BMJ Open

Pilot study for the registry of complications in rheumatic diseases from the German Society of Surgery (DGORh): evaluation of methods and data from the first 1000 patients

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ABSTRACT

Objective Most patients suffering with rheumatic diseases who undergo surgical treatment are receiving immune-modulating therapy. To determine whether these medications affect their outcomes a national registry was established in Germany by the German Society of Surgery (DGORh). Data from the first 1000 patients were used in a pilot study to identify relevant corisk factors and to determine whether such a registry is suitable for developing accurate and relevant recommendations.

Design and participants Data were collected from patients undergoing surgical treatments with their written consent. A second consent form was used, if complications occurred. During this pilot study, in order to obtain a quicker overview, risk factors were considered only in patients with complications. Only descriptive statistical analysis was employed in this pilot study due to limited number of observed complications and inhomogeneous data regarding the surgery and the medications the patients received. Analytical statistics will be performed to confirm the results in a future outcome study.

Results Complications occurred in 26 patients and were distributed equally among the different types of surgeries. Twenty one of these patients were receiving immune-modulating therapy at the time, while five were not. Infections were observed in 2.3% of patients receiving and in 5.1% not receiving immunosuppression.

Conclusions Due to the low number of cases, inhomogeneity in the diseases and the treatments received by the patients in this pilot study, it is not possible to develop standardised best-practice recommendations to optimise their care. Based on this observation we conclude that in order to be suitable to develop accurate and relevant recommendations a national registry must include the most important and relevant variables that impact the care and outcomes of these patients.

Strengths and limitations of the study

- ► Data from 1000 patients, from 12 health care centres with varying organizational structures, were available to test.
- ► Due to the small number of patients with complications, the inhomogeneity in the different types of rheumatic diseases and the treatments received by patients, extended statistical analyses was not possible and only tendencies could be derived.

INTRODUCTION

Rheumatoid arthritis (RA) has a prevalence of approximately 1% in Western Europe and the USA, with a cumulative prevalence for all types of rheumatic diseases being 2%, and the incidence of inflammatory arthritis diseases in Germany is 3% (about 2.5 billion patients). About 25 years ago, approximately 25% of these patients underwent total joint replacement, yet recently, the number of these procedures as well as the number of surgical treatments in general in patients with RA has decreased in Europe, the USA and Japan.[1–8] This trend could be the result of the recently introduced, very early 'treat-to-target' treatment and/or the use of modern anti-inflammatory medications,[9] which have increased during the same time period. Actually, about 70% of the patients with RA have received so-called disease-modifying antirheumatic drugs (DMARDs), while about 20% are treated with biologicals such as immune-modulating therapy.[10] This means that most of these patients, undergoing surgical treatments, are receiving immune-modulating therapy for their inflammatory arthritic diseases. However, it remains unclear whether immune-modulating medications affect the outcomes of these surgical treatments or if they contribute to an increase in the number of wound complications.

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Interestingly, for most of the 20 routinely administered DMARDs or biologicals, there are surprisingly few evidence-based recommendations for their perioperative use when complications occur.[2 9] For example, in the case of methotrexate, the recommendation to continue administration was based on the expert opinion of a broad international panel of rheumatologists.[11] National medical societies in France, the Netherlands, the US, UK and Japan recommend that—concerning tumour-necrosis-factor alpha (TMF-α)—therapy should be substituted until wounds are healed.[12–15] Based on this confusion, the German Society for Orthopaedics in Rheumatic Diseases (DGORh) established a national registry that included surgical patients suffering with inflammatory arthritis disease. The aim of this pilot study was to determine if data from this national registry could be used to identify risk factors to develop accurate and relevant treatment recommendations, for example, in patients with RA receiving medications who have subcutaneous or deep wound infections.

This report presents the methods used in this pilot study and the preliminary results, from the first 1000 patients.

MATERIALS AND METHODS

Risk adjustment

Based on rheumatology textbooks, published studies[2 15–19] and the clinical experience of study group members, the following risk factors were identified as being possible confounders as it relates to wound disorders or non-unions in arthrodesis: diabetes mellitus, atherosclerosis, malignant tumours, cachexia due to HIV or other consuming diseases, corticoid therapy with more than 5 mg prednisolone equivalent and/or administration for more than 1 year, current or history of bacterial infection in the wound or alio loco. In addition, other risk factors that were included were: sex, age, body mass index (BMI), American Society of Anesthesiologists (ASA) Physical **Status** classification, alcohol and smoking history.

In order to obtain a quicker overview of these possible risk factors/possible confounders, these were only considered in those patients who had wound disorders during the pilot study. While this might have caused a bias in statistical analyses and interpretation of data concerning wound disorders, seroma and infection, we accept this, since the main focus of this pilot study was to see if risk factors are present and since we did not expect to have enough data to perform statistical analyses. In the actual registry data, this bias would not occur since all risk factors and confounders must be reported in the basic form, in order to obtain valid statistical data.

Number and structure of centres involved in the pilot study

A total number of 12 centres were included in the pilot study (box).

Each centre had an orthopaedic surgeon with experience treating patients with inflammatory arthritic diseases. In order to have a representative cross-section of the different types of providers in Germany, different types of departments that treat patients with rheumatic diseases were asked to participate: hospitals specialised in rheumatology, university-based hospitals, departments whose focus was elective orthopaedic surgery and departments that focus on treating patients with trauma.

Box Departments participating in the pilot study

- Orthopedic Hospital Harthausen, Bad Aibling
- Department of Rheuma-Surgery, Kreuznacher Diakonie, Bad Kreuznach
- Department of Rheuma-Surgery, Red Cross Hospital, Bremen
- Department of Rheuma-Orthopaedics, St. Elisabeth Hospital, University Hospital (Ruhr University Bochum), Bochum
- Orthopaedics, Traumatology and Rheuma-Orthopaedics Clinic, Katholic Hospital Dortmund-West, Dortmund
- Orthopaedics and Traumatology Clinic, Agaplesion Markus Hospital, Frankfurt/Main
- Orthopaedics, Traumatology and Rheuma-Orthopaedics Clinic, Westpfalzclinic Kusel, Kusel
- Orthopaedic and Policlinic, University Hospital Leipzig, Leipzig
- Rheuma-ortphopedics, Rheinisches Centre for Rheumatology Meerbusch, Meerbusch
- Orthopaedic Department, Collm-Clinic Oschatz, Oschatz
- Rheuma-Orthopaedics, North-Western Centre for Rheumatology St Josef-Stift Sendenhorst, Sendenhorst

Ethical approval

Approval to conduct the study was obtained from the ethics committee at Ruhr University in Bochum (no: 4138–11). The study was carried out in accordance with the Declaration of Helsinki. All patients included in the study were invited and gave their written informed consent in an initial consent form. This form, administered by the attending physician, included information about different types of rheumatic diseases, their onset, types of medications administered to patients with rheumatic disease, details about medication regimens (continued or interrupted, estimated time for restarting medication, etc) and surgical treatments (date and type of surgery).

If a complication occurred, a second consent form was used that included information about risk factors, date and type of observed complication, as well as indicated treatments. This pilot study focused on the following complications and treatments: wound disorders and skin necrosis (delayed removal of stitches, type of local treatment, local suture), seroma (evacuation, local suture, reoperation), subcutaneous infections (CDC A1) (with i.v. antibiotics treatment or reoperation), deep infections (CDC A2+A3) (i.v. antibiotics and reoperation). Minor complications that did not result in an appointment at the outpatient department or readmission but instead were treated in a doctor's office were not taken into account.

Patients

Every patient suffering from inflammatory arthritis disease and receiving surgical treatment in one of the

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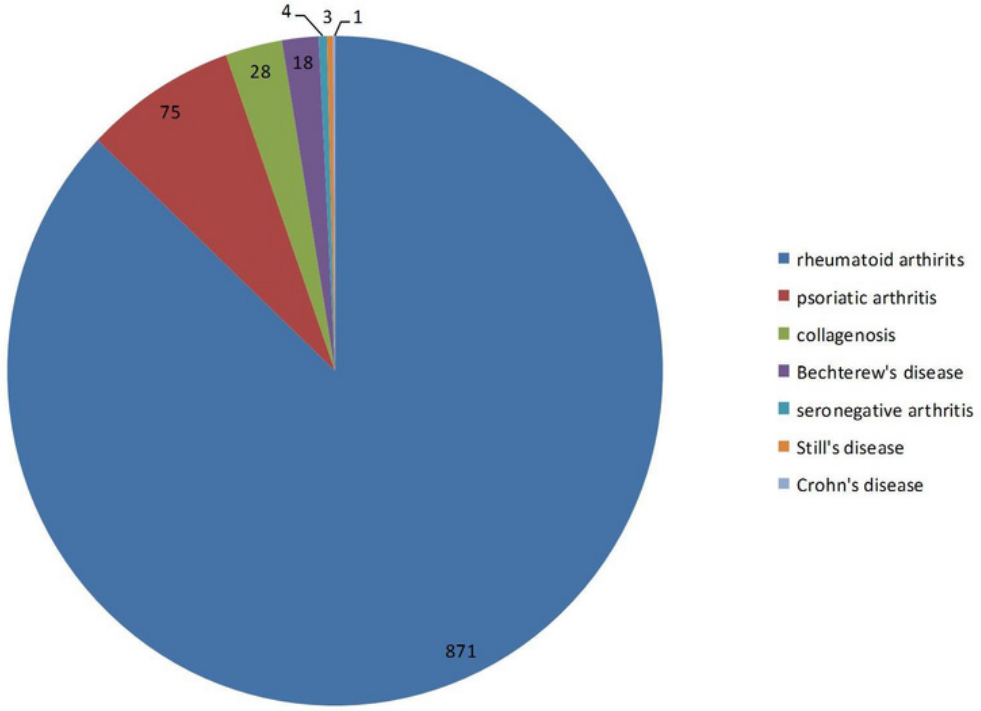

Figure 1 Distribution of different rheumatic diseases among the 1000 pilot study patients.

centres was asked to participate in this study and was included after written informed consent was given. Inflammatory arthritis and elective surgical treatment in the musculoskeletal system was the only inclusion criteria. No exclusion criteria were defined. No drop-outs/withdrawal of consent occurred during this pilot study. The majority of the patients included in this pilot study (871 cases, 87%) suffered from RA, while 7.5% had a psoriatic arthritis, 2.8% suffered from a collagenosis and 1.8% suffered from ankylosing spondylosis. Other rare diagnoses included not differentiated inflammatory arthritis (four cases, 0.4%), Still's disease (three cases, 0.3%) and Crohn's disease (one case, 0.1%) (figure 1).

The median period of time from onset of the disease to the procedure leading to their inclusion in the study was 16 years, with an IQR of 10–25 years, with a maximum of 64 years and a minimum of 1 year.

Statistical methods

This article focuses on the methods and the adaptation of the questionnaires for use in the registry and reports on the initial results from the first 1000 subjects included in the database.

Due to the limited number of observed complications and the inhomogeneous type of the surgical treatments and the medications used, only descriptive statistical analysis was appropriate in this pilot study. However, analytical statistics of the confirmatory questions in midterm outcome can be expected from the registry, which was established in the summer of 2014.

Medians, interquartile ranges, CIs and significance (at 5% level) for the incidence of wound complications in patients treated with immune-modulating medication compared with those not treated were computed using SPSS V.22.0 for Windows (IBM).

RESULTS

Anti-inflammatory drugs

More than 90% of patients (902) received pharmacological therapy, with 6% (60 patients) treated with corticosteroids as a monotherapy and 20% (197 patients) receiving a combination of DMARDs or biologicals and steroids. The majority (84%, 840 patients) were treated with immune-modulating therapy based on DMARDS or biologicals, with 45% (453 patients) receiving methotrexate, either as a monotherapy (19%, 191 patients) or in combination with corticosteroids (11%, 109 patients) or adalimumab (11%, 106 patients). Other common drugs were leflunomide in (18%, 179 patients) of which 7% (67 patients) received a monotherapy, and etanercept (12%, 121 patients) of which 5% (47 patients) received a monotherapy.

Overall, more than half of all patients received a monotherapy (51%, 507 patients), while 32% were treated with two different types of medication. Combinations of three (68 patients) or four different types of immune-modulating medications (2 patients) were rare and were reported in 7% and 0.2% of patients, respectively. The reported combinations are shown in table 1.

Types of surgery

Nearly one third of all procedures can be categorised as bone and joint procedures: total joint replacements,

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Table 1 Pharmacological therapy: steroids, disease-modifying antirheumatic drugs, biologicals and their combinations as reported

	Aldalimumab	Ertanecept	Tocilizumab	Rituximab	Infliximab	Abatecept	Golimumab	MTX	Leflunomide	Azathioprine	Sulfasalazine	Hydroxy-cloroquine	Others	Corticoids	Total
Aldalimumab	28	0	0	0	0	0	0	106	6	1	2	1	4	0	68
Ertanecept	0	47	0	0	0	0	0	41	17	1	4	3	1	24	121
Tocilizumab	0	0	12	0	0	0	0	4	1	0	2	0	0	3	20
Rituximab	0	0	0	16	0	0	0	11	2	0	2	2	0	6	35
Infliximab	0	0	0	0	3	0	0	5	0	0	1	0	0	2	9
Abatecept	0	0	0	0	0	3	0	6	2	0	0	1	0	2	9
Golimumab	0	0	0	0	0	0	3	7	0	0	0	0	0	6	15
MTX	106	41	4	11	5	6	7	191	43	2	31	24	10	109	453
Leflunomide	6	17	1	2	0	2	0	43	67	1	15	5	5	40	179
Azathioprine	1	1	0	0	0	0	0	2	1	10	0	1	0	5	18
Sulfasalazine	2	4	2	2	1	0	0	31	15	0	34	8	0	19	99
Hydroxycloroquine	1	3	0	2	0	1	0	24	5	1	8	11	1	22	57
Others	4	1	0	0	0	0	0	10	5	0	0	1	10	1	32
Corticoids	6	24	3	6	2	2	6	109	40	5	19	22	1	60	253

MTX, methotrexate.

Table 2 Type of surgery performed and affected areas in the 1000 patients

	Tenosynovectomy	Synovectomy	Fusion or resection arthroplasty	Total joint replacement	Others	Total
Vertebra column			3	1	2	6
Shoulder	7	8	6	17		38
Elbow	1	14	7	6	5	33
Wrist		26	55	2	11	94
Flexor tendons (hand)	12					12
Extensor tendons (hand)	19					19
MCP joints		5	9	17	1	32
DIP/PIP joints (hand)		4	19	4	7	34
Hip			3	148		151
Knee	1	56	4	175	4	240
Ankle joint	4	4	21	9	5	43
Subtalar joint	2	1	27		2	32
Toes	3	9	167	1	14	194
Tendons foot	6		3		5	14
Others					58	58
Total:	55	127	324	380	114	1000

DIP/PIP joints, distal interphalangeal/proximal interphalangeal joints; MCP joints, metacarpophalangeal joints.

arthrodeses and resection arthroplasty. Different types of synovectomies were performed in 18% of patients. Surgeries in the lower extremity were represented far more often (67%, 674 cases) than those in the upper extremities (26%, 262 cases). Only two patients with surgical treatment of the vertebral column were included (0.2%). The different types of surgical treatments are listed in table 2.

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Table 3 Patients with reported postoperative complications

Type of complications	Patients (n)	Type of surgery	Risk factor corticosteroids >1 year	Risk factor corticosteroid >5 mg prednisolone equivalent	Further risk factors as postulated	Immune-modulating drugs
Wound disorder stitches in situ >14 days	5	2 total hip replacement 1 ankle arthrodesis 2 forefoot surgery with osteosynthesis	2	0	0	2 mono 3 combination
	6	2 bursectomy or synovectomy (elbow) 2 total joint replacement (hip/knee) 2 procedures in ankle and forefoot	3	2	2 (diabetes and/or carcinoma) in patietns with elbow or ankle surgery	3 mono 2 combination 1 none
Seroma without reoperation	2	1 total elbow replacement with synovectomy 1 synovectomy hip	1	1	0	2 combination
Revision due to seroma	1	1 bursectomy knee	1	1	0	1 combination
Deep infection with revision	11	3 hand surgery 1 total knee replacement 1 total knee replacement 1 open synovectomy knee 4 forefoot surgery with osteosynthesis or total joint replacement 1 osteosynthesis forearm	7	5	4 patients: 2 diabetes 2 vascular disease 1 carcinoma 1 history with infection in addressed area and infection alio loco	5 mono 3 combination
Palsy peroneal nerve	1	1 total knee replacement				1 mono

Wound disorders/infections postoperatively were the most reported complications. The number of patients affected is given in each group. Median age at surgical treatment is 64.9 years (IQR 48.8–72.0; min 13.5; max 78.0). Median duration of rheumatic disease is 20 years (IQR 11.5–29.0; min 5.0; max 46.0). Wound disorders were observed more often in patients not receiving immune-modulating medication. The percentage of patients with infection was slightly higher in those not receiving immune modulating medications (0.9% vs 1%). One patient with a palsy of the peroneal nerve was reported, which has so be considered as a mechanical problem.

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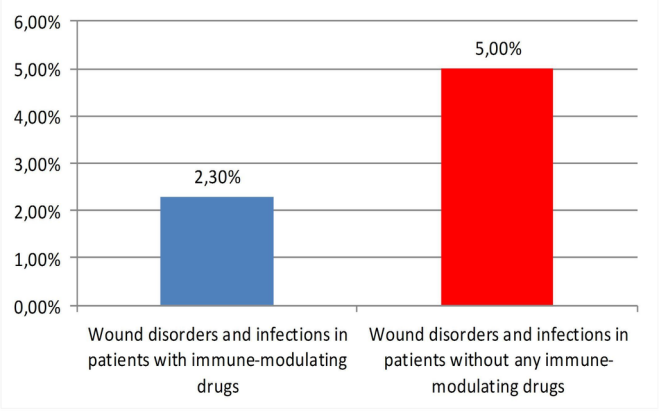

	No wound complications	Wound complications	
No immune-modulating drugs	n= 93 (94.9%)	n= 5 (5.1%)	n= 98
Immune-modulating drugs	n= 881 (97.7%)	n= 21 (2.3%)	n= 902
	n= 974	n= 26	n=1000

Figure 2 Wound disorders and infections occurred more than twice as often in patients not receiving immune-modulating medication, compared with treated patients. There was no statistical significance (Fisher's exact test, p=0.168, 5% level) in the occurrence of wound complications between patients treated with immune-modulating drugs and those not treated.

Complications occurred

Complications, summarised as 'wound disorders,' and infections occurred in 26 patients (2.6%) and were nearly equally distributed among upper limb, total hip or knee replacement and foot and ankle surgeries. Twenty one of these patients received pharmacological immune-modulating therapy (interrupted perioperatively in 11 cases), while five did not receive a specific medication. A total of 2.3% of patients with an immunomodulating therapy had wound complications, while 5.1% receiving no pharmacotherapy for their rheumatoid disease experienced wound complications in the form of infections.

Deep infections requiring revision surgery occurred in nine patients, eight (0.8%) of which were being treated with immune-modulating drugs and one (0.1%) who was not receiving medication.

Of the 26 patients with wound complications, 14 (54%) had been treated with corticosteroids for more than 1 year and 9 patients (35%) were receiving doses greater than a 5 mg prednisolone equivalent. Four patients (15%) had diabetes mellitus, two patients (8%) had vascular disease in the treated limb, two patients (8%) had carcinoma (none with cachexia) and one patient (4%) had a history of infection at the time of surgery. The average age of the patients with wound disorders/infections at the time of surgery was 65 (IQR 49–72, minimum 14, maximum 78) years. The duration of the inflammatory arthritic disease was 18 (IQR 10–29, minimum 5, maximum 46) years (95% CI 11 to 27 years). Details for these 26 patients with wound complications/infections are given in table 3.

DISCUSSION

Our initial results in this pilot study show that wound complications occurred twice as often in patients not receiving immune-modulating medication, while deep infections were nearly equally distributed in patients receiving and not receiving drug therapy. This finding seems to be clinically relevant—even if the statistical significance was not demonstrated, using the Fisher's exact test (p=0.168) (figure 2). However, due to the surprisingly low number of complications, the inhomogeneous surgical procedures and the variance of pharmacotherapy within the pilot data, this observation must be interpreted with care and analytical statistics cannot yet be performed.

That said, these initial observations support the need to collect additional data that include risk factors, types of surgeries and pharmacotherapy in order to be able to formulate evidence-based recommendations for these patients.

This pilot study has helped to identify possible confounders such as risk factors and loss to follow-up due to missing patient identification, both important factors that must be taken into consideration as data collection moves forward.

The postulated risk factors were found in patients with wound disorders, indicating that these risk factors will have to be considered as possible confounders in order to evaluate the influence of pharmacotherapy on wound complications. Based on this observation, these risk factors have been included in the initial patient inclusion criteria forms ('basic questionnaire'). This will make it possible to perform risk-adjusted analyses combined with age, sex, BMI, ASA classification, alcohol and smoking history, type and onset of rheumatic disease, in the actual registry (figure 3). Taking these confounders into account will help formulate more accurate and relevant preoperative recommendations related to the influence of pharmacotherapy in these patients.

The surprisingly low number of patients with postoperative wound disorders and infection compared with the considerably higher figure published in literature[10 20 21] can be explained by the loss to follow-up of patients with minor wound complications treated with local therapy outside the hospital. These patients were not included in this study because the ID assigned to them by their respective hospitals made follow-up impossible as they received care elsewhere. To remedy this, a patient pseudonym was generated based on non-changing patient data consisting of date and location they were attended, place of birth (city and state), Christian name and maiden name. This so called 'salt-protected hash code' ensures that, even in the most complicated forms and between different institutions, patients can be linked to their individual data set, helping to avoid a loss to follow-up in the actual registry.

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DGORh - Sammelstatistik Bogen 1

Erfassung der Basistherapie bei Rheumaoperationen

BASISTHERAPIE 2013

Nur zum internen Gebrauch. Nicht vom Scanner gelesen.

Nachname	Geburtsvorname	Geschlecht m / w
Strasse		Pat.-Nr. *(klinikintern)*
Land	Postleitzahl / Wohnort	
Sozialversicherungsnummer		Geburtstag (TT.MM.JJJJ)
Geburtsnachname	Geburtsort	Bundes- / Geburtsland

Anweisungen

- Alle Fragen beantworten falls kein anderer Vermerk.
- Felder sind komplett auszufüllen.

Einverständnis Patient

○ liegt vor
○ liegt nicht vor

Fragetypen

○ nur eine Antwort erlaubt
mehrere Antworten erlaubt
Pflichtangaben

Generell

Rheumadiagnose

○ R.A. ○ PSA ○ andere .....
Bitte spezifizieren

Grösse** *(cm)* *Exakte Werte bei Bedarf online eintragen* .....

○ 135 ○ 140 ○ 145 ○ 150 ○ 155 ○ 160 ○ 165 ○ 170
○ 175 ○ 180 ○ 185 ○ 190 ○ 195 ○ 200 ○ 205 ○ 210

Gewicht** *(kg)* *Exakte Werte bei Bedarf online eintragen* .....

○ 35 ○ 40 ○ 45 ○ 50 ○ 55 ○ 60 ○ 65 ○ 70
○ 75 ○ 80 ○ 85 ○ 90 ○ 95 ○ 100 ○ 105 ○ 110

Raucher ○ ja ○ nein
Alkohol ○ ja ○ nein

Rheuma seit

19.. 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59
19.. 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79
19.. 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99
20.. 00 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19

Risikofaktoren

keine
Kortison > 1 Jahr
Kortison > 5mg
Karzinom
Diabetes melitus
PAVK
Wundheilungsstörung mit Nachweis pathologischer Keime
HIV / Kachexie
Infektion in der Vorgesch. im OP-Bereich
Infektion in der Vorgesch. alio loco
Infekt alio loco
anderer .....
Bitte spezifizieren

Operation

Bei Komplikationen Bogen 2 ausfüllen

OP Datum Tag 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Monat 01 02 03 04 05 06 07 08 09 10 11 12 **Jahr** 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

CRP prä-OP .....mg/dl

Prä-OP quantitativer Rheumafaktor ..... *(optional)*

Allgemeinzustand (ASA)

○ nicht bekannt ○ ASA1, gesund ○ ASA2, geringe Beeinträchtigung ○ ASA3 starke Beeintr,. ○ ASA4 lebensbedr. Beeintr. ○ ASA5 moribund

OP Art	Tenosynovekt.		Synovektomie		Sehnenplastiken		Arthrodese		Arthroplastik		Endoprothese	
HWS	☐		☐		☐		☐		☐		☐	
	Re	Li	Re	Li	Re	Li	Re	Li	Re	Li	Re	Li
Schulter	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Ellbogen	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Handgelenk	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Strecksehnen Hand	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Beugesehnen Hand	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
MCP / Hand Re	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
MCP / Hand Li	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
MTP Re	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
MTP Li	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
PIP / Hand Re	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
PIP / Hand Li	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
DIP Re	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
DIP Li	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
PIP / Fuss Re	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
PIP / Fuss Li	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
DIP Re	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
DIP Li	1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5	
BWS / LWS	☐		☐		☐		☐		☐		☐	
	Re	Li	Re	Li	Re	Li	Re	Li	Re	Li	Re	Li
Hüfte	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Knie	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
OSG	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
USG	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Beugesehnen Fuss	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Strecksehnen Fuss	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fusswurzel	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Rück- und Mittelfuss	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Zehengelenke	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Andere	○ andere OP											

Bitte spezifizieren .....

Allgemeine Bemerkungen: ..... **Fortsetzung Rückseite**

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** BMI wird online berechnet

Figure 3 Continued

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DGORh - Sammelstatistik Bogen 1

Erfassung der Basistherapie bei Rheumaoperationen

BASISTHERAPIE

Seite 2

Basistherapeutikum

® Handels-name z.B.	HWZ Tage	eingenommen prä-op Monate 0 - 999 Mte.	abgesetzt / ausgeschwemmt prä-op Tage 0 - 99 Tage	angesetzt für Tage post-op. 0 - 99 Tage
Instruktion		max. 3 Markierungen anbringen : - oberste Zeile sind Hunderter - zweite Zeile sind Zehner - unterste Zeile sind Einer	max. 2 Markierungen anbringen : - obere Zeile sind Zehner - untere Zeile sind Einer	Beispiel 19 Tage Markieren Sie 01 in oberer Zeile Markieren Sie 09 in unterer Zeile
Abatacept Orencia	13	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Adalimumab Humira	12	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Anakinra Kineret	0.2	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Antimalaria-mittel Nivaquine	45	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Azathioprin Imurek	0.2	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Cyclopho-sphamid Endoxan	0.4	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Cyclosporin Sandimmun	0.3	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Etanercept Enbrel	4	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Gold Tauredon	45	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Infliximab Remicade	9	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Leflunomid Arava	14/ 52	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Methotrexat Lantarel	0.3	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Mycophenol-säure CellCept	0.25	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Rituximab MabThera	19	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Sulfasalazin Salazopyrin	17	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09
Andere .... (Bitte spezifizieren)	.....	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09	00 01 02 03 04 05 06 07 08 09

Allgemeine Bemerkungen:

.....

.....

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Figure 3 Continued

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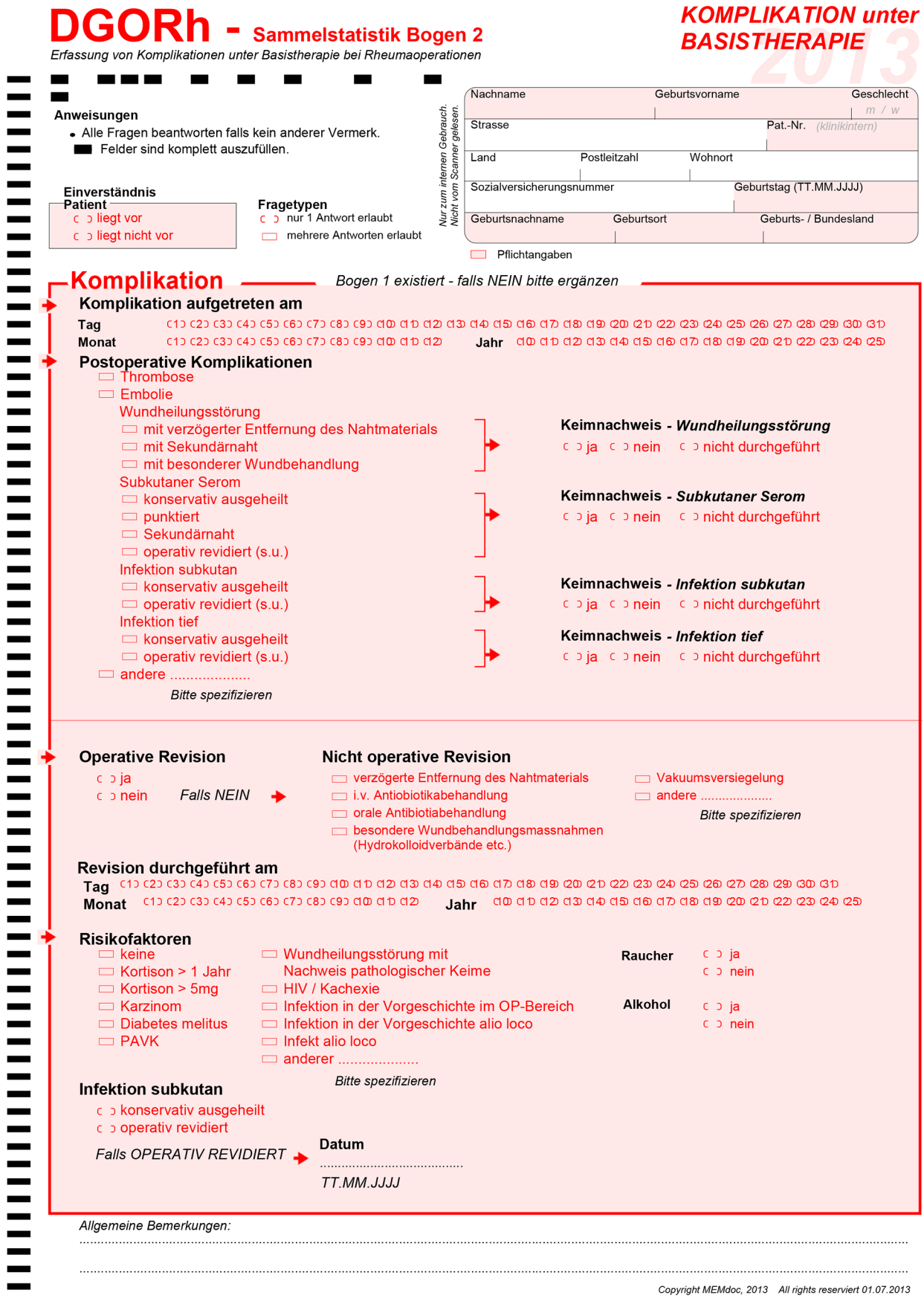

DGORh - Sammelstatistik Bogen 2

Erfassung von Komplikationen unter Basistherapie bei Rheumaoperationen

KOMPLIKATION unter BASISTHERAPIE 2013

Anweisungen

- Alle Fragen beantworten falls kein anderer Vermerk.
- Felder sind komplett auszufüllen.

Nur zum internen Gebrauch. Nicht vom Scanner gelesen.

Nachname | Geburtsvorname | Geschlecht (m / w)

Strasse | Pat.-Nr. (klinikintern)

Land | Postleitzahl | Wohnort

Sozialversicherungsnummer | Geburtstag (TT.MM.JJJJ)

Geburtsnachname | Geburtsort | Geburts- / Bundesland

Pflichtangaben

Einverständnis Patient

○ liegt vor
○ liegt nicht vor

Fragetypen

○ nur 1 Antwort erlaubt
mehrere Antworten erlaubt

Komplikation

Bogen 1 existiert - falls NEIN bitte ergänzen

Komplikation aufgetreten am

Tag 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Monat 01 02 03 04 05 06 07 08 09 10 11 12 **Jahr** 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

Postoperative Komplikationen

- Thrombose
- Embolie
- Wundheilungsstörung
  - mit verzögerter Entfernung des Nahtmaterials
  - mit Sekundärnaht
  - mit besonderer Wundbehandlung
- Subkutaner Serom
  - konservativ ausgeheilt
  - punktiert
  - Sekundärnaht
  - operativ revidiert (s.u.)
- Infektion subkutan
  - konservativ ausgeheilt
  - operativ revidiert (s.u.)
- Infektion tief
  - konservativ ausgeheilt
  - operativ revidiert (s.u.)
- andere .....

Bitte spezifizieren

Keimnachweis - *Wundheilungsstörung*
○ ja ○ nein ○ nicht durchgeführt

Keimnachweis - *Subkutaner Serom*
○ ja ○ nein ○ nicht durchgeführt

Keimnachweis - *Infektion subkutan*
○ ja ○ nein ○ nicht durchgeführt

Keimnachweis - *Infektion tief*
○ ja ○ nein ○ nicht durchgeführt

Operative Revision

○ ja
○ nein *Falls NEIN*

Nicht operative Revision

- verzögerte Entfernung des Nahtmaterials
- i.v. Antiobiotikabehandlung
- orale Antibiotiabehandlung
- besondere Wundbehandlungsmassnahmen (Hydrokolloidverbände etc.)
- Vakuumsversiegelung
- andere .....

Bitte spezifizieren

Revision durchgeführt am

Tag 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Monat 01 02 03 04 05 06 07 08 09 10 11 12 **Jahr** 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

Risikofaktoren

- keine
- Kortison > 1 Jahr
- Kortison > 5mg
- Karzinom
- Diabetes melitus
- PAVK
- Wundheilungsstörung mit Nachweis pathologischer Keime
- HIV / Kachexie
- Infektion in der Vorgeschichte im OP-Bereich
- Infektion in der Vorgeschichte alio loco
- Infekt alio loco
- anderer .....

Bitte spezifizieren

Raucher ○ ja ○ nein

Alkohol ○ ja ○ nein

Infektion subkutan

○ konservativ ausgeheilt
○ operativ revidiert

Falls OPERATIV REVIDIERT **Datum** ..... *TT.MM.JJJJ*

Allgemeine Bemerkungen:

.....

.....

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Figure 3 Questionnaires adapted for use in the registry based on the findings from the pilot study.

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Finally, based on this pilot study, additional data will be collected documenting in more detail the type of treatment wound disorders received and the final status of the wound complication, thus being able to distinguish between minor and major wound complications in the registry.

LIMITATIONS

Due to the small number of patients with observed complications as well as the inhomogeneity in the surgical and pharmacological treatments they received, extended analytical statistics could not be performed. Accordingly, at this time, no recommendations for perioperative management of anti-inflammatory drugs could be derived from these first 1000 datasets.

In the actual registry, the analysis of data reported in high volumes, like monotherapy and single surgeries, will be considered first line, while those occurring in low volumes like multiple surgeries or combinations of medication will be designated second line and will be analysed taking the first line into consideration.

CONCLUSION

Besides age, sex, risk factors, type and duration of the rheumatic disease, the administration of immune-modulating medications may impact wound complications. Due to the inhomogeneity in the disease itself and the treatments received by patients with rheumatic diseases, it is difficult to develop standardised best-practice recommendations to optimise their care. Therefore, the creation of a large, comprehensive national registry that includes the most important and relevant variables that impact the care and outcomes of these patients is essential. This pilot study has helped to identify these variables and in doing so will contribute to improving the national registry so that its data can be used to formulate accurate and relevant recommendations for the care of this vulnerable patient population.

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Contributors TK: writing of manuscript, data analysis, modification of questionnaires for real-time registry. SR: design of pilot questionnaires, review of questionnaires for real time registry, review of manuscript. RMH: data collection and data analysis. CB: providing of references, review of manuscript. REW: providing of references, approval ethics committee. KS: design of pilot questionnaires, data collection, review of manuscript.

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Patient consent Detail has been removed from this case description/these case descriptions to ensure anonymity. The editors and reviewers have seen the detailed information available and are satisfied that the information backs up the case the authors are making.

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