requiring hospitalization): 2% vs 0.2% and the risk presentation format: numbers only, numbers + IA, numbers + BB, and numbers + IA + BB. Route of administration, benefit, and cost were held constant. Each subject responded to a single, randomly-assigned scenario. Dependent variables included perceived riskiness, worry, global gist related to the acceptability of the AE, and willingness to take the medication (all measured on 5-point ordinal scales). We hypothesized that the IA and BB formats would result in 1) lower perceived riskiness and worry, and 2) greater acceptability of the AE and willingness to take the medication in the 0.2% vs 2% scenarios. Socioeconomic status (SES) was defined based on difficulty paying for medication and education level.

Results: We mailed 1453 surveys. 465 patients completed and mailed the survey back (32% response rate). Overall, the mean age of responders was 58.99 (SD=14.85); 79.7% of were female; 83.2% White and 39.1% had a low SES. There were no statistical differences in demographic or clinical characteristics across the four risk presentation formats. Mean (SD) perceived riskiness, worry, global gist, and willingness to take the medication for 2% versus 0.2% chance of the AE, by SES level, are presented in the Image.

Perceived riskiness was lower for a 0.2% versus 2% risk of the AE in the numbers + IA condition in higher SES subjects. Lower SES subjects who viewed both IA and BB were more worried about the AE and found the AE to be less acceptable in the 0.2% versus 2% condition.

Risk Presentation Format		Riskiness Mean (SD)	Worry Mean (SD)	Gist Mean (SD)	Willingness Mean (SD)
Low SES					
Numbers Only					
AE probability	2%	3.12 (0.18)	3.16 (0.23)	3.12 (0.22)	3.20 (0.24)
	0.20%	3.04 (0.19)	3.38 (0.23)	3.69 (0.22)	3.38(0.25)
	p-value	0.77	0.51	0.07	0.61
Numbers + IA					
AE probability	2%	3.4 (0.24)	3.4 (0.29)	3.07 (0.28)	3.20 (0.31)
	0.20%	2.79 (0.21)	3.05 (0.26)	3.61 (0.25)	3.53 (0.28)
	p-value	0.06	0.37	0.15	0.43
Numbers + BB					
AE probability	2%	3.06 (0.23)	3.13 (0.28)	3.32 (0.27)	3.69 (0.30)
	0.20%	3.17 (0.19)	3.17 (0.23)	3.55 (0.22)	3.82 (0.25)
	p-value	0.72	0.91	0.52	0.74
Numbers + IA + BB					
AE probability	2%	2.83 (0.17)	**2.83 (0.21)**	**3.67 (0.2)**	4.03 (0.22)
	0.20%	3.20 (0.17)	**3.40 (0.21)**	**2.99 (0.2)**	3.50 (0.22)
	p-value	0.12	**0.05**	**0.02**	0.09
High SES					
Numbers Only					
AE probability	2%	2.95 (0.15)	3.03 (0.18)	3.52 (0.18)	3.50 (0.20)
	0.20%	2.77 (0.17)	2.71 (0.20)	3.83 (0.20)	3.74 (0.22)
	p-value	0.44	0.25	0.24	0.41
Numbers + IA					
AE probability	2%	**3.29 (0.16)**	3.06 (0.19)	3.61 (0.19)	3.82 (0.21)
	0.20%	**2.78 (0.15)**	2.73 (0.18)	3.82 (0.17)	3.80 (0.19)
	p-value	**0.02**	0.21	0.41	0.93
Numbers + BB					
AE probability	2%	3.25 (0.15)	3.43 (0.18)	3.48 (0.17)	3.43 (0.19)
	0.20%	3.00 (0.16)	3.28 (0.20)	3.49 (0.19)	3.14 (0.21)
	p-value	0.25	0.59	0.97	0.33
Numbers + IA + BB					
AE probability	2%	2.79 (0.15)	2.76 (0.18)	3.89 (0.18)	4.03 (0.20)
	0.20%	3.2 (0.17)	3.27 (0.21)	3.40 (0.2)	3.50 (0.22)
	p-value	0.07	0.07	0.07	0.08

Conclusions: With the exception of the IA's impact on perceived riskiness among subjects with higher SES, the risk formats used did not enable subjects to correctly differentiate between a 0.2% and a 2% risk of a serious AE. These results highlight the lack of impact of quantitative risk information on patients' risk perceptions.

Disclosure of Interest: None declared

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THU0656 ETANERCEPT BIOSIMILAR USAGE AND ASSOCIATED COST SAVINGS IN GERMANY

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Background: The first etanercept biosimilar was approved by the European Commission in January 2016. Of the 27,000 patients* estimated to be treated with etanercept biosimilar in the Europe, 5,122 patients* are estimated to be on the etanercept biosimilar in Germany at the end of the analysis period. Its usage in Europe may support healthcare sustainability by reducing costs, thereby relieving the burden on healthcare budgets and improving patient's ability to get the right care at the right time.

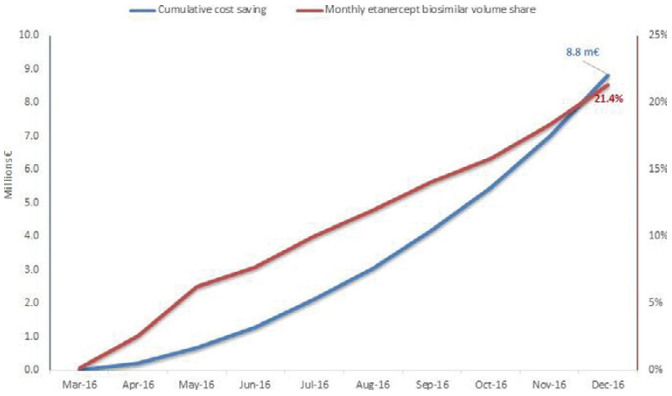
Objectives: The analysis aimed to estimate the pharmacoeconomic impact of etanercept biosimilar use in Germany between March and December 2016.

Methods: The volume of etanercept biosimilar prescribed in Germany was calculated using sell-out data from retail pharmacies to patients sourced from INSIGHT Health. For this analysis, only the pre-filled syringe (PFS) and pre-filled pen (PFP) presentations of 50 mg etanercept were considered. The biosimilar volume share was calculated by dividing the total etanercept biosimilar 50 mg units prescribed by total etanercept 50 mg units prescribed. The cost savings realized through the use of the biosimilar was calculated using the INSIGHT Health volume data and the pharmacies selling price (source: Lauertaxe) of the etanercept reference product and the etanercept biosimilar. (Note: volume, volume share, patient and price data will be updated at time of presentation to reflect most current impact of etanercept biosimilars use).

Results: Based on 5,122 patients currently estimated to be treated with etanercept biosimilar (volume share of 21.4% in Dec 2016) in Germany and on the price differential between etanercept biosimilar and the reference product, a total cost saving of 8.8 million EUR was realized during the analysis period. Assuming these patients remain on etanercept biosimilar treatment, a total savings of 21.1 million EUR** can be returned annually to the healthcare system, compared to using only the reference product. This annual cost savings could be utilized to provide treatment to additional 1,208 patients with etanercept biosimilar.

Table 1. No. of 50 mg Pen/PFS etanercept prescribed: March–Dec 16

Product	Pen	PFS	Total
Reference product	318,317	580,563	898,880
Biosimilar	71,408	40,658	112,066



Conclusions: Experience with etanercept biosimilar has been growing in Germany, as reflected by the growing market share. Based on the current number of patients treated with etanercept biosimilar, savings of 21.1 million EUR are projected to be returned to the health system in Germany annually. The economic burden associated with etanercept treatment is expected to decrease further with an increase in market share for the etanercept biosimilar. These savings can have a significant impact on broadening patient access to biologic treatment in Germany.

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THU0657 A TELE-HEALTH FOLLOW-UP STRATEGY FOR TIGHT CONTROL OF DISEASE ACTIVITY IN RHEUMATOID ARTHRITIS: RESULTS OF THE NON-INFERIORITY RANDOMISED CONTROLLED TRAIL (THE TERA STUDY)

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Background: Despite the increased prevalence of rheumatoid arthritis (RA) in recent years, no studies have yet investigated the effect of monitoring disease activity through a standardized tele-health strategy in patients with RA (1).

Objectives: To test the effect of patient-reported outcome (PRO) based tele-health follow-up for tight control of disease activity in patients with RA, and the differences between tele-health follow-up performed by rheumatologists or rheumatology nurses.

Methods: A total of 294 patients were randomized (1:1:1) to either PRO-based tele-health follow-up carried out by a nurse (PRO-TN) or a rheumatologist (PRO-TR), or conventional out-patient follow-up by physicians. The Flare-RA (2) was used as decision aid for assessing disease activity.
The primary outcome was change in DAS28 after week 52. Secondary outcomes were: physical function, quality of life and self-efficacy. The non-inferiority margin was a DAS28 change of 0.6. Mean differences were estimated following per-protocol, intention to treat (ITT) and imputation (IMP).
Results: Overall patients had low disease activity at baseline and end follow-up. Demographics and baseline characteristics were similar between groups. Non-inferiority was established for DAS28. In the ITT analysis mean difference in DAS28 between PRO-TR vs. control were -0.10 (90% CI -0.30; 0.13) and -0.19 (-0.41; 0.02) between PRO-TN vs. control. When including one yearly visit to the outpatient clinic, patients in PRO-TN had a total of 1.72 (SD 1.03) visit/year, PRO-TR 1.75 (SD 1.03) vist/year and control 4.15 (SD 1.0) visits/year. This included extra visits due to inflammatory flare.
Overall more than 80% of the patients in all three groups answered that they were "very satisfied" with the consultation form they received and no differences were found between the three groups.
Conclusions: Among RA patients with low disease activity or remission a PRO-based tele-health follow-up for tight control of disease activity in RA can achieve similar disease control as conventional outpatient follow-up. The degree of disease control did not differ between patients seen by rheumatologists or rheumatology nurses.
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[2] ClinicalTrails.gov identifier: NCT02155894.
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THURSDAY, 15 JUNE 2017

Validation of outcome measures and biomarkers

THU0658 WNT/β-CATENIN PATHWAY IS AFFECTED IN PRIMARY SJÖGREN'S SYNDROME

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Background: Sjögren's syndrome (SS) is a chronic autoimmune disease that causes salivary and lacrimal gland dysfunction, resulting in oral and ocular dryness. The pathogenesis of SS is still unknown. The Wingless (Wnt)/β-catenin pathway has been recently shown to play an important role in inflammation.
Objectives: The aim of the present study was to determine serum and salivary levels of *Dickkopf-related protein 1* (DKK1) and sclerostin those are inhibitor of Wnt/β-catenin signaling pathway and to evaluate the expression of Wnt-1 and Wnt-3a in the salivary gland, in patients with primary SS.
Methods: 30 patients with primary SS, 30 patients with systemic lupus erythematosus (SLE) and 29 healthy controls were enrolled in the study. Fasting blood and saliva samples were obtained from the participants. Serum and salivary levels of DKK1 and sclerostin were measured by enzyme-linked immunosorbent assay. Wnt-1 and Wnt-3a expression were also immunohistochemically assessed in salivary gland. EULAR SS Disease Activity Index (ESSDAI), and EULAR SS Patient Reported Index (ESSPRI) in the SS group and Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) in the SLE group were recorded.
Results: Serum DKK1 and sclerostin levels were decreased in the SS and SLE groups compared to the controls (Table 1) ($p<0.001$ for both). Salivary sclerostin levels were similar among the study groups ($p>0.05$ for all). Salivary DKK1 levels were higher in the SS group compared to the control and SLE group ($p=0.004$ and $p=0.009$, respectively). Moreover, serum DKK1 level was higher in the SS group than in the SLE group ($p=0.046$). Serum DKK1 level was positively correlated with serum sclerostin level in the SS, SLE and control groups ($r=0.677$; $p<0.001$, $r=0.783$; $p<0.001$, and $r=0.829$; $p<0.001$, respectively). ESSPRI was negatively correlated with serum DKK1 and sclerostin levels ($r=-0.363$; $p=0.049$ and $r=-0.416$; $p=0.022$, respectively) in the SS group.
Moreover, in the salivary gland tissues, the positivities of Wnt-1 (71.4% vs. 46.2%, $p=0.182$) and Wnt-3a (71.4% vs. 53.8%, $p=0.345$) were relatively higher in the SS group compared to the control group, respectively.
Conclusions: According to the best of our knowledge, this study is the first study evaluating the activity of Wnt/β-catenin pathway in the primary SS. The altered serum levels of DKK1 and sclerostin in primary SS and SLE is suggest that Wnt/β-catenin pathway is affected in these inflammatory diseases. Salivary DKK1 level is increased in primary SS in contrast to SLE. On the other hand, Wnt-1 and Wnt-3a expressions on the salivary gland are increased in primary SS. Therefore, it may be concluded that Wnt/β-catenin pathway acts pathogenic roles on the glandular inflammation.

Table 1. Demographics and clinical variables in the study groups

	HC	SLE	SS	P_1 (SLE vs. HC)	P_2 (SS vs. HC)	P_3 (SS vs. SLE)
Serum DKK1, ng/ml	49.8±14.9	27.8±11.8	35.2±8.8	<0.001	<0.001	0.046
Salivary DKK1, ng/ml	30.6±5.9	31.1±6.9	36.3±6.9	0.944	0.004	0.009
Serum Sclerostin, ng/ml	12.9±5.1	5.7±4.1	5.5±3.8	<0.001	<0.001	0.984
Salivary Sclerostin, ng/ml	16.1±3.4	15.7±2.5	15.6±3.7	0.877	0.838	0.996

Disclosure of Interest: None declared
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THU0659 SKIN MICROVASCULAR FLOW ASSESSED BY DYNAMIC OPTICAL COHERENCE TOMOGRAPHY: FIRST NON-INVASIVE QUANTITATIVE OUTCOME MEASURE OF MICROVASCULAR DAMAGE IN SYSTEMIC SCLEROSIS

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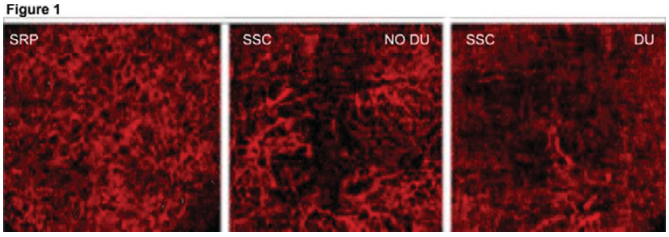
Background: Reduction in capillaries number is the defining feature of microvascular disease in Systemic Sclerosis (SSc) and it concurs to the ischemic manifestations of the disease. Digital Ulcers (DUs) are the major complication of ischemic peripheral vasculopathy.
Dynamic optical coherence tomography (D-OCT) is a recently developed imaging technique that allows non-invasive in vivo study of the microvasculature of the skin. In addition to the skin architecture and vessels morphology, it offers information about flow status, allowing the functional and quantitative evaluation of the microcirculation.[1]
Objectives: To determine the face and content validity of D-OCT as outcome measure of the skin microvascular disease, assuming the presence of current DUs, distal to the DIP joints, as gold standard for ischemic peripheral vasculopathy in SSc.
Methods: A total of 54 patients were enrolled in this cross-sectional study, including 18 SSc patients with current DUs (DU group); 18 SSc patients without current DUs (no DU group) and 18 patients with Raynaud's phenomenon and SSc specific ANA, who did not fulfilled ACR/EULAR 2013 classification criteria (SRP group).
For each patient, we performed a D-OCT scan on both index and middle fingers, on the dorsal aspect of the second phalanx, employing *Vivosight Scanner (Michelson Diagnostics)*. The speckle variance signal of D-OCT images within the first mm of skin depth was extracted, quantified as area under the curve (AUC) and defined as Micro Vascular Flow (MVF).
MVF comparison between the groups was done using parametric or non-parametric tests as appropriate. Statistical Analysis was performed with SPSS V.22.
Results: All three groups were comparable in terms of age and gender distribution ($p>0.80$ for both) as well as disease duration and clinical subset between the two SSc groups ($p=0.839$ and $p=0.646$, resp.). With a scan time <1 minute, D-OCT allowed the visualization and quantification of capillaries within the first millimeter of skin depth (Figure 1).
The distribution of MVF was not significantly different among the four fingers within each group (DU group: $p=0.459$, no DU group: $p=0.953$ and SRP group: $p=0.616$). On the contrary, the distribution and median MVF for all fingers was significantly different among the 3 groups: DU group=0.134 (IQR 0.121–0.134), no DU group=0.153 (IQR 0.132–0.153) and SRP group=0.167 (IQR 0.148–0.167) ($p<0.0001$), as well as in the DU group vs. no DU group ($p<0.001$) or DU vs SRP group ($p<0.001$).
Further, sub analysis of the DU group showed that 10 of the total 20 DUs were on the left index finger. Within this subgroup the MVF of patients on Sildenafil (n=6) was significantly higher than the rest of the group (0.148±0.021 vs. 0.113±0.019, $p=0.03$).

Figure 1



Conclusions: MVF assessed by D-OCT is a quantitative, non-invasive surrogate outcome measure of severe peripheral ischemic vasculopathy in SSc. Longitudinal