Multicentre study ‘rehabilitation of occupational skin diseases—optimization and quality assurance of inpatient management (ROQ)’—results from 12-month follow-up

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Summary

Background. Occupational skin disease (OSD) is common, and imposes a considerable personal and public burden. To tackle OSD, the German stepwise procedure of handling OSD was set up. It contains an interdisciplinary, integrated inpatient rehabilitation measure [tertiary individual prevention (TIP)] [dermatological treatment and diagnostic procedures, and patient education (health and psychological)]. The primary aims of the TIP are reduction of the severity of OSD, reduction in the use of corticosteroids, facilitation of return to work, decreased absence from work, and enhanced quality of life (QoL). It was positively evaluated for a period of 4 weeks after return to work.

Objectives. To investigate whether the observed short-term effects remain significant and meaningful over a period of 12 months after discharge from the TIP.

Methods. A prospective design was used to compare clinical and patient-reported outcome data between admission to a 3-week inpatient TIP and 12 months after discharge (12-month follow-up).

Results. Of 1788 individuals admitted to the TIP, data from 1617 individuals were available for analysis. We observed a significant reduction in the severity of OSD, the use of topical corticosteroids, and days of absence from work because of OSD. QoL was significantly improved, and 87.4% were able to return to work and remain in the workforce.

Conclusions. A randomized controlled trial would have been desirable, but was not possible, for legal and other reasons. However, the long-term 12-month follow-up shows that the TIP is associated with sustained improvements in terms of ability to work, QoL, and prognosis, and reductions in days of absence from work because of skin conditions and topical corticosteroid application. These results indicate that the TIP provided a reduction in the personal and public burden of OSD.

Key words: evaluation; intervention; longitudinal; occupational skin disease; prospective.

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Occupational skin disease (OSD) is the most common occupational disease in industrial countries (1–4), and is associated with substantial reductions in quality of life (QoL) (5, 6), negative prognosis (1), and a considerable socio-economic burden (2, 7, 8). Although registers exist in a variety of countries, they very probably underestimate the actual occurrence of OSD, as a result of underreporting and underdiagnosis of the condition (1, 2). In response to the former, a hierarchical prevention concept was developed in Germany, consisting of primary, secondary and tertiary prevention components (9). Tertiary individual prevention (TIP) programmes represent the final stage in this concept, aimed at individuals in whom OSD has become refractory to secondary prevention efforts, but a formal evaluation in terms of efficacy, generalizability/transferability and sustainability is still lacking (10).

Our group was able to show that the TIP was associated with significant improvements in severity of the condition, QoL, and ability to return to work and remain in the workforce, as well as reduced topical corticosteroid use, over a follow-up period of approximately 7–8 weeks after discharge from the inpatient TIP (4 weeks after return to work) (10). Many interventions claim to be successful on the basis of evaluations over relatively short follow-up periods, but short-term effects often wane over more extended periods of time (11). The present investigation was intended to shed light on the question of whether the observed short-term effects remained significant and meaningful over a period of 12 months after completion of an inpatient multidisciplinary tertiary prevention programme.

**Materials and Methods**

A detailed description of how the intervention (TIP) came about, its content and how the study was designed is provided elsewhere (9, 10, 12, 13). The TIP consists of a 3-week inpatient phase, a 3-week post-inpatient phase, and an after return to the workplace phase (12). The 3-week inpatient phase comprises an interdisciplinary intervention programme including dermatological/allergy assessment and treatment and patient education and counselling (12, 13). The second phase is a 3-week period of absence from work after the 3-week inpatient period, with the purpose of establishing complete remission of the skin disease. The third phase commences at the end of the (sometimes variable) 6-week period, when the patient returns to the workplace. These latter periods are marked by transition-free outpatient dermatological care, improved personalized skin protection behaviour in the workplace and at home, and a modified organizational structure to facilitate optimal skin protection behaviour and minimal exposure to irritants and allergens. This is achieved in conjunction with the respective statutory accident insurance organization that funds the measure. TIP participation is voluntary, but patients are obliged to co-operate with the respective insurance organizations in order not to lose their compensation claim. For this reason, the sample can be considered to be largely representative of the population of severe cases of suspected OSD for whom outpatient secondary individual prevention measures have been insufficient. Patients are consecutively admitted to the TIP.

Assessments for the purpose of the formal evaluation are embedded in a prospective longitudinal study, and take place at admission to and discharge from the TIP, and 4 weeks, 12 months and 3 years after the end of the post-inpatient phase. Skudlik et al. (10) provides the results of the period up to 4 weeks after the end of the post-inpatient phase (4 weeks after return to work). The 1-year follow-up examination and assessment took place between November 2006 and January 2011. It consisted of a standardized clinical examination, including the Osnabrueck Hand Eczema Severity Index (OHSI) (14), severity of OSD according to the Bamberg Medical Bulletin (15), and topical corticosteroid use within the previous 12 months, and completion of the Dermatology Life Quality Index (DLQI) (16) with a recall period of 7 days, and of the Life Quality Index Occupational Dermatoses (LIOD) (17) with a recall period of 3 months. Seven individual LIOD items are summed to give a total score in the range of 7–28. Higher scores denote more impaired OSD-specific QoL. Besides many other variables not relevant in the context of this article, the total number of days of absence from work because of OSD was assessed. Participants were also assessed on whether they were able to return to work and remain in their profession within the follow-up period.

All centres participating in the study independently obtained ethical approval from their respective institution’s ethics committee. The study was conducted in full accordance with the World Medical Association’s Declaration of Helsinki, and results are reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations (18, 19). All participants provided written informed consent after having received, in print, a comprehensive explanation of the study’s goals.

Statistical analyses were conducted with SPSS™ 19 (IBM SPSS Statistics). Descriptive statistics report means and standard deviations for continuous variables, and relative frequencies for categorical variables. Differences between baseline and 12-month follow-up were calculated with
t-tests for dependent samples for continuous variables, and with McNemar tests for dichotomous variables. Differences were considered significant if the \( p \)-value obtained with the test was \( \leq 0.05 \).

Results

Detailed sociodemographic data and both clinical and vocational characteristics of the intervention group (\( n = 1788 \) patients), including the results of the follow-up assessment 4 weeks after return to work, are reported elsewhere (10). Of the 1788 patients included in the study, 1617 were assessed again at the 12-month follow-up (response rate = 90.4%). Drop-out analyses (Table 1) comparing the 1617 patients for whom 12-month follow-up data were available with those for whom they were not (\( n = 171 \)) showed no significant differences in terms of sex, time between onset of OSD and admission to the TIP, and days of absence from work because of OSD prior to admission. However, those for whom follow-up data were available were significantly older and had a longer exposure time in their profession prior to admission. No significant differences in the distribution of specific skin disease between the two groups were detected (results not shown, all \( p \)-values \( > 0.05 \)). The majority of those who could not be followed up consisted of individuals who did not respond to repeated contact attempts.

Severity of hand eczema

We observed a significant reduction in OHSI scores between TIP admission and the 12-month follow-up (Table 2).

Table 1. Drop-out analyses

<table>
<thead>
<tr>
<th></th>
<th>No 12-month follow-up (( n = 171 ))</th>
<th>12-month follow-up (( n = 1617 ))</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female sex (%)(^a)</td>
<td>56.1 (48.65–63.42)</td>
<td>50.2 (47.72–52.59)</td>
<td>0.148</td>
</tr>
<tr>
<td>Age at admission (years)(^b)</td>
<td>38.6 ± 13.2</td>
<td>43.7 ± 11.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time between onset of OSD to admission (months)(^b)</td>
<td>75.1 ± 85.5</td>
<td>86.9 ± 100.7</td>
<td>0.138</td>
</tr>
<tr>
<td>Days of absence from work because of OSD (12 months prior to admission)(^b)</td>
<td>43.9 ± 59.1</td>
<td>36.6 ± 63.5</td>
<td>0.153</td>
</tr>
<tr>
<td>Exposure time in months(^c)</td>
<td>166.4 ± 141.3</td>
<td>214.7 ± 141.3</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

OSD, occupational skin disease.
\(^a\)Percentage ± 95% confidence interval.
\(^b\)Mean ± standard deviation.
\(^c\)Exposure to occupationally relevant irritants and allergens.

Severity of OSD

Severity scores of OSD not only including the hands were significantly reduced between TIP admission and the 12-month follow-up (Table 2).

Use of topical corticosteroids

Whereas almost 90% of the patients had used topical corticosteroids in the 12 months prior to TIP admission, only 42.8% still needed to use them in the 12 months prior to follow-up. This difference was significant (Table 2).

Quality of life

Both indicators of QoL, DLQI and LIOD scores, were significantly improved at follow-up in comparison with TIP admission (Table 2). DLQI scores at admission were in the range of having a moderate to large effect on patients’ lives, whereas at follow-up skin condition had only a small effect on QoL.

Return to workforce

Of the 1617 individuals for whom follow-up data were available, the vast majority were able to return to work and remain in the workforce in their previous profession. Only 3.9% of the sample was not able to return to the workforce at all because of still acute OSD, and 0.8% attempted a return that was thwarted by the reoccurrence of OSD (total unable to return to workforce: 4.7%). Another 4.7% were in professional retraining programmes, and 3% were either unemployed or on parental leave (Fig. 1).

Days of absence from work because of OSD

In the 12 months prior to TIP admission, each individual was, on average, absent from work for 29.6 days because of OSD. In the 12 months prior to follow-up, individuals were, on average, absent from work for only 14.0 days because of OSD. This difference was significant (Table 2). In absolute terms, the total number of days of absence from work were 41,810 in the 12 months prior to admission and 19,988 in the 12 months prior to follow-up. This represents a reduction of 52%.

Other indicators

The frequency of hand washing and hand disinfection were significantly reduced at the 12-month follow-up in comparison with admission to the TIP. Skin protection creams were used more regularly, but the difference failed to be statistically significant. However, at follow-up, patients reported significantly more use of emollients.
Table 2. Outcome evaluation (N = 1617)

<table>
<thead>
<tr>
<th>Primary outcomes</th>
<th>Admission</th>
<th>12-month follow-up</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>OHSIa (n = 1617)</td>
<td>6.35 ± 3.45</td>
<td>3.34 ± 3.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Severity of OSDb (n = 1616)</td>
<td>2.88 ± 0.74</td>
<td>2.13 ± 0.79</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Topical corticosteroids within previous 12 months (%) (n = 1574)</td>
<td>88.8</td>
<td>42.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DLOIa (n = 1409)</td>
<td>10.21 ± 6.47</td>
<td>5.45 ± 6.27</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LIODa (n = 1392)</td>
<td>18.04 ± 4.65</td>
<td>13.21 ± 5.06</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Days of absence from workc,d (n = 1411)</td>
<td>29.58 ± 53.64</td>
<td>14.04 ± 43.07</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Other indicators

| Hand washing frequencya,e (n = 1614)                    | 2.42 ± 0.66     | 2.16 ± 0.48        | <0.001  |
| Hand disinfection frequencya,e (n = 1611)              | 1.55 ± 0.90     | 1.48 ± 0.81        | <0.001  |
| Use of skin protection creams (n = 1593) (%)           | 75.5            | 77.8               | NS      |
| Use of emollients (n = 1587) (%)                        | 85.7            | 90.4               | <0.001  |
| Use of protective gloves (n = 1609) (%)                 | 95.1            | 83.7               | <0.001  |
| Self-assessment of OSD severitya,f (n = 1616)           | 2.32 ± 0.72     | 2.12 ± 0.89        | <0.001  |
| Belief in being able to remain in occupationa,g (n = 1561) | 2.14 ± 1.06     | 2.02 ± 1.40        | 0.002   |

DLQI, Dermatology Life Quality Index; LIOD, Life Quality Index Occupational Dermatoses; NS, not significant; OHSI, Osnabrueck Hand Eczema Severity Index; OSD, occupational skin disease.

Mean ± standard deviation.

aAccording to Bamberg Medical Bulletin [no (1), mild (2), moderate (3), severe (4)] (15).

bNumber of days of absence from work attributable to OSD in the past 12 months.

cComparison based on individuals who (1) returned to work and (2) are not retired, not in professional retraining, and not unemployed; n in parentheses indicates pairs of N = 1617 for whom data were not missing.

dNever, <1/day, 1–10/day, >10/day.

eNever, <10/day, 10–20/day, >20/day.

fCleared, better, unchanged, worse, far worse.

gYes (1), possibly yes (2), no idea (3), possibly no (4), no (5).

Fig. 1. Work status 12 months after tertiary individual prevention (TIP) in per cent. OSD, occupational skin disease. *Due to still acute OSD.

Discussion

To our knowledge, this is the largest and most comprehensively documented intervention study in a cohort of patients with refractory OSD. The low drop-out rate (attesting to the dedication of the intervention providers and all others involved) and the results of the drop-out analyses suggest good reliability and validity of the findings of this investigation.

One of the main objectives of the TIP is to enable individuals with refractory OSD to remain in their profession and in the workforce. The present analyses attest to the success of this ambitious aim, as 87.4% of the patients were still in the active workforce 12 months after discharge from the programme. This is the more impressive as the more immediate follow-up result (about 7 weeks after discharge = 4 weeks after return to work), which had shown that 88.8% were able to return to work (10), was roughly maintained after a prolonged period of time.

The 12-month follow-up was also able to show a significant reduction in the number of days of absence from work attributable to OSD in the previous 12 months as compared with baseline. The indirect costs of OSD are considerable, and a large proportion of the indirect costs constitute sick-leave payments (7). The observed mean reduction in days of absence from work of approximately 15.5 days per individual equals a reduction of 52%. This impressive reduction will eventually benefit the statutory
accident insurance, which pays for the TIP and is funded by employer contributions, whose amount is also based on risk assessments in each respective company. In other words, any savings associated with a reduction in absence from work may also be associated with monetary benefits in other areas.

The observed reduction in days of absence from work is likely to be the result of another finding of the study; that is, the significant reduction in severity of OSD. Both indicators of severity were found to remain significantly reduced at the 12-month follow-up, and hence also extend the previous findings of the immediate follow-up in terms of severity reduction (10).

We also observed a reduction in the frequency of hand washing. Wet work constitutes one of the main risks for the development and maintenance of occupational hand dermatitis. The frequency of hand disinfection decreased slightly, but patients may not have had to disinfect that frequently, because of changes in the work environment brought about by the framework of health-educational and workplace-related interventions within the TIP. Similarly, the use of protective gloves did not significantly increase, but, first, patients may not work under conditions of high exposure to irritants or allergens anymore, and second, they may avoid peaks of unnecessarily high exposure to irritants or allergens because of increased health literacy. Patients were also significantly more optimistic about being able to remain in their work. However, this may also reflect a more realistic appraisal of their situation than at admission to the TIP. Also in favour of the TIP is the observation that patients judged their OSD to be less severe at follow-up than at admission.

A direct comparison with other studies is difficult to make. Another study employing a randomized controlled trial design was also able to show the effectiveness of an intervention. When standard care was compared with integrated care provided by a multidisciplinary team, a significantly higher reduction in Hand Eczema Severity Index (HECSI) scores was observed in the intervention group, but no difference in any other outcome (QoL, patient global assessment, and days of absence from work) (20). Our findings cannot show that there are superior effects in the intervention group than in a control group, owing to the observational design, but the outcomes intended to be affected by the TIP were more comprehensive and long-term, and our analyses showed that the intended change took place. The present analyses were also able to show that the TIP is associated with persistently improved skin disease-specific QoL, as shown by significant reductions in DLQI scores at the 12-month follow-up, again showing a continuation of the previously reported more immediate improvements in DLQI scores (10). We also observed significant reductions in LIOD scores. LIOD is a QoL instrument that is specific to occupational skin disease, and this finding is therefore also indicative of the TIP being associated with positive changes in impaired QoL resulting from OSD.

Some limitations need to be mentioned. Although a randomized controlled trial (with a waiting list control group) is the gold standard for the evaluation of the effectiveness of an intervention, as it provides the strongest evidence for potential effects being the result of an intervention, it was, unfortunately, not possible to conduct one, for the following reasons. First, the individual organizations providing the statutory accident insurance are required by law to promptly offer affected individuals all necessary preventive and curative measures (9). Second, for ethical reasons, it would have been impossible to postpone the necessary course of action, particularly as the consequences of non-action are associated with extended absence from work, poor QoL, financial hardship for the patient, and the threat of potential long-term unemployment (9, 21, 22).

Hence, when we attempt to link the observed effects to the TIP, a fair level of caution is necessary. We cannot draw a conclusion on whether the effects are inevitably attributable to the TIP. The provisional evidence, however, suggests that the rate of OSD has been declining (23) since the integrated programme was introduced in Germany (24). Some of the effects may not be attributable to the TIP alone, but also to other parts of the German hierarchical prevention concept, alone and/or in combination (25). For instance, patients are looked after locally by dermatologists, the statutory accident insurance initiates changes in occupational safety procedures in organizations, and employers may do more about ensuring minimal risk exposure to irritants and allergens and provision of appropriate protective materials once the hierarchical prevention concept is initiated for an individual. Nevertheless, for patients with refractory OSD, the TIP ranks very high within this integrated concept in terms of complexity and intensity, and, without it, many affected individuals would have to face a potential job loss because of persistent and recalcitrant OSD instead of being able to remain in the workforce and have a better QoL.

Conclusion

Although interventions have often produced significant and meaningful short-term effects, which often vanish over time (11), this 12-month follow-up was able to show the persistence of the previously reported more immediate reductions in severity of OSD, topical steroid use, and number of days of absence from work, and improvements
in QoL. Studies such as the present one are important for at least two reasons: first, they can show how such programmes work in Germany; and second, they can evaluate, over extended periods of time, whether the intended effects take place, which this follow-up analysis was able to show.

References