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Swedish national survey of patients with hard-to-heal ulcers, focusing on diagnoses, ulcer healing, ulcer treatment time, pain, and prescription of analgesics and antibiotics.

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Swedish national survey of patients with hard-to-heal ulcers, focusing on diagnoses, ulcer healing, ulcer treatment time, pain, and prescription of analgesics and antibiotics.

Rut Frank Öien,¹ Jenny Roxenius,¹ Maria Boström,^{1,2} Hanna L Wickström^{1,3}

Correspondence to

Dr Rut F Öien

Blekinge Centre of Competence, Vårdskolevägen 5, 371 41 Karlskrona, Sweden

rut.oien@regionblekinge.se

+46 706 68 72 02

1 Blekinge County Council, Blekinge Centre of Competence, Karlskrona, Sweden

2 Regional Department of Competence in Family Medicine and Primary Health Care, Växjö, Sweden

3 Department of Clinical Sciences in Malmö, Center for Primary Health Care Research, Lund University, Malmö, Sweden

Keywords: National survey; Aetiological diagnosis; Wound management; Hard-to-heal ulcers; Ulcer healing

ABSTRACT

Objective To investigate whether patients with hard-to-heal ulcers in Sweden were treated according to an aetiological diagnosis, and to explore ulcer healing and treatment time, ulcer related pain and the prescription of analgesics and antibiotics.

Design A national mapping of data from the patients' medical records between April 2021 and March 2023.

Setting: Data from medical records for patients with hard-to-heal ulcers from a randomized clustered sample of two units per level of care and region.

Participants Patients with hard-to-heal ulcers treated in primary, community and specialist care, public or private, within units covering all 21 regions in Sweden.

Primary outcome measures comprise the demographic description of data from the patients' medical records.

Secondary outcome measures include a sensitivity analysis to evaluate if the results from the largest units affected the overall result.

Results A total of 2470 patients from 168 units were included, of which 39% were treated in primary care, 24% in community care and 37% in specialist care. A total of 49% of the patients were treated without an aetiological diagnosis. Healing occurred in 37% of the patients and ulcer-related pain was experienced by 1224 patients (50%). Antibiotics were given to 56% of the patients. Amputation occurred in 5% and 11% were deceased.

Conclusions Only 51% of patients with hard-to-heal ulcers had a documented aetiological ulcer diagnosis, which means that approximately 20 000 patients in Sweden might receive suboptimal treatment. Future research needs to explore why so many patients are undiagnosed and also how to improve diagnosing, which would lead to faster healing and shorter treatment times.

Article Summary

Strengths and limitations of this study

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- Study data is geographically distributed in accordance with the Swedish population.
- Number of patients for each level of care is adequate for generalizations of results for all levels of care.
- Difficulties for participating units in filtering out patients from the health care records might have affected coverage and results.
- Any skewness in results due to units with a disproportionally large number of patients has been analysed and accounted for.
- Only patient outcomes and treatment specifics which have been documented in health care records are included.

INTRODUCTION

There are approximately 40 000 patients with hard-to-heal ulcers in Sweden, as the prevalence is estimated at 0.2%–0.4% of the population [1, 2].

Since patients with hard-to-heal ulcers belong to a medically complex group with co-morbidities, they are often treated across the boundaries of different levels of care. The 21 regions in Sweden provide healthcare at primary and specialist levels of care. The regions and the 290 municipalities have a shared responsibility for patients in community care. However, the main responsibility for wound management rests in primary and community care [1, 3].

Hard-to-heal ulcers have different underlying causes, such as circulatory impairments (venous, arterial and arteriovenous ulcers), diabetes mellitus (diabetic foot ulcers), pressure, trauma, malignancy or inflammatory diseases, and thus different aetiological diagnoses. Furthermore, the underlying cause of the ulcers must be attended to, in order to initiate healing and avoid recurrences [1, 4]. Providing an aetiological diagnosis to initiate the proper treatment is thus crucial in wound management.

It is known that patients with hard-to-heal ulcers are often treated without an aetiological diagnosis and structured care [1], which leads to suboptimal treatment. To offer systematic wound management, the Swedish National Registry for Ulcer Treatment (RUT) was initiated nationally in 2009. The registry provides a structured work procedure focusing on treatment based on aetiological diagnosis [3]. Some registry-based studies have presented reduced healing times and reduced antibiotic treatment due to the RUT [5, 6].

Suboptimal treatment leads to prolonged healing times – months or years – during which time the patients often experience ulcer pain [7], disturbed sleep and anxiety, which in turn have a huge negative impact on their quality of life (QoL) [8, 9].

Pain is a common but often undertreated symptom in patients with hard-to-heal ulcers. Several studies show that nurses do not consistently assess pain in these patients even though knowledge of pain exists [1]. A direct correlation between pain and quality of life has previously been reported [10]. Pain is also reported to be the symptom that has the highest negative impact on QoL for patients with hard-to-heal ulcers [11, 12].

Earlier studies have found that antibiotic treatment is liberally prescribed to these patients, even in the absence of signs of infection requiring treatment, due to clinical difficulties in assessing a local ulcer infection [6]. Apart from increasing the general burden of antibiotic resistance it also impacts the patients’ well-being because of medical interactions and side effects [6]. Overprescription of antibiotics might thus impact negatively on the patients’ QoL.

The aim of our study was to investigate whether patients with hard-to-heal ulcers in different levels of care in Sweden were treated according to an aetiological diagnosis. A

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further aim was to explore ulcer healing and ulcer treatment time. Still another purpose was to identify whether pain and prescription of analgesics and antibiotics were documented.

METHODS

Design

This study, which was approved by the Swedish Ethical Review Authority [ref: 2021-00178], was a survey of data from medical records concerning clinical outcomes related to quality of life (QoL). Collection of data was carried out between April 2021 and March 2023 and was conducted during four different rounds, of which the first round was a pilot study including three regions. The inclusion period for every unit was the last 12 months starting from the date of registration in the study.

Target population was patients with hard-to-heal ulcers treated in four types of health care units: Primary care, Community care (Nursing homes and Home health care) and Specialist care in each of the 21 regions in Sweden.

In this study we did not consider acute wounds but hard-to-heal leg, foot, and pressure ulcers. The definition of a hard-to-heal ulcer was an ulcer that had not or was not expected to heal within four to six weeks, and included venous, arterial and arteriovenous ulcers, diabetic foot ulcers, pressure ulcers, traumatic ulcers and atypical ulcers, located on the leg or foot. However, pressure ulcers were not restricted to leg or foot as these can be located anywhere on the body. The chosen diagnoses were retrieved from the National Clinical Practice Guidelines for hard-to-heal ulcers [2]. Information about deceased patients was to be registered.

Since the organization of wound care differs throughout Sweden, we started by identifying all units in all four levels of care, private as well as public, to get sampling frames for health care units treating patients with hard-to-heal ulcers on each level. In specialist care we identified departments of dermatology, infectious diseases, orthopaedics and vascular surgery, and diabetic foot clinics, to be included in the study.

A randomized clustered sample of two units per level of care and region was drawn using a random number generator. All patients with hard-to-heal ulcers in the sampled units were included in the study. We aimed to include 10% of the target population, i.e. 2000–4000 patients. The study population was treated in primary care, community care and specialist care and the units covered every region in Sweden. Community care entails both nursing homes and home health care and results from these units were amalgamated and reported together.

As patients are often treated by more than one caregiver, there might be a risk of duplicate patients in our data. However, with a clustered sample where the target frame has many units in primary care and community care (approximately 1200 primary care units, 310 home health care units and 1700 nursing homes), the risk of the duplicates in the study is very small.

The units were asked to scrutinize their medical records to find documentation on their patients with hard-to-heal ulcers treated during the last 12 months. The journal entries were compiled and submitted into a digital form for each patient. Only anonymized data was submitted. Initially a pilot run (n=436) of data collection was carried out with recurrent meetings with the participating units, at which the units provided feedback on the study variables, thus strengthening the validity of the measurements.

Patient and public involvement

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Neither the patients nor the public were involved in the design, conducting or reporting of the study.

Measurements

Data concerning number of patients (n), gender (female/male), age (years), aetiological diagnosis coded according to the International Statistical Classification of Diseases and Related Health Problems (ICD-10) [13] and whether the patient was diagnosed by a physician (yes/no) were collected and submitted by the units.

The units were also to note in the digital form whether the ulcer was healed, stating date of first visit and date of healing to calculate treatment time in days. For not-yet-healed ulcers the units stated date of first visit and date of submitting data, to calculate treatment time in days. Further variables were pain (yes/no) and pain treatment (yes/no), antibiotic treatment due to the ulcer (yes/no), amputation (yes/no), and death (yes/no).

Statistical analysis

Statistical descriptive analysis was performed using V.25 of IBM SPSS Statistics. Normally distributed variables were expressed as mean values and SD. Non-normally distributed variables were expressed as median values and ranges. Categorical variables were expressed as percentages.

A sensitivity analysis was performed to determine how robust the results were, by comparing results with and without extreme values – in this case, units with disproportional numbers of patients [14, 15].

Results

| | Primary care (n= 962) | Community care (n=582) | Specialist care (n=926) | All levels of care (n=2470) |
|--|--------------------------|------------------------------|----------------------------|--------------------------------|
| Age in years, mean (SD) | 75 (14) | 84 (11) | 72 (16) | 76 (15) |
| Female, % | 48 | 63 | 50 | 52 |
| Underwent amputation, % | 4 | 5 | 6 | 5 |
| Deceased, % | 7 | 22 | 9 | 11 |
| Healed ulcer, % | 50 | 37 | 23 | 37 |
| Treatment time, healed ulcers, in days, median (range) | 84 (4–2277) | 115 (6–2047) | 95 (7–961) | 92 (4–2277) |
| Treatment time, unhealed ulcers, in days, median (range) | 247 (12–7289) | 228 (4–2632) | 264 (7–5294) | 252 (4–7289) |
| Having pain, % | 46 | 52 | 52 | 50 |
| Whereof receiving analgesics, % | 82 | 91 | 88 | 87 |
| Receiving antibiotic treatment, % | 57 | 48 | 61 | 56 |

Table 1. Patient demographics

Basic data are presented in Table 1. A total of 2470 patients from 168 units were included in the study during the study of which 39% were treated in primary care, 24%

in community care and 37% in specialist care respectively. More than half (54%) of the patients were treated by more than one caregiver; this was mostly the case in specialist care (70%) and community care (54%) and to a lesser degree in primary care (37%).

The mean age of patients in the whole group was 76 years (median 79, range 8–102 years) and women constituted 52% (n=1291). Patients in community care were older (mean 84 years, median 86, range 35–102 years) than patients treated in primary and specialist care. Community care also had a larger proportion of women – 63% compared with 48% in primary care and 50% in specialist care.

In total 127 patients (5%) had amputations due to their ulcers. The median age of patients with amputations was 78 years (range 23–99 years) and male patients (n=81) were in the majority (64%) with predominantly arterial ulcers, 30%, and diabetic foot ulcers, 31%. Among female amputees (n=46) arterial ulcers dominated at 50% (n=23) followed by diabetic foot ulcers at 15% (n=7) and pressure ulcers at 11% (n=5). Among all amputees, 24% (n=30) had no aetiological diagnosis.

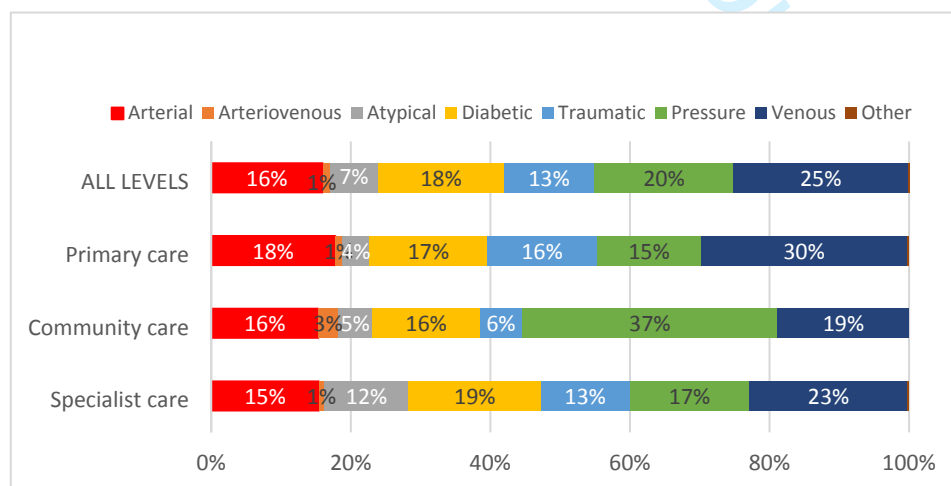
Ulcer diagnoses

Among all patients included in the study, 51% (n=1249) had an ulcer diagnosis showing the cause of the ulcer, i.e. an aetiological diagnosis. Among the remaining patients roughly half had an unspecified ulcer diagnosis such as *Ulcer of lower limb, not elsewhere classified* and *Chronic ulcer of skin, not elsewhere classified*, or had no ulcer diagnosis documented in their medical record.

The proportion of patients receiving an aetiological diagnosis varied between levels of care: in community care, 42%; in primary care, 51%; and in specialist care, 55%. The proportion of patients receiving an aetiological diagnosis did not increase with treatment time.

Figure 1 shows the distribution of ulcer diagnoses (n=1249) in the different levels of care. Ulcers without aetiological diagnoses are not included. The single largest ulcer diagnosis in primary and specialist care was venous ulcers. In community care the single largest diagnosis was pressure ulcers (Figure 1).

Figure 1—distribution of ulcer diagnoses by level of care, % (patients without aetiological diagnosis excluded)



Healing, and treatment time for healed and unhealed ulcers

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During the study period healing occurred in 37% (n=911) of the patients (Table 1), while 51% (n=1264) were not yet healed and 5% (n=127) underwent amputation because of the ulcer. For 7% (n=168) of the patients there was no record of healing status. Of the 911 patients with healed ulcers, 26 (3%) had missing data for treatment time. Of the 1264 unhealed patients, 95 (7%) had missing data for treatment time.

Median treatment time for patients in the whole group of healed ulcers was 92 days (Figure 2). The longest median treatment time was found in community care (115 days) (see Table 1). Median treatment time for patients in the whole group of non-healed ulcers was 252 days, and the longest median treatment time was found in specialist care (264 days) (see Table 1).

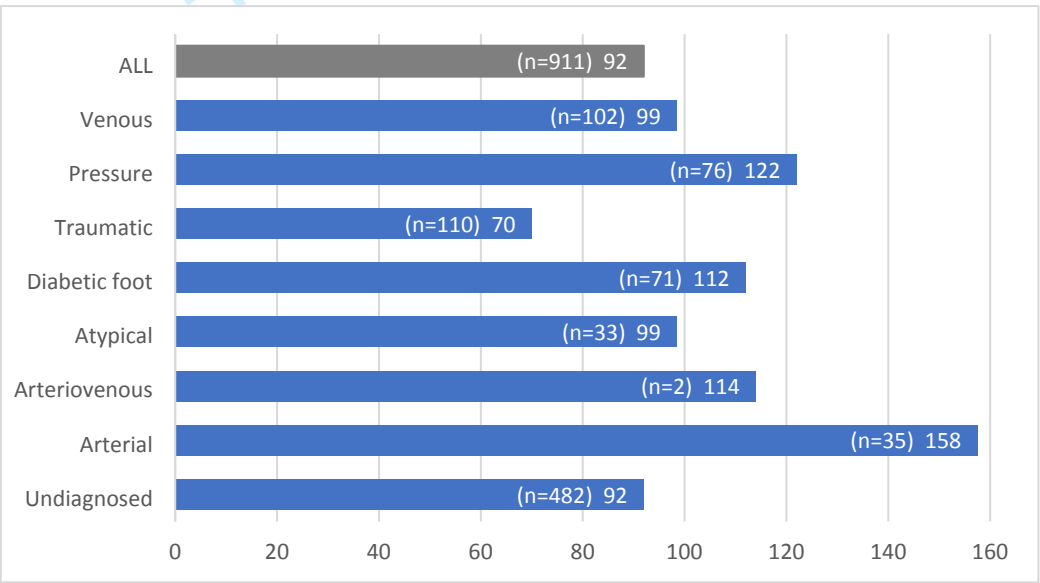


Figure 2. Median treatment time, in days, for healed ulcers, by ulcer diagnosis

In all, 1264 ulcers were unhealed, of which 77% (n=967) had a treatment time exceeding 90 days. Arteriovenous ulcers were one of smallest but the most notable group, where 92% (n=13) had a treatment time of more than 90 days, followed by atypical ulcers at 91% (n=45).

Of unhealed diabetic foot ulcers (n=113), arterial ulcers (n=110) and venous ulcers (n=177), 79%, 78% and 77% respectively had treatment times exceeding 90 days. For unhealed pressure and traumatic ulcers, 69% and 66% respectively had treatment times exceeding 90 days.

Pain and pain treatment

Data reveals that 50% (n=1224) of the patients experienced ulcer-related pain (see Table 1). Of these, 87% were under pain management. A comparison of levels of care shows that 82% of patients with ulcer pain in primary care received pain management, compared with 88% and 91% in community and specialist care respectively. Comparing ulcer diagnosis shows a variation in pain management ranging from 83% for traumatic and undiagnosed ulcers to 100% for arteriovenous ulcers. For 11% of the patients there

was no documentation of pain or pain management in the medical records, varying from 4% in community care to 7% in primary care and 12% in specialist care. Figure 3 shows the proportion of patients experiencing pain due to the ulcer according to ulcer diagnosis.

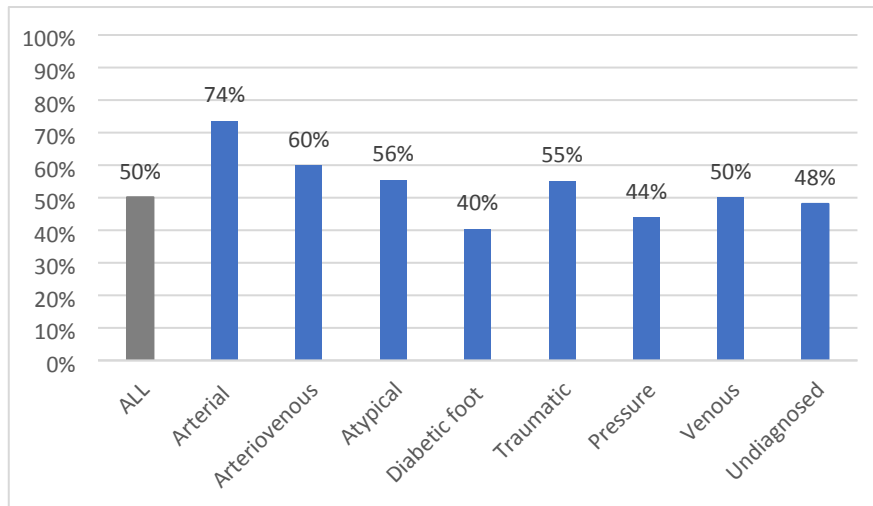


Figure 3. Proportion (%) of patients experiencing pain due to ulcer, by ulcer diagnosis

Antibiotics

Treatment with oral or intravenous antibiotics was given to 56% of the patients – more commonly in specialist care at 61% of the patients, compared to 57% in primary care and 48% in community care (see Table 1).

Diabetic foot ulcers and arterial ulcers were treated with antibiotics to a greater extent (77% and 67% respectively) than ulcers of other aetiologies (see Table 2). As the distribution of ulcer diagnoses varied between the levels of care, the proportion of antibiotic treatment in each ulcer diagnosis is presented in Table 2.

| | Primary care | Community care | Specialist care | All levels of care |
|-------------------|--------------|----------------|-----------------|--------------------|
| Undiagnosed ulcer | 55% (261) | 40% (135) | 59% (245) | 52% (641) |
| Arterial | 67% (58) | 76% (29) | 62% (49) | 67% (136) |
| Arteriovenous | 100% (4) | 71% (5) | 0% (0) | 60% (9) |
| Atypical | 67% (12) | 55% (6) | 53% (33) | 56% (51) |
| Diabetic foot | 71% (60) | 87% (33) | 78% (76) | 77% (169) |
| Traumatic | 47% (36) | 40% (6) | 78% (51) | 60% (93) |
| Pressure | 47% (34) | 44% (39) | 73% (64) | 55% (137) |
| Venous | 57% (82) | 62% (28) | 39% (45) | 51% (155) |

Table 2. Proportion of patients treated with antibiotics, by ulcer type and level of care, % (n=1391)

Results controlled for disproportionally large units

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In specialist care, two units out of 21 treated 27% (n=250) of all the study patients in this level of care (n=926). In primary care, one unit out of 40 units, a wound healing centre, treated 17% (n=163) of the study patients (n=962). A sensitivity analysis shows that median age increases by three years, median healing time increases from 84 to 92 days, and median treatment time increases from 247 to 259 days when the largest unit in primary care is omitted. In specialist care, the proportion of healed ulcers increases from 23% to 30%, median healing time decreases from 95 to 91 days, median treatment time decreases from 264 to 231 days, and antibiotic treatment increases from 61% to 74% when the two largest units are omitted. In community care there were no units with disproportionate amounts of patients.

DISCUSSION

Our mapping gives an insight into the group of patients with hard-to-heal ulcers in Sweden as a whole and reflects the challenges of wound management that both patients and health care staff encounter.

The main finding in this study was that 49% of the patients with hard-to-heal ulcers were treated without an aetiological diagnosis. In community care 58% were treated without aetiological diagnosis, in primary care 49% and in specialist care 45%. According to the National Clinical Practice Guidelines for hard-to-heal ulcers, it is crucial to treat patients according to an aetiological diagnosis, to induce the healing process, handle the underlying cause of the ulcer and prevent recurrences [2]. Healing is thus important in wound management and relates to ulcer diagnosis. Among ulcers without an aetiological diagnosis we found two groups, almost equally large. One group comprised the unspecified ulcer diagnoses *Ulcer of lower limb/chronic ulcer of the skin*. For the other group of patients, no diagnosis at all was documented. This complex group probably consists of a mix of all kinds of diagnoses, but the true distribution is unknown. One assumption, solely based on clinical experience, is that the majority might consist of traumatic ulcers, as these ulcers are often caused by an accident and may not be regarded as hard to heal.

We further found that the incidence of pain (50%) in the study group was in line with a recent study showing that 46% of patients experienced ulcer pain [7]. Pain intensity differed depending on the ulcer aetiology, where 74% of the study patients with an arterial ulcer experienced pain compared with 40% for patients with diabetic foot ulcers. These findings are in accordance with earlier publications [10, 8, 7].

Previous research has reported inadequate pain relief for patients with hard-to-heal ulcers [7]. In our study 87% of the patients reporting pain were given pain relief.

Another finding was the high rate of prescription of antibiotics in every level of care. Infection requiring treatment are reported to occur in 8–27% of hard-to-heal ulcers [16–18]. Our study shows that 56% receive antibiotics, which indicates an overprescription of antibiotics according to earlier publications [5, 6]. A recent study on patients registered in the RUT [6] presents much lower antibiotic prescription (26%), in line with infection requiring treatment [16–18], and even lower prescription rates (8%) when using the registry together with a digital decision support system [6].

Median treatment time for patients in the whole group of healed ulcers was 92 days. The longest median treatment time was found in community care (115 days). Median treatment time for patients in the whole group of non-healed ulcers was 252 days, and the longest median treatment time was found in specialist care (264 days). Previous studies have reported median treatment times in patients with any kind of ulcer diagnosis to be between 49 and 82 days [6, 19]. When introducing the Swedish Registry of Ulcer Treatment (RUT), where staff can follow a structured schedule for wound

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management, median treatment time for hard-to-heal ulcers significantly decreased from 146 days to 63 days [5]. We found that only 37% of the ulcers were documented as healed, while the majority (51%) were documented as unhealed, and for 7% there was no record of healing status. Five per cent of the patients had undergone an amputation because of the ulcer, which is slightly higher than the 2% presented in the RUT [20]. Another finding was that patients were treated by more than one caregiver during the healing process; this was mostly in specialist and community care. Sharing medical data might be demanding, both legally and technically, depending on different systems for documentation. As we noted, and as previously reported, documentation may also be neglected and lacking [21].

As for gender and age, there was a difference between the levels of care. Community care had a larger proportion of women, 63%, compared with 48% in primary care and 50% in specialist care. Patients treated in community care were older, median 86 years, compared with 79 years for the whole group. In Sweden the oldest and most frail patients are treated in community care, so it is not surprising that we found these differences between the various levels of care [1]. This difference is also evident in terms of deaths, with a death rate of 22% in community care compared with 11% for the entire group. One study reported an increased mortality risk for patients with hard-to-heal ulcers irrespective of age, sex, and ulcer aetiology [22]. The same study also reported that the mortality risk was highest among those with arterial ulcers; these patients often have known cardiovascular diseases. In one earlier study on patients with pressure ulcers it was noted that 40% of the patients were deceased within six months, indicating that patients with pressure ulcers belong to an exceptionally frail patient group [23].

The strength of the current study is the national coverage of wound management in every level of care with a substantial number of patients. The use of a large, representative sample of patients with hard-to-heal ulcers means that the results of the study are generalizable for the target population. The weaknesses are the uncertainties regarding what clinical practices and viewpoints staff use to make an ulcer diagnosis and what role the local organization plays in the assessment and treatment of patients with hard-to-heal ulcers, concerning age, gender, level of care and type of ulcer. However, our mapping might give policy makers a good basis for the improvement of wound diagnosis and management on a national level.

CONCLUSION

Only 51% of patients with hard-to-heal ulcers in Sweden receive a documented aetiological ulcer diagnosis according to this study. This indicates a lack of care that contradicts the National Clinical Practice Guidelines. Future research needs to explore why patients with hard-to-heal ulcers are undiagnosed and how this affects the patients' quality of life. Finally, it underscores the importance of improving the use of proper ulcer diagnosis to achieve faster ulcer healing and minimising the need for long-term ulcer treatment. This will benefit quality of life as well as reduce costs.

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Author contributions All authors – RFÖ, JR, MB and HLW – contributed to the concept and design of the study. Data analysis was carried out by JR and HLW. The drafting of the initial manuscript was carried out by RFÖ. RFÖ is the author responsible for the overall content as guarantor. All authors provided critical revision of the paper and have read and approved the final submitted version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Swedish Ethical Review Authority (ref: 2021-00178)

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

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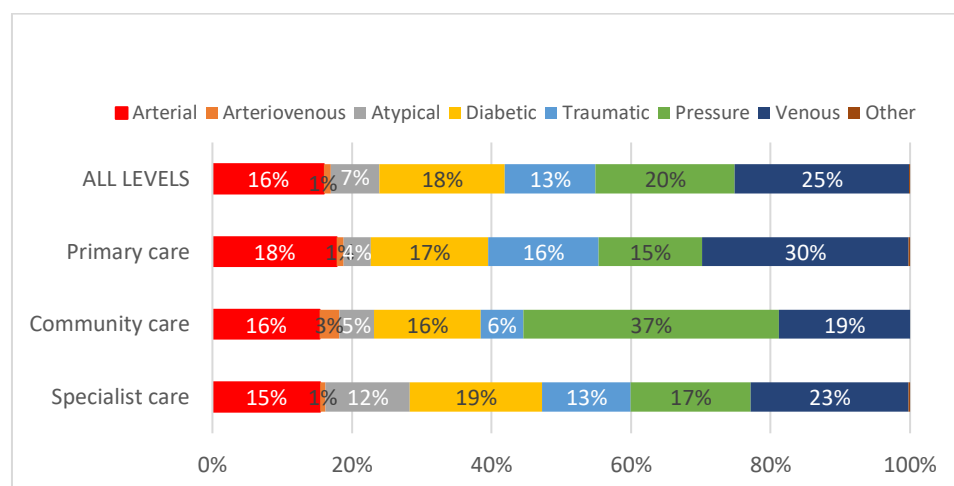
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Figure 1—distribution of ulcer diagnoses by level of care, % (patients without aetiological diagnosis excluded)



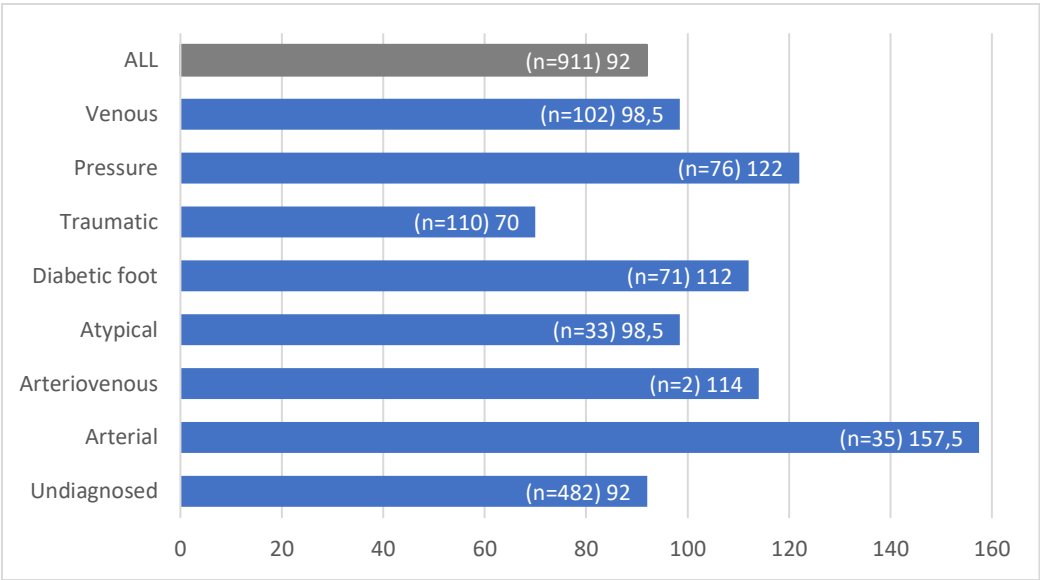


Figure 2. Median treatment time, in days, for healed ulcers, by ulcer diagnosis

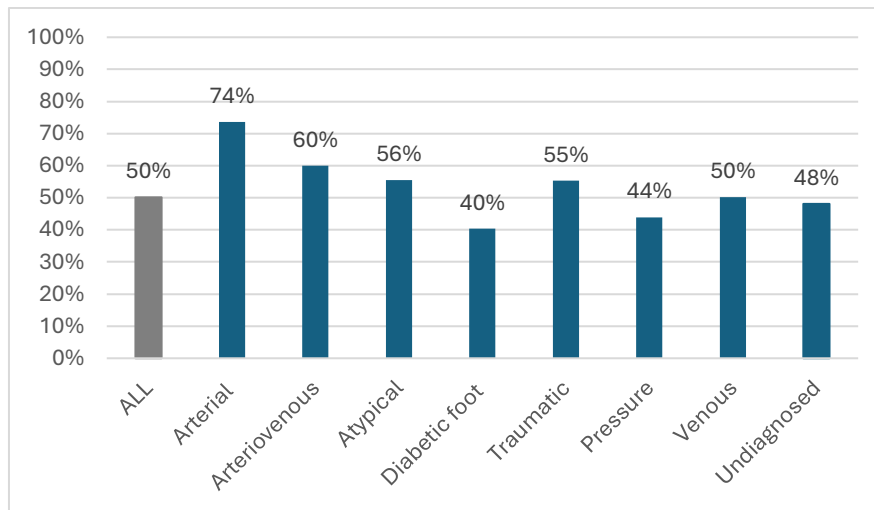


Figure 3. Proportion (%) of patients experiencing pain due to ulcer, by ulcer diagnosis

| | Primary care (n= 962) | Community care (n=582) | Specialist care (n=926) | All levels of care (n=2470) |
|---|--------------------------|------------------------------|-------------------------------|-----------------------------------|
| Age in years, mean (SD) | 75 (14) | 84 (11) | 72 (16) | 76 (15) |
| Female, % | 48 | 63 | 50 | 52 |
| Underwent amputation, % | 4 | 5 | 6 | 5 |
| Deceased, % | 7 | 22 | 9 | 11 |
| Healed ulcer, % | 50 | 37 | 23 | 37 |
| Treatment time, healed ulcers, in days, median (range) | 84 (4–2277) | 115 (6–2047) | 95 (7–961) | 92 (4–2277) |
| Treatment time, unhealed ulcers, in days, median (range) | 247 (12– 7289) | 228 (4–2632) | 264 (7–5294) | 252 (4–7289) |
| Having pain, % | 46 | 52 | 52 | 50 |
| Whereof receiving analgesics, % | 82 | 91 | 88 | 87 |
| Receiving antibiotic treatment, % | 57 | 48 | 61 | 56 |

Table 1. Patient demographics

| | Primary care | Community care | Specialist care | All levels of care |
|-------------------|--------------|----------------|-----------------|--------------------|
| Undiagnosed ulcer | 55% (261) | 40% (135) | 59% (245) | 52% (641) |
| Arterial | 67% (58) | 76% (29) | 62% (49) | 67% (136) |
| Arteriovenous | 100% (4) | 71% (5) | 0% (0) | 60% (9) |
| Atypical | 67% (12) | 55% (6) | 53% (33) | 56% (51) |
| Diabetic foot | 71% (60) | 87% (33) | 78% (76) | 77% (169) |
| Traumatic | 47% (36) | 40% (6) | 78% (51) | 60% (93) |
| Pressure | 47% (34) | 44% (39) | 73% (64) | 55% (137) |
| Venous | 57% (82) | 62% (28) | 39% (45) | 51% (155) |

Table 2. Proportion of patients treated with antibiotics, by ulcer type and level of care, % (n=1391)

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

| | | | Page Number |
|---------------------------|---------------------|---|-------------|
| Reporting Item | | | |
| Title and abstract | | | |
| Title | #1a | We have followed the recommendation | 1 |
| Abstract | #1b | We have followed the recommendation | 1, 2 |
| Introduction | | | |
| Background / rationale | #2 | We have explained the scientific background and rationale in Introduction | 2,3 |
| Objectives | #3 | We have stated the specific objectives, including any prespecified hypotheses | 3 |
| Methods | | | |
| Study design | #4 | The key elements of study design are presented early in the paper | 1 |

| | | | |
|----------------------------|----------------------|--|-----|
| Setting | #5 | The setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection are described | 3 |
| Eligibility criteria | #6a | The eligibility criteria, and the sources and methods of selection of participants are described | 3,4 |
| | #7 | All outcomes, exposures, predictors, potential confounders, and effect modifiers are clearly defined | 4 |
| Data sources / measurement | #8 | Sources of data and details of methods of assessment (measurement) for each variable of are given. | 4 |
| Bias | #9 | Since we have taken every patient treated during the past 12 months in every randomized unit, we considered it not necessary to discuss sources of bias | 4 |
| Study size | #10 | We have described the results for every patient documented in every randomized unit on every level of care nationwide. | 3 |
| | | A total of 2470 patients were included in the study during the study period. | 5 |
| Quantitative variables | #11 | Data were disclosed from primary care as one group, and from specialist care as one group. Since community care entails both nursing homes and home health care the results from these units were amalgamated and reported together. | 4 |
| Statistical methods | #12a | Statistics are thoroughly described for every moment | 4 |
| Statistical methods | #12b | n/a: No subgroups or interactions were examined | 4 |
| Statistical methods | #12c | Number and proportion of missing data are presented in Results. | 5 |
| Statistical methods | #12d | n/a | |
| Statistical methods | #12e | We have described a sensitivity analysis | 4 |

Results

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| | | | |
|--------------------------|----------------------|--|--------|
| Participants | #13a | This section is written according to the check-list | 3, 4 |
| Participants | #13b | All participating units delivered all relevant data from the patients' medical records. | 4 |
| Participants | #13c | Consider use of a flow diagram? | |
| Descriptive data | #14a | Characteristics of study participants are given in Table1. | 4 |
| Descriptive data | #14b | Number of participants with missing data are presented. | 5 |
| Outcome data | #15 | n/a. Not applicable in this mapping where outcome only was collected once for each patient. | |
| Main results | #16a | We have indicated SD where it applies (Table 1) | 4 |
| Main results | #16b | We have reported category boundaries when continuous variables were categorized (Table 1) and in Results | 4 5 |
| Main results | #16c | n/a | |
| Other analyses | #17 | A sensitivity analysis was performed A comparison between unhealed ulcers with a treatment time shorter/longer time than 90 days. | 4 6 |
| Discussion | | | |
| Key results | #18 | Key results with reference to study objectives have been summarised | 7,8 |
| Limitations | #19 | Limitations of the study are discussed in Article summary | 2 |
| Interpretation | #20 | An overall interpretation of results considering objectives, limitations are being discussed. No similar studies have been undertaken. | 7-8 |
| | | The weaknesses of the study are discussed | 8 |
| Generalisability | #21 | The generalisability of the study results are discussed in Article Summary | 2 |
| Other Information | | | |
| Funding | #22 | The study was supported by the Kamprad Family Foundation for Entrepreneurship, Research & Charity, grant number 20210052. | 8 |

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Management and outcomes among patients with hard-to-heal ulcers in Sweden: a national mapping of data from patients' medical records, focusing on diagnoses, ulcer healing, ulcer treatment time, pain, and prescription of analgesics and antibiotics

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|---------------------------------|---|
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Management and outcomes among patients with hard-to-heal ulcers in Sweden: a national mapping of data from patients' medical records, focusing on diagnoses, ulcer healing, ulcer treatment time, pain, and prescription of analgesics and antibiotics

Rut Frank Öien,¹ Jenny Roxenius,¹ Maria Boström,^{1,2} Hanna L Wickström^{1,3}

¹ Blekinge County Council, Blekinge Centre of Competence, Karlskrona, Sweden

² Regional Department of Competence in Family Medicine and Primary Health Care, Växjö, Sweden

³ Department of Clinical Sciences in Malmö, Center for Primary Health Care Research, Lund University, Malmö, Sweden

Correspondence to

Dr Rut F Öien

Blekinge Centre of Competence, Vårdskolevägen 5, 371 41 Karlskrona, Sweden

rut.oien@regionblekinge.se

+46 706 68 72 02

Keywords: National survey; Aetiological diagnosis; Wound management; Hard-to-heal ulcers; Ulcer healing

ABSTRACT

Objective: To investigate whether patients with hard-to-heal ulcers in Sweden were treated according to an aetiological diagnosis, and to explore ulcer healing and treatment time, ulcer related pain and the prescription of analgesics and antibiotics.

Design: A national mapping of data from the patients' medical records, between April 2021 and March 2023.

Setting: Data from medical records for patients with hard-to-heal ulcers from a randomized clustered sample of two units per level of care and region.

Participants: Patients with hard-to-heal ulcers treated in primary, community and specialist care, public or private, within units covering all 21 regions in Sweden.

Outcome measures: Descriptive analysis of data from the patients' medical records.

Results: A total of 2470 patients from 168 units were included, of which 39% were treated in primary care, 24% in community care and 37% in specialist care. A total of 49% of patients were treated without an aetiological diagnosis. Healing occurred in 37% of patients and ulcer-related pain was experienced by 1224 patients (50%). Antibiotics were given to 56% of the patients. Amputation occurred in 5% and 11% were deceased.

Conclusions Only 51% of patients with hard-to-heal ulcers had a documented aetiological ulcer diagnosis, which means that approximately 20 000 patients in Sweden might receive suboptimal treatment. Future research needs to explore why so many patients are undiagnosed and how to improve diagnosis, which could lead to faster healing and shorter treatment times.

Strengths and limitations of this study

- Study data is geographically distributed in accordance with the Swedish population.
- Number of patients for each level of care is adequate for generalizations of results for all levels of care.

- Any skewness in results due to units with a disproportionally large number of patients has been analysed and accounted for.
- Difficulties for participating units in filtering out patients from the health care records might have affected coverage and results.
- Only patient outcomes and treatment specifics that have been documented in health care records are included.

INTRODUCTION

There are approximately 40 000 patients with hard-to-heal ulcers in Sweden, as the prevalence is estimated at 0.2%–0.4% of the population [1, 2]. A hard-to-heal (formerly chronic) ulcer is defined as a break in the skin which has not healed within 4–6 weeks [1–3].

Since patients with hard-to-heal ulcers belong to a medically complex group with co-morbidities, they are often treated across the boundaries of different levels of care. The 21 regions in Sweden provide healthcare at primary and specialist levels of care. The regions and the 290 municipalities have a shared responsibility for patients in community care. However, the main responsibility for wound management rests in primary and community care [1, 3].

Hard-to-heal ulcers have different underlying causes, such as circulatory impairments (venous, arterial and arteriovenous ulcers), diabetes mellitus (diabetic foot ulcers), pressure, trauma, malignancy or inflammatory diseases, and thus different aetiological diagnoses. Furthermore, the underlying cause of the ulcers must be attended to, in order to initiate healing and avoid recurrences [1, 4]. Providing an aetiological diagnosis to initiate the proper treatment is thus crucial in wound management.

It is known that patients with hard-to-heal ulcers are often treated without an aetiological diagnosis and structured care [1], which leads to suboptimal treatment. To offer systematic wound management, the Swedish National Registry for Ulcer Treatment (RUT) was initiated nationally in 2009. The registry provides a structured work procedure focusing on treatment based on aetiological diagnosis [3]. Some registry-based studies have presented reduced healing times and reduced antibiotic treatment due to the RUT [5, 6].

Suboptimal treatment leads to prolonged healing times – months or years – during which time the patients often experience ulcer pain [7], disturbed sleep and anxiety, which in turn have a huge negative impact on their quality of life (QoL) [8, 9].

Pain is a common but often undertreated symptom in patients with hard-to-heal ulcers. Several studies show that nurses do not consistently assess pain in these patients even though knowledge of pain exists [1]. A direct correlation between pain and quality of life has previously been reported [10]. Pain is also reported to be the symptom that has the highest negative impact on QoL for patients with hard-to-heal ulcers [11, 12].

Earlier studies have found that antibiotic treatment is liberally prescribed to these patients, even in the absence of signs of infection requiring treatment, due to clinical difficulties in assessing a local ulcer infection [6]. Apart from increasing the general burden of antibiotic resistance it also impacts the patients’ well-being because of medical interactions and side effects [6]. Overprescription of antibiotics might thus impact negatively on the patients’ QoL.

The aim of our study was to investigate whether patients with hard-to-heal ulcers in different levels of care in Sweden were treated according to an aetiological diagnosis. A further aim was to explore ulcer healing and ulcer treatment time. Still another purpose

was to identify whether pain and prescription of analgesics and antibiotics were documented.

METHODS

Design

This study, which was approved by the Swedish Ethical Review Authority [ref: 2021-00178], was a survey of data from medical records concerning clinical outcomes related to quality of life (QoL). Collection of data was carried out between April 2021 and March 2023 and was conducted during four different rounds, of which the first round was a pilot study including three regions. The inclusion period for every unit was the last 12 months starting from the date of registration in the study.

Target population was patients with hard-to-heal ulcers treated in four types of health care units: Primary care, Community care (Nursing homes and Home health care) and Specialist care in each of the 21 regions in Sweden.

In this study we did not consider acute wounds but hard-to-heal leg, foot, and pressure ulcers. The definition of a hard-to-heal ulcer was an ulcer that had not or was not expected to heal within four to six weeks, and included venous, arterial and arteriovenous ulcers, diabetic foot ulcers, pressure ulcers, traumatic ulcers and atypical ulcers, located on the leg or foot. However, pressure ulcers were not restricted to leg or foot as these can be located anywhere on the body. The chosen diagnoses were retrieved from the National Clinical Practice Guidelines for hard-to-heal ulcers [2]. Information about deceased patients was to be registered.

Since the organization of wound care differs throughout Sweden, we started by identifying all units in all four levels of care, private as well as public, to get sampling frames for health care units treating patients with hard-to-heal ulcers on each level. In specialist care we identified departments of dermatology, infectious diseases, orthopaedics and vascular surgery, and diabetic foot clinics, to be included in the study.

A randomized clustered sample of two units per level of care and region was drawn using a random number generator. All patients with hard-to-heal ulcers in the sampled units were included in the study. We aimed to include 10% of the target population, i.e. 2000–4000 patients. The study population was treated in primary care, community care and specialist care and the units covered every region in Sweden. Community care entails both nursing homes and home health care and results from these units were amalgamated and reported together.

As patients are often treated by more than one caregiver, there might be a risk of duplicate patients in our data. However, with a clustered sample where the target frame has many units in primary care and community care (approximately 1200 primary care units, 310 home health care units and 1700 nursing homes), the risk of the duplicates in the study is very small.

The units were asked to scrutinize their medical records to find documentation on their patients with hard-to-heal ulcers treated during the last 12 months. The journal entries were compiled and submitted into a digital form for each patient. Only anonymized data was submitted. Initially a pilot run (n=436) of data collection was carried out with recurrent meetings with the participating units, at which the units provided feedback on the study variables, thus strengthening the validity of the measurements.

Measurements

Data concerning number of patients (n), gender (female/male), age (years), aetiological diagnosis coded according to the International Statistical Classification of Diseases and Related Health Problems (ICD-10) [13] and whether the patient was diagnosed by a physician (yes/no) were collected and submitted by the units.

The units were also to note in the digital form whether the ulcer was healed, stating date of first visit and date of healing to calculate treatment time in days. For not-yet-healed ulcers the units stated date of first visit and date of submitting data, to calculate treatment time in days. Further variables were pain (yes/no) and pain treatment (yes/no), antibiotic treatment due to the ulcer (yes/no), amputation (yes/no), and death (yes/no).

Statistical analysis

Statistical descriptive analysis was performed using V.25 of IBM SPSS Statistics. Normally distributed variables were expressed as mean values and SD. Non-normally distributed variables were expressed as median values and ranges. Categorical variables were expressed as percentages.

A sensitivity analysis was performed to determine how robust the results were, by comparing results with and without extreme values – in this case, units with disproportional numbers of patients [14, 15].

Patient and public involvement

None.

RESULTS

Patient demographic and clinical data are presented in Table 1. A total of 2470 patients from 168 units were included in the study during the study of which 39% were treated in primary care, 24% in community care and 37% in specialist care respectively. More than half (54%) of the patients were treated by more than one caregiver; this was mostly the case in specialist care (70%) and community care (54%) and to a lesser degree in primary care (37%).

The mean age of patients in the whole group was 76 years (median 79, range 8–102 years) and women constituted 52% (n=1291). Patients in community care were older (mean 84 years, median 86, range 35–102 years) than patients treated in primary and specialist care. Community care also had a larger proportion of women – 63% compared with 48% in primary care and 50% in specialist care.

In total 127 patients (5%) had amputations due to their ulcers. The median age of patients with amputations was 78 years (range 23–99 years) and male patients (n=81) were in the majority (64%) with predominantly arterial ulcers, 30%, and diabetic foot ulcers, 31%. Among female amputees (n=46) arterial ulcers dominated at 50% (n=23) followed by diabetic foot ulcers at 15% (n=7) and pressure ulcers at 11% (n=5). Among all amputees, 24% (n=30) had no aetiological diagnosis.

| | | | | |
|--|--------------------------|------------------------------|----------------------------|--------------------------------|
| | Primary care (n= 962) | Community care (n=582) | Specialist care (n=926) | All levels of care (n=2470) |
|--|--------------------------|------------------------------|----------------------------|--------------------------------|

| | | | | |
|--|---------------|--------------|--------------|--------------|
| Age in years, mean (SD) | 75 (14) | 84 (11) | 72 (16) | 76 (15) |
| Female, % | 48 | 63 | 50 | 52 |
| Underwent amputation, % | 4 | 5 | 6 | 5 |
| Deceased, % | 7 | 22 | 9 | 11 |
| Healed ulcer, % | 50 | 37 | 23 | 37 |
| Treatment time, healed ulcers, in days, median (range) | 84 (4–2277) | 115 (6–2047) | 95 (7–961) | 92 (4–2277) |
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| Having pain, % | 46 | 52 | 52 | 50 |
| Whereof receiving analgesics, % | 82 | 91 | 88 | 87 |
| Receiving antibiotic treatment, % | 57 | 48 | 61 | 56 |

Table 1. Patient demographic and clinical data

Ulcer diagnoses

Among all patients included in the study, 51% (n=1249) had an ulcer diagnosis showing the cause of the ulcer, i.e. an aetiological diagnosis. Among the remaining patients roughly half had an unspecified ulcer diagnosis such as *Ulcer of lower limb, not elsewhere classified* and *Chronic ulcer of skin, not elsewhere classified*, or had no ulcer diagnosis documented in their medical record.

The proportion of patients receiving an aetiological diagnosis varied between levels of care: in community care, 42%; in primary care, 51%; and in specialist care, 55%. The proportion of patients receiving an aetiological diagnosis did not increase with treatment time.

Figure 1 shows the distribution of ulcer diagnoses (n=1249) in the different levels of care. Ulcers without aetiological diagnoses are not included. The single largest ulcer diagnosis in primary and specialist care was venous ulcers. In community care the single largest diagnosis was pressure ulcers (Figure 1).

Healing and treatment time for healed and unhealed ulcers

During the study period healing occurred in 37% (n=911) of the patients (Table 1), while 51% (n=1264) were not yet healed and 5% (n=127) underwent amputation because of the ulcer. For 7% (n=168) of the patients there was no record of healing status. Of the 911 patients with healed ulcers, 26 (3%) had missing data for treatment time. Of the 1264 unhealed patients, 95 (7%) had missing data for treatment time.

Median treatment time for patients in the whole group of healed ulcers was 92 days (Figure 2). The longest median treatment time was found in community care (115 days) (see Table 1). Median treatment time for patients in the whole group of non-healed ulcers was 252 days, and the longest median treatment time was found in specialist care (264 days) (see Table 1).

In all, 1264 ulcers were unhealed, of which 77% (n=967) had a treatment time exceeding 90 days. Arteriovenous ulcers were one of smallest but the most notable group, where 92% (n=13) had a treatment time of more than 90 days, followed by atypical ulcers at 91% (n=45).

Of unhealed diabetic foot ulcers (n=113), arterial ulcers (n=110) and venous ulcers (n=177), 79%, 78% and 77% respectively had treatment times exceeding 90 days. For unhealed pressure and traumatic ulcers, 69% and 66% respectively had treatment times exceeding 90 days.

Pain and pain treatment

Data reveals that 50% (n=1224) of the patients experienced ulcer-related pain (see Table 1). Of these, 87% were under pain management. A comparison of levels of care shows that 82% of patients with ulcer pain in primary care received pain management, compared with 88% and 91% in community and specialist care respectively. Comparing ulcer diagnosis shows a variation in pain management ranging from 83% for traumatic and undiagnosed ulcers to 100% for arteriovenous ulcers. For 11% of the patients there was no documentation of pain or pain management in the medical records, varying from 4% in community care to 7% in primary care and 12% in specialist care. Figure 3 shows the proportion of patients experiencing pain due to the ulcer according to ulcer diagnosis.

Antibiotics

Treatment with oral or intravenous antibiotics was given to 56% of the patients – more commonly in specialist care at 61% of the patients, compared to 57% in primary care and 48% in community care (see Table 1).

Diabetic foot ulcers and arterial ulcers were treated with antibiotics to a greater extent (77% and 67% respectively) than ulcers of other aetiologies (see Table 2). As the distribution of ulcer diagnoses varied between the levels of care, the proportion of antibiotic treatment in each ulcer diagnosis is presented in Table 2.

| | Primary care | Community care | Specialist care | All levels of care |
|-------------------|--------------|----------------|-----------------|--------------------|
| Undiagnosed ulcer | 55% (261) | 40% (135) | 59% (245) | 52% (641) |
| Arterial | 67% (58) | 76% (29) | 62% (49) | 67% (136) |
| Arteriovenous | 100% (4) | 71% (5) | 0% (0) | 60% (9) |
| Atypical | 67% (12) | 55% (6) | 53% (33) | 56% (51) |
| Diabetic foot | 71% (60) | 87% (33) | 78% (76) | 77% (169) |
| Traumatic | 47% (36) | 40% (6) | 78% (51) | 60% (93) |
| Pressure | 47% (34) | 44% (39) | 73% (64) | 55% (137) |
| Venous | 57% (82) | 62% (28) | 39% (45) | 51% (155) |

Table 2. Proportion of patients treated with antibiotics, by ulcer type and level of care, % (n=1391)

Results controlled for disproportionally large units

In specialist care, two units out of 21 treated 27% (n=250) of all the study patients in this level of care (n=926). In primary care, one unit out of 40 units, a wound healing centre, treated 17% (n=163) of the study patients (n=962).

A sensitivity analysis shows that median age increases by three years, median healing time increases from 84 to 92 days, and median treatment time increases from 247 to 259 days when the largest unit in primary care is omitted. In specialist care, the proportion of healed ulcers increases from 23% to 30%, median healing time decreases from 95 to 91 days, median treatment time decreases from 264 to 231 days, and antibiotic treatment increases from 61% to 74% when the two largest units are omitted. In community care there were no units with disproportionate amounts of patients.

DISCUSSION

Our mapping gives an insight into the group of patients with hard-to-heal ulcers in Sweden as a whole and reflects the challenges of wound management that both patients and health care staff encounter.

The main finding in this study was that 49% of the patients with hard-to-heal ulcers were treated without an aetiological diagnosis. In community care 58% were treated without aetiological diagnosis, in primary care 49% and in specialist care 45%. According to the National Clinical Practice Guidelines for hard-to-heal ulcers, it is crucial to treat patients according to an aetiological diagnosis, to induce the healing process, handle the underlying cause of the ulcer and prevent recurrences [2]. Healing is thus important in wound management and relates to ulcer diagnosis. Among ulcers without an aetiological diagnosis we found two groups, almost equally large. One group comprised the unspecified ulcer diagnoses *Ulcer of lower limb/chronic ulcer of the skin*. For the other group of patients, no diagnosis at all was documented. This complex group probably consists of a mix of all kinds of diagnoses, but the true distribution is unknown. One assumption, solely based on clinical experience, is that the majority might consist of traumatic ulcers, as these ulcers are often caused by an accident and may not be regarded as hard to heal.

We further found that the incidence of pain (50%) in the study group was in line with a recent study showing that 46% of patients experienced ulcer pain [7]. Pain intensity differed depending on the ulcer aetiology, where 74% of the study patients with an arterial ulcer experienced pain compared with 40% for patients with diabetic foot ulcers. These findings are in accordance with earlier publications [10, 8, 7].

Previous research has reported inadequate pain relief for patients with hard-to-heal ulcers [7]. In our study 87% of the patients reporting pain were given pain relief.

Another finding was the high rate of prescription of antibiotics in every level of care. Infection requiring treatment are reported to occur in 8–27% of hard-to-heal ulcers [16–18]. Our study shows that 56% receive antibiotics, which indicates an overprescription of antibiotics according to earlier publications [5, 6]. A recent study on patients registered in the RUT [6] presents much lower antibiotic prescription (26%), in line with infection requiring treatment [16–18], and even lower prescription rates (8%) when using the registry together with a digital decision support system [6].

Median treatment time for patients in the whole group of healed ulcers was 92 days. The longest median treatment time was found in community care (115 days). Median treatment time for patients in the whole group of non-healed ulcers was 252 days, and the longest median treatment time was found in specialist care (264 days). Previous studies have reported median treatment times in patients with any kind of ulcer diagnosis to be between 49 and 82 days [6, 19]. When introducing the Swedish Registry of Ulcer Treatment (RUT), where staff can follow a structured schedule for wound

management, median treatment time for hard-to-heal ulcers significantly decreased from 146 days to 63 days [5]. We found that only 37% of the ulcers were documented as healed, while the majority (51%) were documented as unhealed, and for 7% there was no record of healing status. Five per cent of the patients had undergone an amputation because of the ulcer, which is slightly higher than the 2% presented in the RUT [20]. Another finding was that patients were treated by more than one caregiver during the healing process; this was mostly in specialist and community care. Sharing medical data might be demanding, both legally and technically, depending on different systems for documentation. As we noted, and as previously reported, documentation may also be neglected and lacking [21].

As for gender and age, there was a difference between the levels of care. Community care had a larger proportion of women, 63%, compared with 48% in primary care and 50% in specialist care. Patients treated in community care were older, median 86 years, compared with 79 years for the whole group. In Sweden the oldest and most frail patients are treated in community care, so it is not surprising that we found these differences between the various levels of care [1]. This difference is also evident in terms of deaths, with a death rate of 22% in community care compared with 11% for the entire group. One study reported an increased mortality risk for patients with hard-to-heal ulcers irrespective of age, sex, and ulcer aetiology [22]. The same study also reported that the mortality risk was highest among those with arterial ulcers; these patients often have known cardiovascular diseases. In one earlier study on patients with pressure ulcers it was noted that 40% of the patients were deceased within six months, indicating that patients with pressure ulcers belong to an exceptionally frail patient group [23].

The strength of the current study is the national coverage of wound management in every level of care with a substantial number of patients. The use of a large, representative sample of patients with hard-to-heal ulcers means that the results of the study are generalizable for the target population. The weaknesses are the uncertainties regarding what clinical practices and viewpoints staff use to make an ulcer diagnosis and what role the local organization plays in the assessment and treatment of patients with hard-to-heal ulcers, concerning age, gender, level of care and type of ulcer. However, our mapping might give policy makers a good basis for the improvement of wound diagnosis and management on a national level.

CONCLUSION

Only 51% of patients with hard-to-heal ulcers in Sweden receive a documented aetiological ulcer diagnosis according to this study. This indicates a lack of care that contradicts the National Clinical Practice Guidelines. Future research needs to explore why patients with hard-to-heal ulcers are undiagnosed and how this affects the patients' quality of life. Finally, it underscores the importance of improving the use of proper ulcer diagnosis to achieve faster ulcer healing and minimising the need for long-term ulcer treatment. This would benefit quality of life as well as reduce costs.

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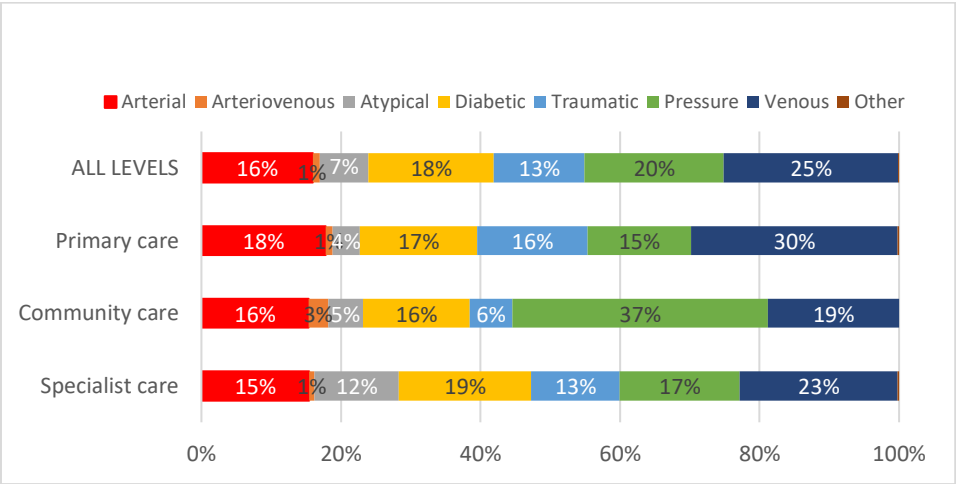
FIGURE TITLES

Figure 1. Distribution of ulcer diagnoses by level of care, % (patients without aetiological diagnosis excluded)

Figure 2. Median treatment time, in days, for healed ulcers, by ulcer diagnosis

Figure 3. Proportion (%) of patients experiencing pain due to ulcer, by ulcer diagnosis

Figure 1—distribution of ulcer diagnoses by level of care, % (patients without aetiological diagnosis excluded)



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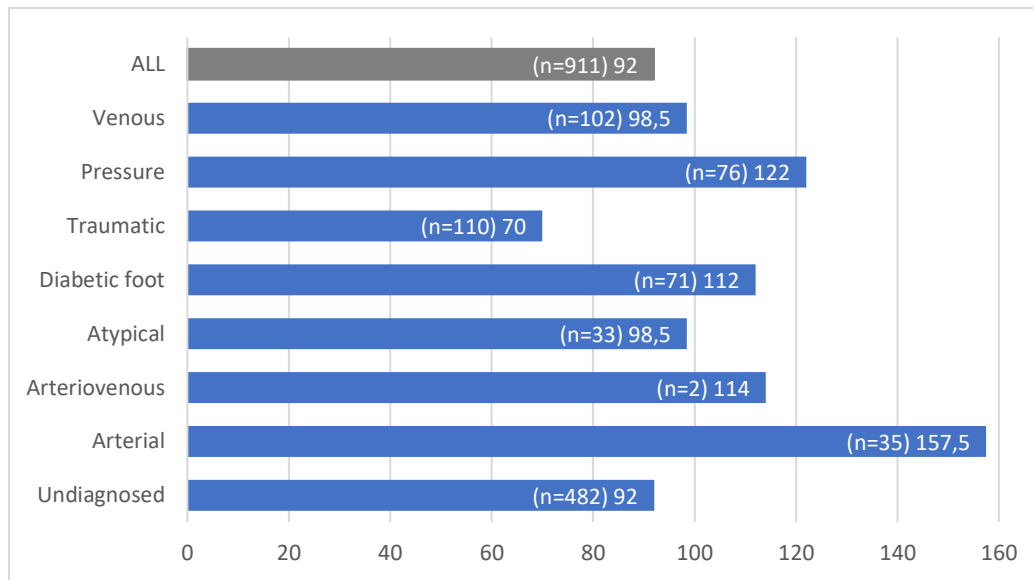


Figure 2. Median treatment time, in days, for healed ulcers, by ulcer diagnosis

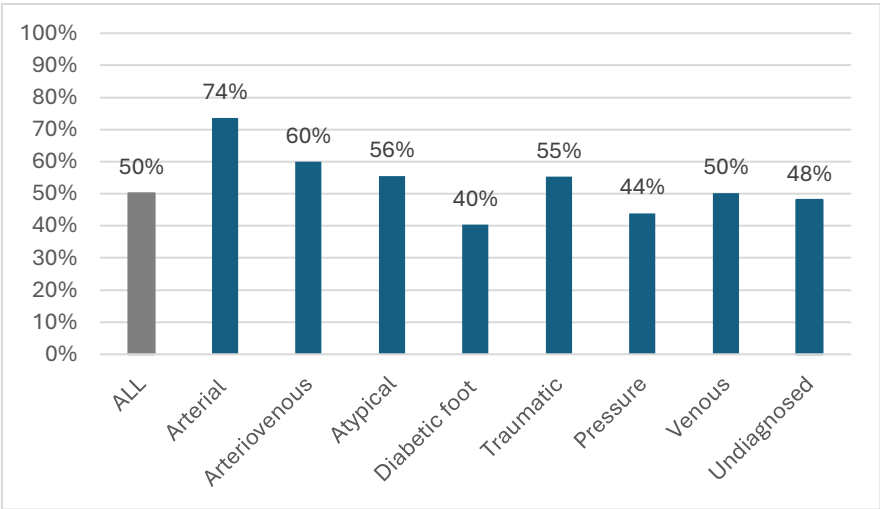


Figure 3. Proportion (%) of patients experiencing pain due to ulcer, by ulcer diagnosis

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

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| | | | Page Number |
|---------------------------|---------------------|---|-------------|
| Title and abstract | | | |
| Title | #1a | We have followed the recommendation | 1 |
| Abstract | #1b | We have followed the recommendation | 1, 2 |
| Introduction | | | |
| Background / rationale | #2 | We have explained the scientific background and rationale in Introduction | 2,3 |
| Objectives | #3 | We have stated the specific objectives, including any prespecified hypotheses | 3 |
| Methods | | | |
| Study design | #4 | The key elements of study design are presented early in the paper | 1 |

| | | | | |
|----|----------------------|----------------------|--|-----|
| 1 | Setting | #5 | The setting, locations, and relevant dates, including periods | 3 |
| 2 | | | of recruitment, exposure, follow-up, and data collection are | |
| 3 | | | described | |
| 4 | | | | |
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| 6 | Eligibility criteria | #6a | The eligibility criteria, and the sources and methods of | 3,4 |
| 7 | | | selection of participants are described | |
| 8 | | | | |
| 9 | | | | |
| 10 | | #7 | All outcomes, exposures, predictors, potential confounders, | 4 |
| 11 | | | and effect modifiers are clearly defined | |
| 12 | | | | |
| 13 | | | | |
| 14 | Data sources / | #8 | Sources of data and details of methods of assessment | 4 |
| 15 | measurement | | (measurement) for each variable of are given. | |
| 16 | | | | |
| 17 | Bias | #9 | Since we have taken every patient treated during the past 12 | 4 |
| 18 | | | months in every randomized unit, we considered it not | |
| 19 | | | necessary to discuss sources of bias | |
| 20 | | | | |
| 21 | | | | |
| 22 | | | | |
| 23 | Study size | #10 | We have described the results for every patient documented | 3 |
| 24 | | | in every randomized unit on every level of care nationwide. | |
| 25 | | | | |
| 26 | | | | |
| 27 | | | A total of 2470 patients were included in the study during the | 5 |
| 28 | | | study period. | |
| 29 | | | | |
| 30 | | | | |
| 31 | Quantitative | #11 | Data were disclosed from primary care as one group, and | 4 |
| 32 | variables | | from specialist care as one group. Since community care | |
| 33 | | | entails both nursing homes and home health care the results | |
| 34 | | | from these units were amalgamated and reported together. | |
| 35 | | | | |
| 36 | | | | |
| 37 | | | | |
| 38 | Statistical | #12a | Statistics are thoroughly described for every moment | 4 |
| 39 | methods | | | |
| 40 | | | | |
| 41 | Statistical | #12b | n/a: No subgroups or interactions were examined | 4 |
| 42 | methods | | | |
| 43 | | | | |
| 44 | | | | |
| 45 | Statistical | #12c | Number and proportion of missing data are presented in | 5 |
| 46 | methods | | Results. | |
| 47 | | | | |
| 48 | | | | |
| 49 | Statistical | #12d | n/a | |
| 50 | methods | | | |
| 51 | | | | |
| 52 | | | | |
| 53 | Statistical | #12e | We have described a sensitivity analysis | 4 |
| 54 | methods | | | |
| 55 | | | | |
| 56 | | | | |
| 57 | Results | | | |
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| | | | |
|--------------------------|----------------------|--|--------|
| Participants | #13a | This section is written according to the check-list | 3, 4 |
| Participants | #13b | All participating units delivered all relevant data from the patients' medical records. | 4 |
| Participants | #13c | Consider use of a flow diagram? | |
| Descriptive data | #14a | Characteristics of study participants are given in Table1. | 4 |
| Descriptive data | #14b | Number of participants with missing data are presented. | 5 |
| Outcome data | #15 | n/a. Not applicable in this mapping where outcome only was collected once for each patient. | |
| Main results | #16a | We have indicated SD where it applies (Table 1) | 4 |
| Main results | #16b | We have reported category boundaries when continuous variables were categorized (Table 1) and in Results | 4 5 |
| Main results | #16c | n/a | |
| Other analyses | #17 | A sensitivity analysis was performed A comparison between unhealed ulcers with a treatment time shorter/longer time than 90 days. | 4 6 |
| Discussion | | | |
| Key results | #18 | Key results with reference to study objectives have been summarised | 7,8 |
| Limitations | #19 | Limitations of the study are discussed in Article summary | 2 |
| Interpretation | #20 | An overall interpretation of results considering objectives, limitations are being discussed. No similar studies have been undertaken. | 7-8 |
| | | The weaknesses of the study are discussed | 8 |
| Generalisability | #21 | The generalisability of the study results are discussed in Article Summary | 2 |
| Other Information | | | |
| Funding | #22 | The study was supported by the Kamprad Family Foundation for Entrepreneurship, Research & Charity, grant number 20210052. | 8 |

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None The STROBE checklist is distributed under the terms of the Creative Commons Attribution License CC-BY. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

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