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ORIGINAL ARTICLE

Quality registry improves the data of chronic ulcers: Validation of Tampere Wound Registry

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Abstract

Quality registries are potential tools for improving health care documentation, but the quality and completeness of each registry should be ensured. This study aimed to evaluate the completion rate (completeness) and accuracy of data, first contact-to-registration time (timeliness), and case coverage of the Tampere Wound Registry (TWR) to assess whether it can be reliably used in clinical practice and for research purposes. Data from all 923 patients registered in the TWR between 5 June 2018 and 31 December 2020 were included in the analysis of data completeness, while data accuracy, timeliness and case coverage were analysed in those registered during the year 2020. In all analyses values over 80% were considered good and values over 90% excellent. The study showed that the overall completeness of the TWR was 81% and overall accuracy was 93%. Timeliness achieved 86% within the first 24 h, and case coverage was found to be 91%. When completion of seven selected variables was compared between TWR and patient medical records, the TWR was found to be more complete in five out of seven variables. In conclusion, the TWR proved to be a reliable tool for health care documentation and an even more reliable data source than patient medical records.

KEYWORDS

chronic ulcer, data quality, health care data, quality registry

Key Messages

- quality care of chronic ulcer patients requires a multidisciplinary approach and comprehensive documentation
- quality registers are valuable assets for clinical practice and research, but their reliability needs to be evaluated
- the data quality of the Tampere Wound Registry was assessed on data completeness, data accuracy, timeliness, and case coverage
- data in the registry were found to have high completion and accuracy rates, and the right patients were shown to be documented in the registry in a timely manner

1 | INTRODUCTION

Chronic ulcers are a considerable global health concern and have significant consequences for individuals and society. Patients with chronic ulcers seem to be at increased mortality risk regardless of aetiology, and ulcers are known to cause a significant decline in patients' quality of life.[1-3] In addition to the humanistic burden on individuals, chronic ulcers impose direct economic costs on society in terms of resources used, but also indirect costs through productivity losses.[4,5] Moreover, it is foreseeable that the challenge of managing patients with chronic ulcers will become even greater as people live longer and chronic diseases accumulate.[6]

Quality care for a patient with a chronic ulcer requires the involvement of multiple professionals from different disciplines. When examining a patient with a chronic ulcer, it is crucial to identify the aetiology of the ulcer but also to consider factors contributing to its development and poor healing. A thorough examination and care of the ulcer patient require expertise from the clinician and comprehensive documentation, especially as during treatment professionals often change.[7] In the absence of a structured documentation system, essential information is typically fragmented in the medical records[8]; it is entirely up to the treating professional to decide what information is included, and moreover, there may be variation in the terminology used.[9]

A structured, checklist-based approach has been recommended when treating patients with chronic ulcers,[10] but as such, is not a sufficient tool for documentation. Valid documentation provides all relevant information on diagnosis and treatment decisions allowing information to be transmitted reliably and effortlessly to all professionals involved in the patient's care by using standardised forms and terminology.[11] Health care quality registries offer structured, continuous collection of specified data on patients, treatments and outcomes in various medical fields. Thus, quality registries are potentially important tools for improving quality of care by harmonising practices and enabling reliable and systematic monitoring, comparison and evaluation of the care provided.[12] A quality registry is also a valuable source of information for studying a decidedly heterogenous population such as patients with ulcers[13,14] and such registers are presently in use for instance in Sweden, the United States and Wales.[15,16] However, simply maintaining a quality registry does not suffice to improve the quality of documentation if the data collected are irrelevant or incomplete. Register holders are responsible for ensuring the correctness and completeness of the data, yet only a limited number of validity assessments of registry data have been conducted.[17,18]

In Tampere University Hospital, Finland, a quality registry for chronic ulcers has been in use since June 2018. The aim of this study was to evaluate the quality of data in the Tampere Wound Registry (TWR) by analysing data completeness, accuracy, timeliness and case coverage to assess the usability and value of the registry for clinical practice and research purposes.

2 | METHODS

2.1 | Tampere wound centre

Tampere University Hospital provides medical care for over 900 000 citizens in Pirkanmaa wellbeing services county and its catchment area for highly specialised medical care. Tampere University Hospital Wound Centre is a multidisciplinary tertiary care unit for patients with chronic ulcers. Approximately 300 patients are treated monthly at the outpatient clinic and on inpatient ward. Almost one-third of patients treated are new referrals, mainly from primary care, the private sector, or other units of Tampere University Hospital. The physicians primarily responsible for care in the Wound Centre are dermatologists, internists and plastic surgeons, and the most common wound aetiologies in the Wound Centre are diabetic foot ulcers (DFU), venous and arterial ulcers, pressure ulcers and atypical ulcers.

2.2 | Tampere Wound Registry

TWR is a clinical, web-based quality registry of the Tampere University Hospital Wound Centre and the first quality registry for chronic ulcers in Finland. A team of four health care professionals and specialists in ulcer care, a dermatologist, a plastic surgeon, and two wound care nurses, were mainly responsible for the design and development and also selected the variables for the registry. The TWR was established for clinical use at the Wound Centre's outpatient clinic in June 2018 and subsequently at the inpatient ward in August 2019. All Wound Centre patients with chronic ulcers are routinely registered in the TWR and the registrations are performed at each visit or contact to the Wound Centre by nurses, podiatrists and physicians currently involved in patient care.

The TWR holds data concerning patient demographics, medical history, current comorbidities and medications used, medical status, specific data on each ulcer, diagnostic procedures, planned treatment and follow-up. The registry has a patient history report containing 24 variables and, in addition, five separate report forms: first visit, follow-up, nurse-led follow-up, surgery and inpatient treatment. The five forms cover over 220 variables in total, and it is mandatory to report variables considered essential for diagnostics or treatment; a form cannot be completed if mandatory data are missing. Moreover, the TWR consists of four different pathways with slightly different numbers of variables depending on the type of ulcer: DFU, lower extremity ulcer other than DFU, ulcer not located in lower extremity and multiple ulcers of different types. Some of the data elements are automatically prefilled based on previously registered data, such as the patient's clinical pathway and details on ulcers, or on data collected from the electronic patient records by integrations in particular medication and laboratory results.

2.3 | Study population

The study population consisted of all patients (n = 923) registered in the TWR between 5 June 2018 and 31 December 2020. All 923 patients were included in the analysis of data completeness (Figure 1, Table 1). When assessing data accuracy and timeliness, data on patients registered in the TWR between 1 January and 31 December 2020 (n = 417) were analysed. Data completeness comparison between TWR and patient medical records also included 417 patients registered in 2020. In the analysis of case coverage, of these 417 patients, 30 patients registered in an inpatient ward were excluded due to unclear data in the hospital administration system concerning hospitalizations, and one patient was

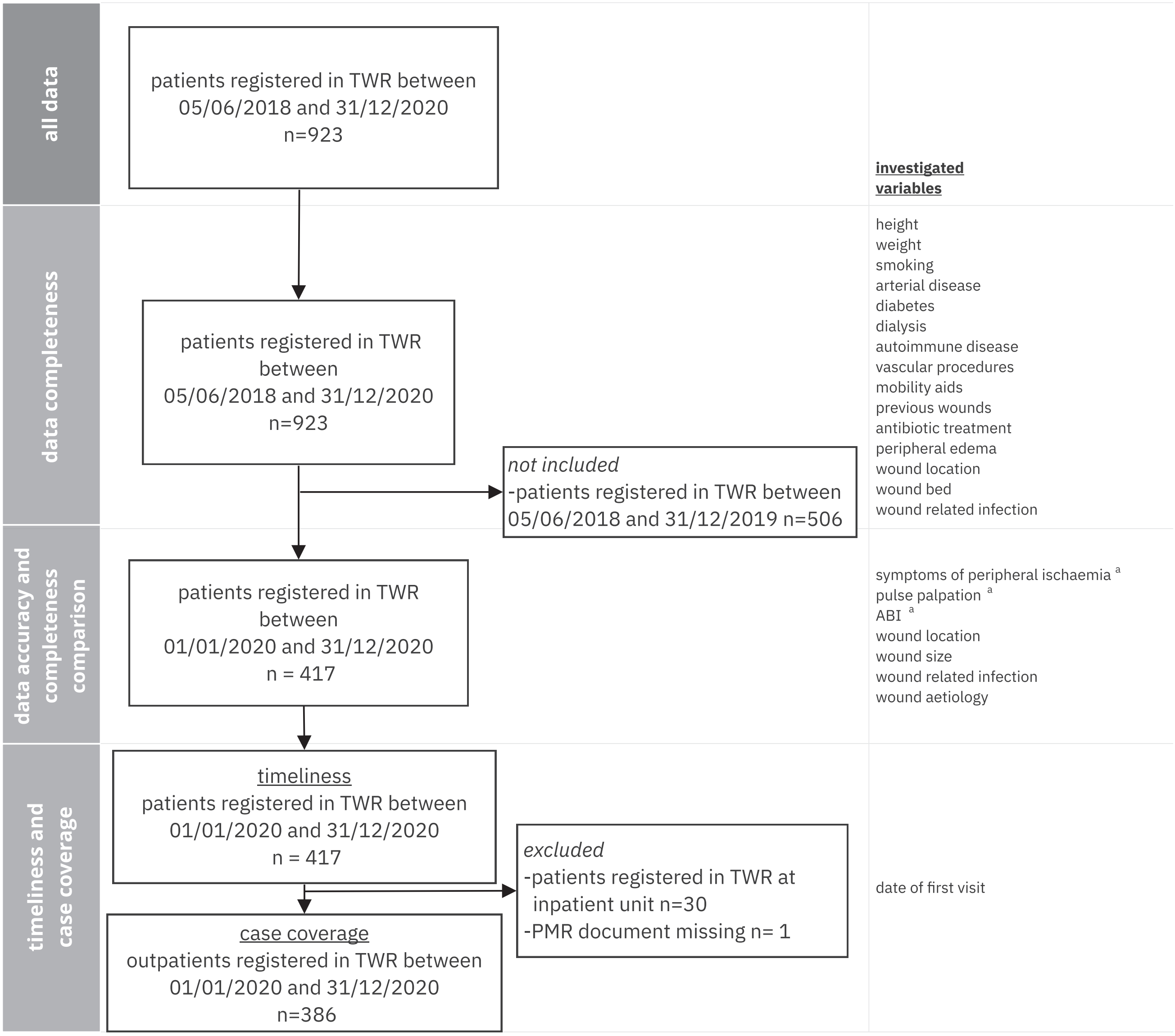

FIGURE 1 Study patients and investigated variables in the study. TWR: Tampere Wound Registry; PMR: patient medical records; ABI: ankle-brachial index. [a] Disabled variable in *ulcer not located in lower extremity* pathway (n = 360).

TABLE 1 Definitions of data quality aspects used to evaluate the Tampere Wound Registry (TWR).

Data completeness	Percentage of documented values in each of the 15 selected variables in TWR
Data accuracy	Percentage of values in TWR that are similar or within an acceptable range compared to patient medical records in seven selected variables
Timeliness	Time in days between the date of first contact to Wound Centre and the date of first registration in TWR
Case coverage	Percentage of registered outpatients in TWR out of patients with chronic ulcers treated in the Wound Centre

excluded due to lacking patient medical record data. Thus, data on 386 patients were included in the analysis of case coverage.

2.4 | Data analysis

For each analysis, the relevant variables were selected by three specialists in chronic ulcers and professionals involved in the development of the TWR based on national guidelines and clinical expertise.[19] Evaluation of all original data was conducted by one specialist (author AP). Analysis for data completeness included 15 selected TWR variables (Figure 1) from patient history reports and first visit forms. In the analysis, the presence of the value but not the exact content was assessed, and percentage of documented values was studied for each of the TWR variables (Table 1). Overall completeness of the data was also analysed by calculating the total number of documented values in relation to the total of eligible data. Moreover, data completeness for seven selected variables from the first visit form was assessed in both the TWR and patient medical record data and compared.

Data accuracy evaluation included registered values in seven variables mentioned above (Figure 1 and Table 1), and percentage of accurate values for each variable was studied. Accuracy was assessed by comparing TWR data to the patient medical records, which were considered the gold standard for valid data. When comparing data on wound size, a variation of ±0.2 cm in length and width between different data sources was considered acceptable. Also, when analysing the accuracy of ulcer aetiology, TWR data were compared to both ICD-10 diagnostic codes and physicians' written entries in the medical records, as ICD-10 codes are imprecise for several ulcer aetiologies. Data on the remaining five variables were considered accurate only if the information in the TWR concurred with the medical record data. Overall accuracy was assessed by calculating the ratio of correct data to all documented data.

To evaluate timeliness, the date of the first TWR registration was compared to the date of the first contact to the Wound Centre and the time delay in days was determined. Finally, in the case coverage analysis, the percentage of outpatients registered in the TWR out of the patients with chronic ulcers treated in the Wound Centre's outpatient clinic was calculated.

2.5 | Statistical methods

Percentages and descriptive methods were used for calculations. Values over 80% in data completeness, accuracy, timeliness and case coverage analysis were considered good, and values over 90% were excellent. A chi-squared test was used to compare data completeness between TWR and patient medical records and P-values $\leq .05$ were considered statistically significant.

3 | RESULTS

Out of the 923 patients registered in the TWR in 2018–2020, and also out of 417 patients registered in 2020, 47% were female. The median age of patients registered in 2018–2020 was 72 (range 14–99) years and 71 (range 20–97) years for those registered in 2020. The median number of ulcers at the first visit was 1 and ranged between 1 and 12 in both groups. The largest patient group based on clinical pathway was patients with lower extremity ulcer other than DFU, consisting of 66% of patients registered between 2018 and 2020 and 68% of those registered in 2020. The other clinical pathways included DFU in 20% and 17%, ulcer not located in lower extremity in 12% and 14%, and multiple ulcers of different types in 2% and 1% of the patients in the respective groups.

Overall data completeness in 15 selected TWR variables was 81% (11 182 documented values out of a possible 13 736). Two variables achieved excellent completion rates of over 90%, and the variables with the highest completion rates were diabetes and wound location (Figure 2). Five variables were found to reach over 80% completeness, and the remaining eight variables all reached over 70% completeness. The variables with the highest number of missing values were weight and peripheral edema recorded in 71% of the patients.

When completion of seven selected variables was compared between the TWR and the patient medical records, in five out of seven variables, the data found in the TWR were more complete, and in four out of the five variables, the

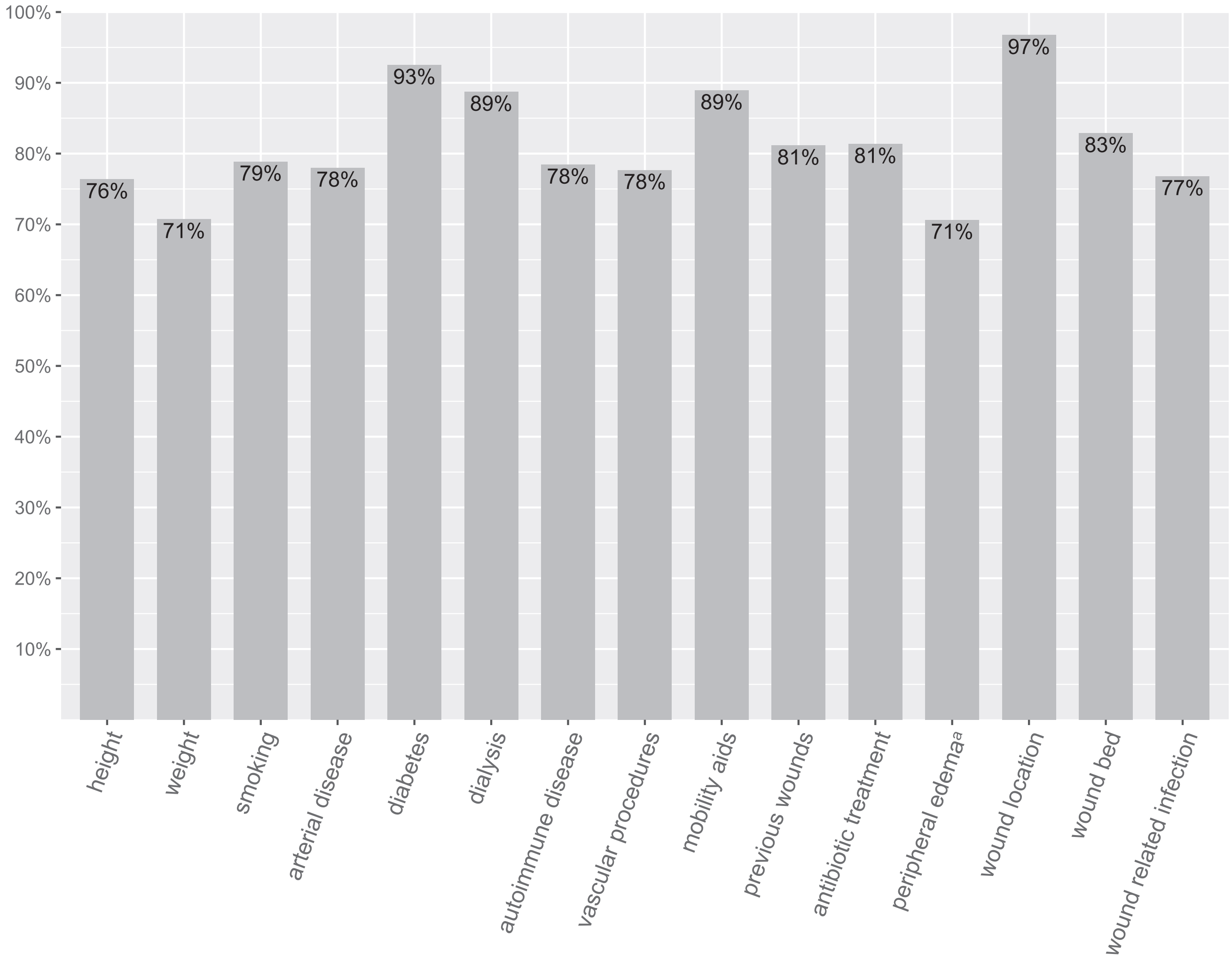

FIGURE 2 Data completeness of the Tampere Wound Registry during 2018–2020 analysed from 923 patients with chronic ulcers and 15 selected variables. ^{a}n = 814.

difference was statistically significant ($P < .001$ in all analyses) (Figure 3A). Out of these variables, the one with the highest completion rate in the TWR was pulse palpation with 100% completion rate, and the lowest ankle-brachial index (ABI), reaching 37% completion. Patient medical records had the highest completion rates in wound location and aetiology, both being 99%, and the lowest in symptoms of peripheral ischaemia with 26% completion.

In the analysis of data accuracy, the data were found to be accurate in 1710 variables out of 1838 in the TWR, and thus the overall accuracy was 93%. TWR data accuracy was found to exceed values of 80% in all seven, selected variables (Figure 3B), and in five out of seven the accuracy was found to be >90%. Symptoms of peripheral ischaemia and pulse palpation variables had the lowest level of accuracy at 86% for symptoms of peripheral ischaemia and 85% for pulse palpation.

The timeliness analysis of the TWR data showed that 86% of the registered patients had been recorded within the first 24 h and within 3 days, 90% of the patients had been recorded in the TWR (Figure 4). Median time from first contact to the Wound Centre to registration was 0 days (within the first 24 h), while the maximum delay in registration was 133 days. A review of the TWR and hospital administration system concerning the year 2020 disclosed 36 unregistered ulcer patients out of 422 patients, indicating a case coverage of 91% for the TWR concerning outpatients with chronic ulcers.

4 | DISCUSSION

In this study, the reliability of the quality registry for chronic ulcers established at Tampere University Hospital was verified as a reliable source of information. The registry data were proven to be complete, accurate and timely. In addition, it was discovered that the TWR is a more comprehensive source of information than the

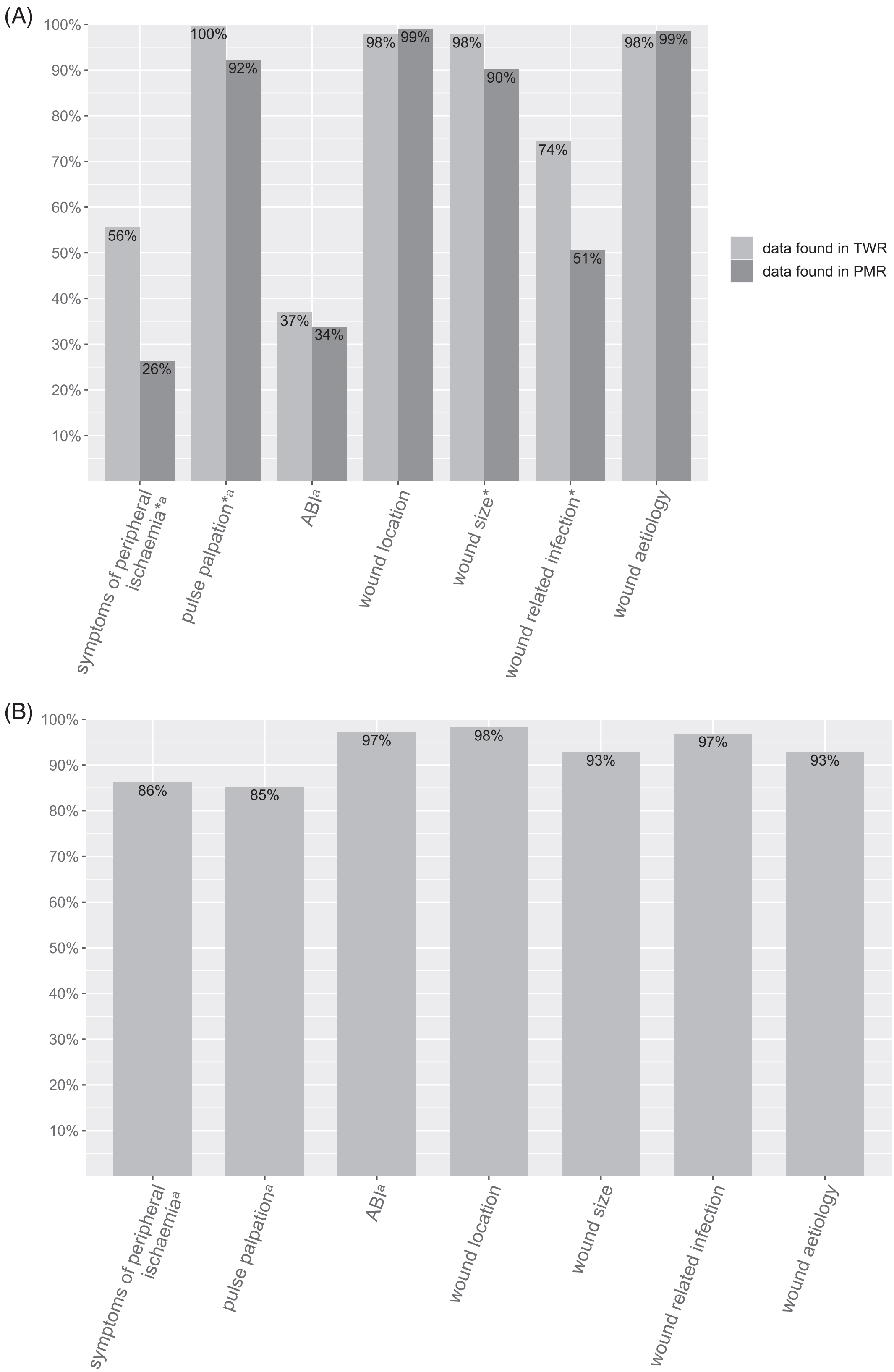

FIGURE 3 (A) Data completeness comparison between Tampere Wound Registry (TWR) and patient medical records (PMR) during 2020 analysed from 417 patients with chronic ulcers and seven selected variables. ^{a} n = 360. * statistically significant difference ($P < .001$). ABI: ankle-brachial index. (B) Data accuracy of Tampere Wound Registry during 2020 analysed from 417 patients with chronic ulcers and seven selected variables. ABI: ankle-brachial index. ^{a}n = 360.

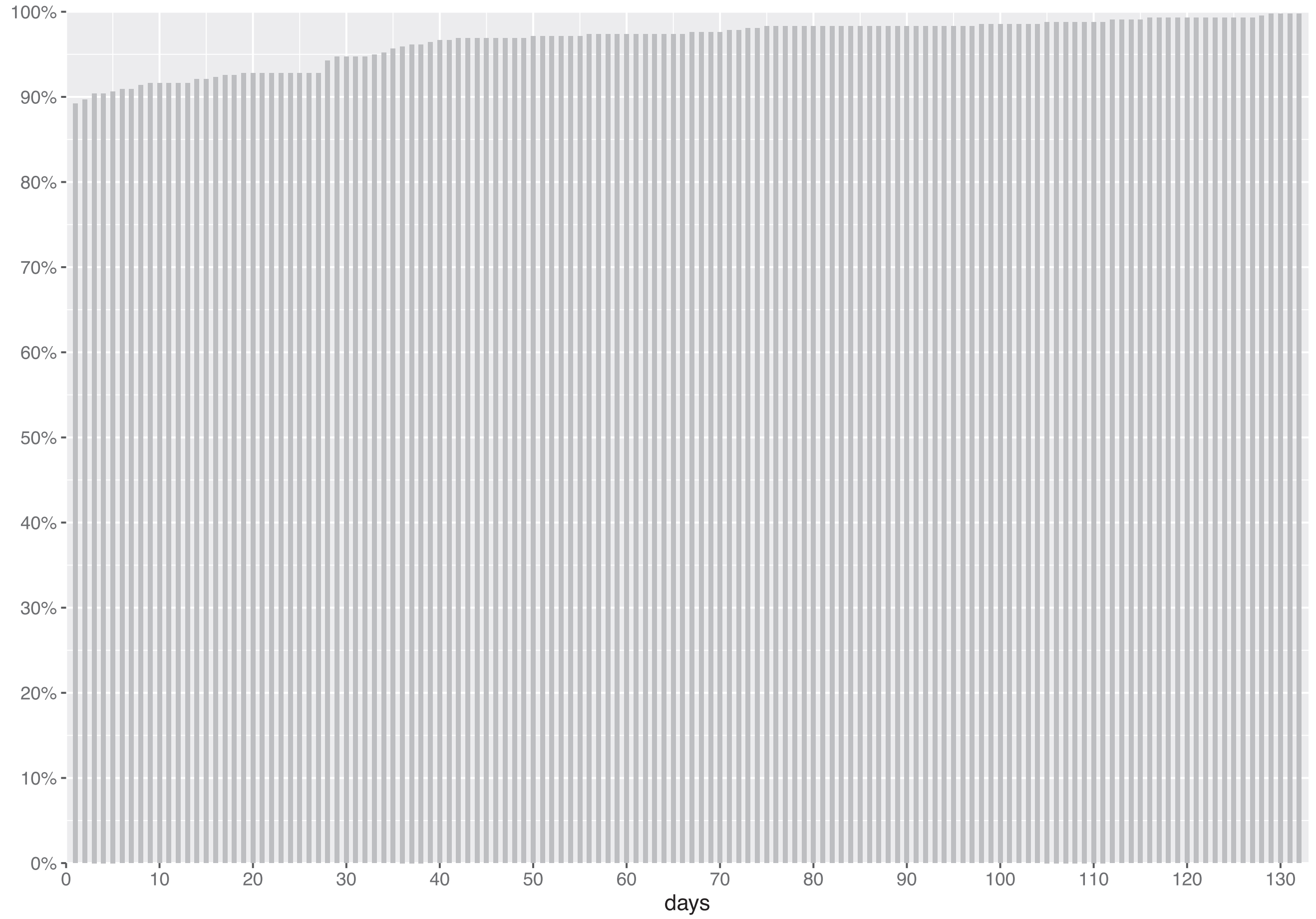

FIGURE 4 Timeliness of patient registration in the Tampere Wound Registry during 2020, was analysed from 417 patients with chronic ulcers.

patient medical records, which are currently considered a gold standard for documentation.

Quality registries for ulcers are still scarce, but in addition to a few currently existing registries in Sweden, the United States and Wales,[15,16] publications mention registries being planned in Australia and Singapore.[16,20] Detailed comparisons between ulcer registries cannot be made as they are not described in detail in the publications available, but regardless, there are obvious differences in their use. Other established registries are national registries, and for example, the Swedish registry is used in primary care,[15] while the TWR is currently designed for tertiary care and is used locally in Tampere University Hospital's Wound Centre. Another significant difference between the Swedish registry and TWR is that the Swedish registry only records baseline and endpoint data and is thus not structured for ongoing monitoring at every visit like the TWR.[15]

Nonetheless, a quality registry is potentially a valuable tool for clinicians and can help enhance the care of patients with ulcers. In addition to providing a systematic method of documentation, quality registries may also have beneficial impacts on treatment policies and outcomes.[21] For example, in Sweden, a web-based ulcer registry was established in 2009, and within 3 years, the median healing time for ulcers as well as usage of antibiotic treatments decreased significantly, and the costs of ulcer treatment were found to have diminished.[22,23] However, the authors provide no details on the case coverage of the Swedish ulcer registry in their publications, and it remains unclear whether the registry data have been validated.

In general, maximum benefit can only be derived from a quality registry if the content of the data is relevant, valid and accessible to all stakeholders.[24,25] To the best of our knowledge, there are no published validation studies on chronic ulcer registries. Nevertheless, quality registries in general, for instance in the Nordic countries, for maternal care, breast cancer and trauma patients, have been audited, and the most evaluated aspects have been data completeness and correctness. Overall, earlier registry validations have proven the data reliable for purposes of research, clinical care and quality improvement. In addition, data evaluation has helped to detect shortcomings in registration practices or in variables.[26-28] There is a need to define more precisely how quality registries should be validated, but while studies have proposed various approaches, none have yet been standardised.[29,30]

In Tampere University Hospital Wound Centre, the TWR is routinely used as a tool for patient care and monitoring, as well as for operational improvement, education and research. A validation of the registry was considered of paramount importance in order to ensure that the registry data can be used with confidence. In addition to data accuracy and completeness, case coverage and timeliness were also analysed to ensure that the registry was representative of the appropriate population. Thresholds for good and excellent outcomes were set at 80% and 90%, with the aim of setting a high standard at the first assessment of the Registry.

In this study, overall data completeness reached 81%. However, 80% completeness was not achieved in all variables, but all variables achieved over 70% completeness. The two variables with the lowest completion rate of 71% were weight and peripheral edema, both of which were considered relevant to patient care. Absence of information on weight is at least partly explained by real-life challenges when treating ulcer patients with multiple morbidities and impaired mobility. As regards peripheral edema, compression therapy is currently recommended for all patients with chronic lower extremity ulcers if there are no contraindications,[31] and therefore the clinical implications for the slightly lower completion rate in this variable seem relatively minor. Also, the TWR data proved to be more complete than the data in the medical records, which are traditionally used as a source of information, making the registry as such an improvement in data quality. Nonetheless, recognition of the reasons for insufficient data is imperative, and means to improve the completion rate should be sought. In general, if missing data in the registry is caused by poor functionality, improvements in data quality can be achieved by adjusting the registry properties.[32] Also, a better completion rate could be achieved by automatic and immediate feedback from the registry to the user in the case of incomplete data.[9,33]

Data accuracy in the TWR was found to be excellent, with most of the selected variables being recorded correctly in more than 90% of cases. This result is considerable for a routinely used clinical registry, as clinical data may not be recorded as carefully as research data due to differences in priorities.[28] In general, data accuracy can be enhanced by register holders by providing user training and guidance, and variable names must also be understandable and unambiguous with as few open-ended questions as possible.[26,34] In this study, the weaker result for pulse palpation may be explained by the ambiguous value name, which has since been modified to be more explicit. In the TWR, there are features enhancing data accuracy, for example, data entry guidance provided by multi-select or drop-down menus, as well as immediate feedback on incorrect values prompting on the correct value range.

Timeliness in the TWR data was found to be good, very close to excellent, as the majority of patients were registered at their first contact, whether at the outpatient clinic or inpatient ward. Looking at the timeline, it seems that if a first contact was not registered within the first 3 days, it most likely occurred after 28–30 days, potentially during follow-up. Delays in data entry reduce the usability of the register as a clinical tool[26]; hence, it is necessary to further review data entry practices to improve timeliness. Data currency may not be as important for retrospective scientific research if the data eventually end up in the Registry.[35] However, it is quite possible that if the data are not entered in real time, they will not be entered at all if the patient's treatment does not continue at the Wound Centre. This leads to deterioration in data quality through distorted case coverage. The grounds for not registering a patient may include a difficult user interface, the challenges of urgent care situation or loosely defined inclusion criteria. Integrations with the hospital admission system could improve case coverage.[36]

A notable strength of this TWR evaluation study was that a large amount of data was investigated. Further, the authors had vast experience in TWR development and routine usage; thus, the Register properties and the clinical environment were familiar beforehand, and any ambiguities in the data could be detected before the analysis phase. As a limitation, only one auditor conducted the evaluation of the original data, which may have caused human error, and the inter-rater reliability could not be determined. However, the data were systematically reviewed multiple times, and any deficiencies were revised with the research team.

5 | CONCLUSION

The first data quality audit of the TWR showed that the information recorded in the registry is complete, accurate and current at the required level. Thus, the registry data can be used with confidence in research and clinical practice. Moreover, the TWR data were found to be more comprehensive than the patient's medical records. The TWR validity assessment made it possible to identify register-based weaknesses that may be causing missing values or inaccuracies in the data, and it is crucial to detect discrepancies in the registry to maintain data quality. Weaknesses in the TWR found during this study have already been addressed in recent updates to ensure quality data, and in order to maintain high data quality, re-evaluations of the TWR are needed in the future.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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