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Original Article

The Danish Amputation Database

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ABSTRACT

INTRODUCTION. National data has the potential to advance future research and drive quality improvements for patients with major lower-extremity amputations (MLEA). This study aimed to evaluate the implementation of the Danish Amputation Database (DanAmp) by investigating data completeness and validity.

METHODS. Demographic, surgical and post-surgery data were collected during hospital admission. After implementation at three departments, completeness and validity were evaluated from 1 February to 1 June 2024. Completeness was evaluated by comparing the number of surgical procedures in the hospital's electronic system with registrations in DanAmp. Data validity was evaluated by an audit of up to 15 consecutive patient records per department. The percentage agreement was calculated (agreement (n)/total possible numbers (N)). Variables with an agreement exceeding 90% were considered satisfactory.

RESULTS. A total of 68 procedures were registered in DanAmp across the three departments, and 71 procedures were registered in the hospital's electronic system, corresponding to 96% completeness for all types of procedures. A total of 43 patient records were audited, revealing that 29 of 35 variables had a satisfactory validity exceeding 90% agreement.

CONCLUSIONS. This study demonstrated a high completeness and satisfactory validity of data from three orthopaedic departments, underscoring DanAmp's potential in driving research and quality improvements for MLEA.

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Major lower-extremity amputations (MLEAs) represent a national healthcare challenge with considerable consequences for the patient. In Denmark, around 1,300 MLEAs are performed annually, primarily due to advanced ischaemia caused by atherosclerosis [1-3]. The patients are some of the most vulnerable patients in the orthopaedic wards, with an average age above 70 years and a high prevalence of multi-morbidity such as diabetes, ischaemic heart disease and chronic kidney disease [3, 4]. Their prognosis is often poor, re-amputation is performed in around 11-30% of patients [1, 5], and mortality is high, ranging from 11 to 23% after one month and 29-48% after one year [6, 7].

A recent report showed regional differences in amputation rates across Denmark [2], and amputation rates in

Denmark are around 50% higher than in Norway and Sweden [8].

Following MLEA, many patients face significant challenges in regaining mobility and quality of life. Only an estimated one in three patients receives a prosthesis after an average waiting time of five months, leaving many with long-term functional impairment and reduced health-related quality of life [9, 10].

Despite these challenges, several Danish studies indicate a potential for improving outcomes through standardised treatment pathways, early mobilisation and targeted interventions for high-risk patients [7, 11, 12]. However, the lack of comprehensive national data on treatment, rehabilitation and long-term outcomes has hindered efforts to optimise the treatment of MLEAs.

To address this gap, the Danish Amputation Database (DanAmp) was established as a cross-regional research initiative to systematically collect and analyse data on the perioperative treatment and long-term outcomes of patients undergoing MLEAs in Denmark. By identifying prognostic factors and evaluating variations in treatment, DanAmp seeks to facilitate evidence-based improvements in treatment quality and patient outcomes.

When using data for research and decision-making, it is essential to ensure its validity and generalsability to minimise bias and support robust conclusions. This study aimed to evaluate the implementation of DanAmp by investigating the completeness and validity of data.

Methods

DanAmp database

DanAmp was established in 2022 by an interdisciplinary steering committee with representatives from all five Danish regions. The database is registered as a research database at each of the five regions' internal registries of research projects (see Supplementary Material for registration numbers). Data collection is based on the patient's written informed consent.

DanAmp is an online database using REDCap software, which is hosted and supported by the Open Patient data Explorative Network (OPEN), Odense University Hospital, Region of Southern Denmark. REDCap is approved for storage and processing of sensitive personal data. To minimise errors, the database has built-in validation features that reduce typing errors and flag outliers in numerical fields.

All patients with MLEA at the orthopaedic department are screened for inclusion to ensure a consecutive sample. Eligibility criteria are listed in **Table 1**. If excluded, a screening form in REDCap is completed and the cause of exclusion is stated.

TABLE 1 Eligibility criteria.

Inclusion
Patients who undergo MLEA are defined by the following anatomical levels: transtibial amputation, knee disarticulation, transfemoral amputation and hip disarticulation
Amputation is performed at including hospitals
A primary amputation or re-amputation is performed
The patient is included ≤ 28 days after the procedure
The patient can provide written informed consent
Exclusion
Patients not residing in Denmark and not having a Danish civil registration (CPR) number
Patients with cognitive challenges or language barriers who cannot provide informed consent
Definitions
Index operation: an operation resulting in patient inclusion
Re-amputation[a]: a patient who previously had a MLEA and is now re-amputated at a higher anatomical level
Revision: a surgical procedure on the stump, which may include soft tissue or/and bone resection but at the same anatomical level

MLEA = major lower extremity amputation.
a) Re-amputation is considered an index operation to "catch" as many amputations as possible. Over time, the proportion of patients entering the database based on re-amputation will decrease.

Perioperative data (demographic, surgical and post-surgery data) are entered into the database either by the surgeon or by other dedicated staff. Events occurring after the index operation (revisions, re-amputation or amputation of the second leg) are also registered. Follow-up patient-reported outcome (PRO) data are collected using an online questionnaire sent via e-box or traditional mail at three, six, 12, 24 and 36 months after the index operation. A full list of all variables collected in DanAmp is available from Supplementary File, **Table A**. Variables are based on available evidence and clinical guidelines. PRO data and response rates will not be evaluated in this publication.

Development and implementation

Development and implementation of the database followed an iterative approach. Initially, fictive data were used to test and adjust the setup and variables. Next followed a six-month pilot phase in early 2023 involving patient inclusion at three orthopaedic departments. Monthly online meetings and workshops were conducted, and barriers to and facilitators for implementation were uncovered and evaluated, leading to adjustments of the database and inclusion procedures.

Gradual implementation in other departments was initiated in December 2023. Interested departments received a one-hour online introduction to DanAmp and the data entry process. Feedback from departments on barriers to and facilitators for implementation was continuously evaluated to refine data collection, e.g., further specifying ambiguous variables. Barriers and facilitators identified during the implementation are presented in **Supplementary File, Table B.**

Currently, 11 of the 21 departments performing MLEA in Denmark are entering data into DanAmp. Correspondence and introductions are ongoing with seven other departments.

Material

Three departments were selected for evaluation of completeness and data validity based on geographic location in different regions and full implementation of data collection procedures. Furthermore, the departments differed regarding the organisational approach; at Site 1 and Site 3, patient inclusion and data entry were performed by surgeons, while at Site 2, these were performed by an "amputation care manager" and a quality consultant. Data were collected from 1 February to 1 June 2024.

Completeness of data

Completeness was evaluated by comparing the number of performed surgical procedures with registrations made in the DanAmp database. All procedures performed at the departments were identified through the hospital's electronic systems using surgical classification codes (SKS). SKS-codes are based on the Danish Version of the Nordic Medico-Statistical Committee Classification of Surgical Procedures (NOMESCO). A list of searched codes is presented in **Table 2**. The DanAmp registrations included both screened and included patients. Furthermore, both primary amputations/re-amputations and revisions were registered. For Site 1, amputations based on tumour (malignancy) were not part of the evaluation.

TABLE 2 List of surgical classification codes used for evaluation of completeness.

Procedure	SKS[a] for major lower leg amputations
Above-knee amputation	
Hip disarticulation	KNFQ09
Transfemoral amputation	KNFQ19
Other amputation on the femur/hip	KNFQ99
Below-knee amputation	
Knee disarticulation	KNGQ09
Transtibial amputation	KNGQ19
Other amputation on knee/tibia	KNGQ99
Revision codes	
Stump revision, knee/lower leg	KNGQ29
Stump revision after knee disarticulation	KNGQ29A
Stump revision after transtibial amputation	KNGQ29B
Stump revision, hip/tight	KNFQ29
Stump revision after hip disarticulation	KNFQ29A
Stump revision after transfemoral amputation	KNFQ29B

SKS = surgical classification code.
a) Codes are based on the Danish Version of the Nordic Medico-Statistical Committee Classification of Surgical Procedures (NOMESCO).

Data are presented descriptively as numbers and total agreement in percentages (number of procedures in DanAmp/number of procedures (SKS) in the electronic hospital systems).

Validity of data

The validity of perioperative clinical data (not patient-reported) entered into DanAmp was evaluated through an audit of up to 15 consecutive patient records from each department. The audit of patient records was based on data entered for the index operation. The auditor was a researcher with clinical and research experience in orthopaedics.

Data entered in DanAmp records was compared to data available from the electronic patient record. The number

of records with agreement and non-agreement was summarised. Non-agreement covered both discrepancies between DanAmp and the electronic patient record and variables missing in REDCap. Non-retrievable variables from the electronic patient record were registered as missing and excluded from the analysis of agreement.

The variables "surgeon educational level" and "educational level for assistant/supervisor" were not included in the audit, as the educational level was not documented in the patient record.

Results are presented in three categories: demographic, surgery-related and post-operative variables. Percentage agreement is calculated as numbers with agreement (n)/total possible numbers (N). Variables for which agreement exceeded 90% were considered highly valid (90% is an arbitrary limit inspired by previous studies [13, 14]).

Trial registration: not relevant.

Results

Completeness

During the four-month period, 68 amputation procedures were registered in DanAmp and 71 amputation procedures were registered with an SKS code across the three departments (**Table 3**), corresponding to a 96% completeness for all types of procedures.

TABLE 3 Completeness of procedures registered in DanAmp compared to procedures registered with a surgical classification code in the hospital electronic system during the validation period, from 1 February to 1 June.

	Site no., n								
	1		2		3		Total		
Procedure[a]	DA[b]	SKS	DA[b]	SKS	DA[b]	SKS	DA, n[b]	SKS, N	n/N, %
Above-knee amputation									
Hip disarticulation	1	1	-	-	-	-	1	1	100
Transfemoral amputation	9	12	9	10	19	19	37	41	90
Below-knee amputation									
Transtibial amputation	6	6	10	10	5	5	21	21	100
Revision									
Stump revision after transtibial amputation	2[c]	1	1	1	-	-	3	2	100[d]
Stump revision after transfemoral amputation	3	3	2	2	1	1	6	6	100
Procedures, total	21	23	22	23	25	25	68	71	96

DA = DanAmp; SKS = surgical classification code.
a) All procedures searched are presented in Table 2, but only procedures performed at ≥ 1 site during the period are presented in this table.
b) Numbers include both patients screened and patients included.
c) 2 revisions after transtibial amputation were registered in the DA, but only 1 was registered with an SKS code in the e-journal, due to incorrect SKS coding of the procedure.
d) %-agreement adjusted, based on corrected SKS data.

Validity

Site 1 and Site 2 each included 14 consecutive patients with an index operation, and Site 3 included 15 consecutive patients during the period. Data from the audit is presented in **Table 4**. The audit revealed an above 90% agreement for all demographic variables between the data in DanAmp and the electronic patient record. For surgical variables, only three out of 18 variables had below 90% agreement (Indication date (81%), Myodesis (88%) and Blood loss (85%). Three out of 16 post-operative variables had below 90% agreement (Post-operative invasive pain treatment (88%), Oedema prophylaxis (56%) and Date of Basic Amputee Mobility Score at last physiotherapy assessment (80%).

TABLE 4 Validity of data entered into DanAmp in the period from 1 February to 1 June.

	Site no., n						Total agreement, (n/N) %
	1 (n_1 = 14)		2 (n_2 = 14)		3 (n_3 = 15)		
Variable	Agree	non-agree	agree	non-agree	agree	non-agree	(N = 43)
Demographic							
Age	14	-	14	-	15	-	(43/43) 100
Gender	14	-	14	-	15	-	(43/43) 100
Comorbidity	13	1	11	3	15	-	(39/43) 91
Smoking status	14	-	12	2	13	2	(39/43) 91
Residence pre-amputation	13	1	12	2	14	1	(39/43) 91
Surgical							
Indication date[a]	13	1	9	5	13	2	(35/43) 81
Amputation side	14	-	13	1	15	-	(42/43) 98
Amputation type	14	-	14	-	15	-	(43/43) 100
Amputation level	14	-	14	-	15	-	(43/43) 100
Amputation indication	13	1	14	-	15	-	(42/43) 98
Previous operation distal to the amputation: yes/no	13	1	14	-	13	2	(40/43) 93
If yes: type of previous operation	1	-	9	1	-	-	(10/11) 91
Previous amputation opposite leg: yes/no	13[b]	-	14	-	15	-	(42/42) 100
If yes: level of previous amputation	-	-	1	-	3	-	(4/4) 100
Vascular surgical assessment: yes/no	12	2	14	-	14	1	(40/43) 93
Date/time amputation	14	-	13	1	15	-	(42/43) 98
Myodesis	13	1	10	4	15	-	(38/43) 88
Use of torniquet	13	1	13	1	15	-	(41/43) 95
Blood loss in ml	7	4	14	-	13	2	(34/40[c]) 85
Surgical entrance: type of tool	12	2	14	-	15	-	(41/43) 95
Wound closure: type of material	13	1	13	1	15	-	(41/43) 95
Post-operative							
Post-operative invasive pain treatment	13	1	10	4	15	-	(38/43) 88
Oedema prophylaxis	13	1	3	11	8	7	(24/43) 56
Date of 1st mobilisation	12	1	11	2	14	1	(37/41) 90
BAMS 1st PT assessment: yes/no[d]	14	-	13	1	15	-	(42/43) 98
If yes: date of BAMS	12	-	2	1	14	-	(28/29) 97
If yes: BAMS total	11	1	2	1	14	-	(27/29) 93
BAMS last PT-assessment: yes/no[d]	14	-	12	2	15	-	(41/43) 95
If yes: date of BAMS	8	-	1	2	11	3	(20/25) 80
If yes: BAMS total	8	-	2	1	14	-	(23/24) 96
Rehabilitation plan	10	-	14	-	13	1	(37/38e) 97
Discharge date	14		13	1	14	1	(41/43) 95
Discharge destination	14	-	14	-	15	-	(43/43) 100
Dead during hospital admittance	1	-	2	-	1	-	(4/4) 100
If yes: date	1	-	2	-	1	-	(4/4) 100

BAMS = Basic Amputee Mobility Score; PT = physiotherapist.
a) For non-agreement: 1-9 day deviation due to unclear definition of variable.
b) Question only relevant for 13 patients as 1 patient had bilateral amputation with the same procedure.
c) For 3 records, values were not found in the e-journal but surgeon has entered the value directly to REDCap.
d) If "yes": the BAMS matrix unfolds.
e) Plan is not completed due to death during hospital admittance or transfer to another hospital/department (n = 5).

Discussion

The study demonstrated successful implementation with a high completeness (96%) in three orthopaedic departments. The validity of perioperative data entered into DanAmp was very satisfactory, as 33 of 39 variables showed an > 90% agreement.

Completeness

The data completeness of 96% for procedures registered in DanAmp exceeds rates reported by other clinical or

research databases in orthopaedic surgery. The Danish Fracture Database (DFDB) reported 83% completeness after initial implementation in two departments [14], but a considerable reduction was observed after four years and nationwide implementation (55%) [15]. The Danish Achilles Tendon Database (DADB) reported 77% completeness for three orthopaedic departments four years after implementation [13]. The Danish Knee Ligament Reconstruction Register (DKRR) and the Danish Shoulder Arthroplasty Registry (DSR) reported 86% and 94% completeness, respectively [16, 17]. However, both registries are hosted by the Danish Clinical Quality Program (RKKP) – National Clinical Registries) and differ from DanAmp as reporting is mandatory. Furthermore, the coverage rate from the Swedish registry for lower-limb amputations (SwedeAmp) was 59% for 36 reporting hospitals during the period from 2018 to 2023 [18]. Hence, a completeness of 96% demonstrates DanAmp's capacity for robust data capture and constitutes a solid base for future research. However, findings from the DFDB and SwedeAmp emphasise the need for ongoing monitoring of data completeness [15, 18] and highlight the sustained effort required to ensure successful long-term implementation.

Validity

The audit of patient records demonstrated an agreement exceeding 90% for 33 out of 39 variables, underscoring the high validity of data entered into DanAmp. The validity of variables in DanAmp aligns with findings in the DFDB (82-100%) [14] and the DADB (83-100%) [13].

For variables with an agreement below 90% (e.g., “Indication date”, “Myodesis” and “Oedema prophylaxis”), challenges such as unclear definitions and inconsistent documentation in the electronic record were identified, leading to targeted adjustments to data entry forms, further training and updates of documents supporting data entry.

The audit identified large differences between the three sites in the numbers registered as having “Previous operations distal to the amputation” (Site 1: 1/14, Site 2: 10/14, Site 3: 0/15). Hence, the data entry form has been adjusted to address this issue.

Audit feedback has been shared with all departments, and upcoming introductory sessions will focus on optimising the reporting of variables with low validity to ensure future data quality and usability.

Strengths, limitations and recommendations

Completeness was assessed during four months at three departments. In comparison, the assessment period for the DFDB covered one month and two departments (n = 322) [14], whereas the DADB assessment spanned one year at three departments (n = 163) [13]. Thus, the study period and number of sites in the present study were considered sufficient to evaluate the initial completeness and validity, while enabling prompt identification of potential data errors and optimising the data entry process.

The three departments varied regarding organisational practices concerning data collection and entry, which is considered a strength, as it mirrors the diverse practices of the eight other departments now reporting to DanAmp, and thereby the representativeness of findings. Initially, in the DFDB, completeness was evaluated at the two founding departments, and the decline in completeness after four years was primarily attributed to the transition to national implementation, where surgeons had less of a sense of ownership and motivation, which was compounded by high workloads [15]. Two out of three participating sites in the present study had a representative in the Steering Committee, but nothing indicated differences between sites that could be attributed to this matter. Variations in variable agreement between sites were more likely to reflect organisational differences and varying quality of documentation in the electronic records. Incomplete and incorrect medical records have previously been reported to be the most cited problem for data collection in registries [19]. The adaptability of data collection and entry processes in DanAmp to department-specific

contexts and the possibility of involving different professions are recognised as facilitators for implementation [20]. To enhance reporting, it is recommended to appoint a dedicated data manager and integrate standardised forms aligned with the DanAmp variables into electronic records for surgeons and physiotherapists.

DanAmp is a research database and relies on patient consent, which distinguishes it from quality databases. The 96% completeness reflects both screened and included patients; however, during the study period, the inclusion rate was 76-87% across the three departments, indicating good coverage, despite some patients not being able/willing to give informed consent.

Conclusions

This study demonstrated a high completeness and validity of data from three selected orthopaedic departments, underscoring DanAmp's potential to advance research and drive quality improvements in the treatment and rehabilitation of MLEAs.

With the inclusion of additional orthopaedic departments and a sustained effort to maintain data quality, DanAmp will constitute a pivotal tool for supporting healthcare providers, enabling evidence-based decision-making, and enhancing the quality of MLEA treatment in Denmark.

In the long term, based on knowledge generated from DanAmp, the intention is to condense the database variables into indicators and apply for status as a national quality database under the RKKP.

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