind the Merit-based Incentive Payment System is a high standard of evidence-based medicine. Doctors get rewarded for advancing care information, improvement activities and especially a high quality of work. In the case of radiologists this high quality means for example including certain information into a radiology report or registry. Important information such as recommendations for follow-up appointments in case of certain pathological findings or the radiation dose from repetitive radiological examinations. Structured reporting with its analyzable data can be an easy proof and a reminder, such information has to be included [59;65-67].

The structured reports, which use standardized vocabulary, could also be used to create an automatic invoice system. It could work as a search engine like tool, scanning the reports for specific codes or words and drawing up an automatic invoice according to the findings [23;68;69].

Studies have also shown that templates can be adjusted with clickable coding systems. Coding systems, which force the radiologist to evaluate image findings for malignancy, can be a safety net for scheduling follow-up appointments. A program which filters every lesion that was rated as suspicions can create lists of patients who need to be followed-up or sent warnings, if no follow-up appointment was scheduled. Hence coding systems can increase the standard of care. [59;66;67;70;71]

Also the progression of diseases can be monitored quite efficiently. An added PACS-integrated lesion tracking tool is capable of measuring and comparing the size of lesions with prior images [38].

The general implementation of multimedia reports is another possibility in the future of structured reporting, because images can be directly linked to expressions in the report. Not only are multimedia reports preferred by physicians, but they also manage to convey an overall impression and a timeline of the pathology [72;73]. Aside from that, they also harbor great teaching opportunities, because image databases of rare pathologies could be accessible for radiology trainees [22].

The importance of big data and data mining has been proven by standard reporting systems using the BI-RADS lexicon. Breast imaging and breast cancer screening have already adapted a structured reporting format for quite some time. This makes it possible to statistically analyze millions of reports, consequently adapting and improving screening algorithms [43].

Unfortunately all this relies on a common data format being used; otherwise data can only be mined and analyzed by medical institutions using the same system. The Annotation and Image Markup project was funded by the National Institutes of Health Cancer Biomedical Informatics Grid of the United States. Unfortunately not commonly used, The Annotation and Image Markup project is a system that saves structured reports in a standardized format, which can also be converted into other commonly used formats such as DICOM and XML, which makes the data minable and accessible [59;74].

This is also essential for statistical analysis, which can lead to an evidence-based improvement of radiology.

3.5 Development of a high quality structured reporting template

In order to determine what to implement into a template, macro or a structured reporting system we should first ask, what determines a good radiology report. Criteria for report quality are clarity, correctness, confidence, concision, completeness, consistency, communication, consultation, timeliness and standardization [25;75;76]. As shown above, structured reporting has the potential to increase most of those criteria mentioned, but only if a few aspects are taken into account.

Template and system quality is the foundation of a good structured report. If the make-up of the structured reports does not address the key clinical question, is chaotic or misses features which are important for clinical decision-making, there is no additional value in them. Consequently a scientific evaluation of every template and reporting system is necessary.

Structured reporting seems to be especially advantageous regarding specific inquiries [34-36]. Consequently the development of committees with experts from different medical areas is recommendable. They can evaluate where the use of structured reporting is sensible, realistic and how to implement it [64].

Furthermore, especially with specific inquiries it is imperative to involve referring physicians in the development process of the report [33] in order to guarantee all the treatment influencing criteria are mentioned.

Finally, even after the implementation of a report template the involved parties (e.g. radiologists, referring physicians) should be able to give feedback and make necessary adaptations. This increases not only the acceptance of the structured approach but also the practicability of the reports themselves [64]. In order to supply a less rigid structured reporting system a combination of clickable options and a free text description field for additional information could be considered.

All these organizational steps combined should ensure the development of a high quality report, with high acceptance by physicians and radiologists.

3.6 Rationale and Aim of Studies

3.6.1 Pulmonary Embolism (#1)

Acute pulmonary embolism (PE) is defined as the acute vascular obstruction or blockage of one or more pulmonary arteries, which leads ultimately to a reduced perfusion of lung tissue. The embolus mostly originates from deep vein thrombosis [77]. PE is a relatively common condition and can lead to intensive care or death [78;79]. With an incidence rate ranging from 60 to 112 per 100,000 inhabitants (United States) it is also the third most common cardiovascular cause of death. Because of the sometimes wide range of unspecific symptoms the clinical diagnosis can be quite challenging [80-84].

CT pulmonary angiography (CTPA) has become a very sensitive diagnostic standard procedure in diagnosing acute PE [77;81;85]. Lung scintigraphy and direct pulmonary angiography are rarely performed anymore while d-dimer testing, N-terminal (NT)-proBNP, troponin, echocardiography and compression venous ultrasonography are mostly used to evaluate the probability of PE or its severity [78;86].

CT enables a complete and fast evaluation of all thoracic structures in patients with suspected PE. A good report can help with the systematic evaluation of the images while providing information regarding the severity of the disease (right ventricle/ left ventricle (RV/LV) diameter ratio, RV dysfunction, thrombus load, location). Especially the RV/LV ratio seems to have a strong predictive value for PE related mortality and an adverse outcome [87].

This risk stratification becomes increasingly important regarding the course of therapy.

At the moment treatment decisions are mostly based on vital signs (hypotension, shock) and RV-dysfunction. Every patient with an acute PE gets supportive care and receives a form of anticoagulation, usually in a hospital setting unfractionated heparin and later on vitamin K antagonists or new oral anticoagulants [86].

Patients with acute PE and shock or hypotension (high risk) typically receive primary reperfusion treatment in form of systemic thrombolysis in order to reduce the RV-dysfunction. Second-line to the systemic thrombolysis is the primary reperfusion therapy in form of a surgical embolectomy or a catheter-directed treatment.

With the pulmonary embolism severity index, the remaining PE patients can be divided into an intermediate and a low risk group. The low risk group shows no RV-dysfunction, no elevation in cardiac laboratory results and no elevated severity index (I-II) which results in a possible outpatient treatment. The intermediate risk group however shows an elevated severity index (III-V), with either both laboratory results and RV-dysfunction positive (intermediate high risk) or one/none of both parameters positive (intermediate low risk). For the intermediate high risk group, a monitored primary reperfusion treatment should be considered and these patients should at least be hospitalized for observation purposes [86].

Therefore, in the emergency situation of acute PE, a clear and fast diagnostic management is essential, suggesting a potential benefit of structured reporting in this situation.

Through the course of this work it has become quite clear, that the potential benefit of structured reporting has to be evaluated separately for each template and reporting system. So far there have been no studies evaluating the effect on content, clarity and clinical usefulness of structured reporting in patients with acute PE, hence it was the aim of our study to fill that gap.

3.6.2 Peripheral Arterial Disease (#2)

Peripheral Arterial Disease (PAD) is defined as the narrowing or obstruction of major peripheral arterial vessels in mainly the lower extremities and as a consequence reduction of flow and perfusion [88;89].

One of the main symptoms is intermittent claudication which can progress to acute limb ischemia and amputation. The reduced perfusion of mainly the lower extremities leads to ischemic pain while the oxygen demand of the tissue is elevated though exercise, e.g. through walking [88].

Statistics show the total prevalence of symptomatic and asymptomatic PAD is about 3-10 %. While 3% of people around 40 years and 6% of people around 60 years have symptomatic PAD (Intermittent Claudication) [88;90-92]. PAD is a common disease, which seems to be highly underdiagnosed because asymptomatic and even symptomatic individuals frequently do not seek medical treatment [88].

The vascular occlusion, usually caused by atherosclerosis, can be detected by various investigation techniques. The ankle-brachial-pressure-index is an excellent initial screening test to detect PAD. Duplex ultrasound is usually the first imaging test. CTA or magnetic resonance angiography are often performed to visualize the exact distribution and extent of PAD [88;93].

Cardiovascular risk factor reduction becomes essential, when it comes to dealing with atherosclerosis-based diseases, consequently the therapy of PAD always starts

with lifestyle management. The risk factor reduction revolves around the prevention of smoking, hyperglycemia, hypercholesterolemia, hypertension and the integration of regular exercise into the everyday routine [88;93;94].

The stage adapted therapy usually follows the Fontaine stages. Stage I is an asymptomatic stage during which the risk factor management (smoking abstinence, blood pressure normalization, statin therapy, diabetes management, weight reduction, exercise) is essential to prevent the progression of the disease. Also antiplatelet therapy is usually started during stage I to reduce the risk of an adverse cardiovascular event. The second Fontaine stage is divided into A and B. IIA stands for mild claudication and a painless walking distance of >200m. IIB describes a moderate-severe claudication with a painless walking distance of less than <200m. During this stage exercise walking training (only for < or = stage II) is added to the therapy of stage I. Exercise encourages angiogenesis and muscle adaptation to low oxygen levels, which helps to increase quality of life. If the pain cannot be tolerated, vasoactive drugs can additionally be used. Starting from stage III (ischemic rest pain) revascularization should be seriously considered to avoid or delay the necessity for amputation. During stage IV (ulceration or gangrene) wound treatment becomes also necessary [94;95].

The revascularization therapy for patients with either chronic limb ischemia or strongly life style limiting claudication, can be divided into two options: endovascular interventions or open surgical treatment. The Inter-Society Consensus for the Management of PAD (TASCII) provides a treatment recommendation on the basis of the TASC Classification. The four different categories (A-D) are used to classify different types of stenoses in the aortic and femoral-popliteal area [88]. An extension of the Classification including the infrapopliteal segment was later on added to the original [96].

While the endovascular approach (e.g. angioplasty with/without stent) is usually the first-line therapy when dealing with short or singular Typ A lesions. The open surgical (e.g. bypass or endarterectomy) approach is the treatment of choice when dealing with long, complex or multiple stenoses which depending on their severity, extent and location can be referred to as TACS Typ D lesions.

Typ B and C lesions do not have a clear recommendation. With Typ B the endovascular approach seems to be preferable, while with Typ C lesions the surgical option is favored. In both cases co-morbidities, patient preference and the long-term success rate of the individual surgeon should be taken into account before deciding on a course of therapy [88].

There have been a lot of discussions regarding the two interventional therapy options. The BASIL study in which surgical and endovascular approaches were compared suggests a similar outcome regarding amputation-free survival within the first year after intervention [97]. Furthermore because of the cost efficiency, the

lower peri-interventional complications and the reduced hospitalization time endovascular treatment may be advisable for patients with significant comorbidities, high surgical risk profile and low life expectancy [93;97;98]. Goodney et al. found a strong increase in endovascular procedures and a decrease in bypass surgery between the years 1996 and 2006 [99]. This might be attributed to recent technical developments in the endovascular field [96]. However this should again be evaluated with more recent data.

So far there have been no studies evaluating the effect of structured reporting of CTA on clarity, completeness, clinical relevance and usefulness in a patient population with known or suspected PAD. Because of the sometimes quite complex CTA findings we also wanted to investigate the impact of structured reporting on further testing and therapy. We hypothesized that the complexity of the pathologies combined with the greater clarity and completeness of structured reporting [3;28] could alter the necessity for retesting and result in a more effective therapy.

3.7 Authors' Contributions

3.7.1 Study #1

Bastian Sabel, Jessica Plum and Felix Meinel reviewed the literature and planned the study. Jessica Plum collected the clinical data of all patients. Bastian Sabel and Felix Meinel developed a structured radiology reporting template. Bastian Sabel created the structured radiology reports, which were then reviewed by Felix Meinel. The combined information was assembled and organized by Jessica Plum and distributed to the raters. Nikolaus Kneidinger, Gabriela Leuschner, Leandra Koletzko and Bijan Raziorrouh compared and rated the randomized reports. The resulting data were collected and analyzed by Jessica Plum. The statistical analysis was performed by Regina Schinner. Jessica Plum prepared the tables. Bastian Sabel prepared the figures and drafted the manuscript, which was then reviewed and approved of by all authors. Franziska Schoeppe, Kolja Thierfelder, Wolfgang Kunz and Wieland Sommer participated in the interpretation of the data and revised the manuscript for intellectual content.

Justification of Shared First Authorship

Bastian Sabel and Jessica Plum contributed equally to this study and are therefore listed as shared first authors on the resulting publication. Both participated substantially in planning the study. Jessica Plum was in charge of collecting, organizing, and analyzing the data and creating the tables, while Bastian Sabel created the radiology reports, drafted the paper and created the figures.

3.7.2 Study #2

Bastian Sabel, Jessica Plum and Felix Meinel reviewed the literature and planned the study. Bastian Sabel and Felix Meinel developed a structured radiology reporting template. Said template was used by Bastian Sabel to create the structured reports, which were reviewed by Felix Meinel and Jessica Plum. Jessica Plum collected the clinical data of all patients. The combined information assembled and organized by Jessica Plum and distributed to the raters.

Michael Czihal, Christian Lottspeich, Frank Schönleben and Gabor Gäbel compared and rated the randomized reports. The resulting data were collected, organized and analyzed by Jessica Plum and Felix Meinel.

The statistical analysis was performed by Regina Schinner. Jessica Plum prepared the tables. Bastian Sabel prepared the figures and drafted the manuscript, which was then reviewed and approved of by all authors.

Franziska Schoeppe participated in the interpretation of the data and revised the manuscript for intellectual content.

4. English Summary

While investigation techniques and image modalities become more and more advanced, radiology reports have remained in their classic form for the past decades.

Structured reporting has shown its potential to increase the clarity, correctness, confidence, concision, completeness, consistency, communication, consultation and standardization of radiology reports.

The increased report quality can mostly be attributed to a complete checklist like approach, standardized vocabulary through RadLex and RSNA provided templates which can be adapted to address very specific inquiries. Especially the interdisciplinary approach necessary to design and adapt those templates can ensure that all therapy influencing criteria are evaluated in the report. This may lead to a different therapy and outcome. Structured reporting also harbors great teaching opportunities, such as a checklist-like approach for young radiology residents and an image database of pathological findings. With a large analyzable database of reports, a statistical analysis becomes possible, which can e.g. lead to increasingly better screening algorithms.

Technological challenges however, different data formats, varying degrees of quality of structured reporting systems and the concerns about work flow efficiency and report rigidity remain difficulties of structured reporting itself.

Despite of this it also provides many future possibilities such as the implementation of medical guide lines into the report format, multi media reports, evaluation of radiation dose, management of follow-up appointments, automatic invoice and reimbursement systems and the improvement of data mining.

Given the potential of structured reporting and its impact on patient care, we decided to evaluate its so far unknown benefit for patients with acute PE and PAD.

For patients with APE, the structured reports were evaluated by two pulmonologists and two general internists and compared to the reports from the clinical routine of the same patient group. While all four referring clinicians perceived the structured CTPA reports as superior in clarity, only the pulmonologists found additional benefit in content and clinical utility. The structured reports did not alter patients' management in patients with acute PE significantly.

In the study concerning patients with diagnosed or suspected PAD the structured reports (run-off CTA/ lower extremities) were evaluated by two vascular surgeons and two vascular medicine specialists. The results showed, both groups regarded structured reports as superior in clarity, completeness, clinical relevance and usefulness. Especially vascular medicine specialists seemed to appreciate the structured reporting format.

As in our PE study, structured reporting did not seem to alter further testing or therapy for the patients included in our study.

Both studies demonstrate that referring clinicians prefer structured reporting of cardiovascular CT examinations over conventional reports.

5. German Summary / *“Zusammenfassung”*

Während Untersuchungstechniken und Bildgebungsformate in ihrer Entwicklung immer weiter fortschreiten, sind Befundberichte von ihrem klassischen Format in den vergangenen Jahrzehnten nicht abgerückt.

Strukturierte Befundung hat das Potenzial, zum einen die Übersichtlichkeit, Richtigkeit, Zuversicht, Präzision, Vollständigkeit, Beständigkeit, Kommunikation, Rücksprache und Standardisierung der Radiologieberichte zu verbessern.

Die gesteigerte Berichtqualität kann man zu großen Teilen auf den katalogartigen Aufbau, durch die von RadLex standardisierte Sprache und die von der RSNA bereitgestellten, auf spezielle Fragestellungen abstimmbaren Templates zurückführen. Vor allem der interdisziplinäre Ansatz, der notwendig ist, um ein Template zu entwickeln oder abzuändern, kann gewährleisten, dass alle therapierelevanten Merkmale im Befundbericht evaluiert werden. Dies kann in der Konsequenz die Therapieempfehlung und das Outcome beeinflussen.

Strukturierte Befundung beinhaltet ebenso große Lehrmöglichkeiten, wie zum Beispiel einen Checklisten ähnlichen Aufbau zur Orientierung für junge radiologische Assistenzärzte und eine Bilderdatenbank mit Pathologien.

Mit einer großen analysierbaren Datenbank von Befundberichten wird auch eine statistische Analyse, welche zum Beispiel dazu führen könnte, Screening Algorithmen zu verbessern, möglich.

Jedoch stellen verschiedene Datenformate, die unterschiedliche Qualität von strukturierten Befundungssystemen etc. Herausforderungen dar. Nicht zu leugnen sind auch Bedenken wegen des starr strukturierten Formates bzw. der Arbeitseffizienz.

Jedoch ermöglicht ein standardisiertes Befundungsverfahren eine Menge zukünftiger Möglichkeiten, wie die Eingliederung von medizinischen Richtlinien in ein Befundformat, Multimedialberichte, Ermittlung der Strahlenexposition, Management von Kontrollterminen, automatische Rechnung und Erstattungssysteme und die Erleichterung einer wissenschaftlichen Nutzung der Befunde.

Angesichts des gezeigten Potenzials der strukturierten Befundung und ihres Einflusses auf die Patientenversorgung haben wir uns dazu entschlossen, den bisher unbekanntem Nutzen für Patienten mit akuter Lungenembolie und peripherer arterieller Verschlusskrankheit zu evaluieren.

In der Studie der Patienten mit akuter Lungenembolie wurden die erstellten strukturierten Befunde von zwei Pneumologen und zwei Internisten anderer Subspezialisierungen evaluiert und mit den normalen Befunden derselben Patienten aus der klinischen Routine verglichen. Während alle vier Zuweiser die strukturierten

CT Befunde als überlegen in der Rubrik „Übersichtlichkeit“ ansahen, sahen nur die Pneumologen einen zusätzlichen Vorteil in Inhalt und klinischer Nützlichkeit. Die strukturierten Befunde hatten keinen signifikanten Einfluss auf das geplante Patientenmanagement von Patienten mit akuter Lungenembolie.

In der Studie der Patienten mit bekannter oder vermuteter peripherer arterieller Verschlusskrankheit wurden die strukturierten Befunde von Becken-Bein-CT-Angiographien durch zwei Gefäßchirurgen und zwei internistische Angiologen evaluiert. Die Ergebnisse zeigten, dass beide Gruppen die strukturierten Befunde als überlegen in Übersichtlichkeit, Vollständigkeit, klinischer Bedeutsamkeit und Nützlichkeit ansahen. Vor allem die Angiologen schienen das strukturierte Format wertzuschätzen.

Auch in diesem Patientenkollektiv hatten die strukturierten Befunde keinen signifikanten Einfluss auf die weitere Diagnostik und Therapie der Patienten.

Zusammenfassend zeigen beide Studien, dass zuweisende Ärzte strukturierte Befunde kardiovaskulärer CT-Untersuchungen konventionellen Befunden vorziehen.

6. Publication #1

For copyright reasons this manuscript could not be added to the electronic version of this thesis. The original article can be found with the following information.

Sabel BO*, **Plum JL***, Kneidinger N, Leuschner G, Koletzko L, Raziorrouh B, Schinner R, Kunz WG, Schoeppe F, Thierfelder KM, Sommer WH, Meinel FG:

Structured Reporting of CT Examinations in Acute Pulmonary Embolism.

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****shared first authorship***

7. Publication #2

For copyright reasons this manuscript could not be added to the electronic version of this thesis. The original article can be found with the following information.

Sabel BO, **Plum JL**, Czihal M, Lottspeich C, Schoenleben F, Gaebel G, Schinner R, Schoeppe F, Meinel FG:

Structured Reporting of Run-off CT Angiography Examinations of the Lower Extremities.

Eur J Vasc Endovasc Surgery 2018 May;55(5):679-687.

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