

Completeness and data validity in the Danish Achilles tendon Database

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ABSTRACT

INTRODUCTION: Acute Achilles tendon rupture is a severe injury causing functional deficits and sick leave. Data from the Danish Achilles tendon Database (DADB) can help us monitor and optimise treatment. The aim of this study was to investigate the completeness and data validity in the DADB.

METHODS: The study was performed as a registry study comparing data in the DADB with data from patient records. Data were collected from three of 11 hospitals registered in the DADB. The study was conducted from 1 January to 31 December 2016. A completeness of 80% was considered satisfactory, and a parameter was valid if there was agreement between the DADB and the patient record in 80% of the cases.

RESULTS: Overall, completeness was 77% (155/201); for the non-operated patients 81% (150/185) and the operated patients 31% (5/16). The seven investigated parameters all showed a validity of 83-100%.

CONCLUSIONS: This study documented a satisfactory completeness of data on the non-operated patients registered in the DADB and an unsatisfactory completeness of data on operated patients. All investigated parameters were valid. These results suggest that data in the DADB on non-operated patients can contribute to research within the field. Due to a limited sample on operated patients, conclusions should be made with caution. The logistics concerning data collection among operated patients warrants optimisation.

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TRIAL REGISTRATION: The study was approved by the Danish Data Protection Agency and the Danish Patient Safety Authority.

Acute Achilles tendon rupture (ATR) is a severe injury that may lead to functional deficits and cause sick leave [1-3]. Rupture is primarily seen in adults with a maximum incidence in the fourth and fifth decades of life. In recent decades, an increased incidence has been reported, also in the Danish population where an increase from 27 to 31 per 100,000/year has been observed [4, 5]. Treatment of ATR remains highly debated and no treatment consensus has yet been established [6, 7].

In past decades, numerous clinical databases have been developed [8-10]. Clinical databases are easily accessible and contain large amount of data, which facilitates epidemiological research [11].

The Danish Achilles tendon Database (DADB) was established in 2012. The DADB is now a nationwide database encompassing more than 2,000 registered patients. The database contains data on the patients, their treatment and the treatment outcome up to two years after injury. Currently, one study based on data from the DADB has been published [12]. When using DADB data for research, it is important to know if patients eligible for registration are registered (completeness) and if the data registered are correct (validity) [11]. A satisfactory completeness and validity implies that data from the DADB may serve as a basis for new epidemiological research, e.g. for investigating the prognostic factors for treatment outcome.

The aim of this study was to investigate the completeness and data validity in the DADB.

METHODS

This was a registry study comparing data from the DADB with patient records.

The Danish Achilles tendon Database

The Danish Achilles tendon Database was established in April 2012 as a private database owned by the participating departments. Currently, 11 orthopaedic departments enter data such as social security number, gender, age, date of rupture, date of treatment, treatment regime, comorbidity, previous injury to the Achilles tendon and cause of rupture. Treatment outcome is registered up to two years after injury by the validated questionnaire Achilles tendon Total Rupture Score [13], the Achilles Tendon Resting Angle [14] and heel rise height [15].

Data are collected and registered at five different time points during the treatment course: 1) first patient contact, 2) 3-4 months after rupture, 3) one year after rupture, 4) two years after rupture, 5) if a complication arises (e.g. re-rupture). No data are gathered about the rehabilitation regime after removal of the orthosis.

Re-rupture is defined as a new rupture of the ten-

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don within the first six months of the first rupture. Six months was chosen as the cut-off as the tendon is expected to have gained sufficient strength by then to withstand the forces of everyday life [16]. Furthermore, reported re-ruptures in the literature have occurred within the first six months after rupture [17, 18]. A rupture is defined in accordance with the following criteria: 1) a sudden pain in the Achilles tendon accompanied with the feeling of a pop; 2) a palpable gap at the site of the rupture; 3) lack of the ability to push-off during walking and to plantarflex against resistance; and 4) a positive calf-squeeze test [16, 19]. Information about re-rupture including its time and cause are registered in the DADB.

With the introduction of the web-based version of the DADB in January 2016, healthcare personnel are asked at the 3-4-month follow-up to report if any complications have occurred post-treatment. Moreover, patients are asked at the one-year follow up to report if any complication have occurred post-treatment.

Population

Completeness and data validity were investigated in the period from 1 January to the 31 December 2016. Three of the four hospitals founding the DADB were included (Hvidovre Hospital, Zealand University Hospital, Køge and Nykøbing Falster Hospital); the fourth (Aalborg Hospital) was excluded for logistical reasons.

Completeness

The completeness of registered patients with ATR was

calculated as “the number of patients correctly registered in the DADB” divided by “the number of patients eligible for registration”, as previously described by Pedersen et al [10].

The eligibility criteria for registration in the database were: 1) diagnosed with acute Achilles tendon rupture; 2) seen at the given hospital within one month after the injury; 3) treatment provided at the given hospital; 4) ability to speak and understand Danish; and 5) no terminal illness.

“The number of patients eligible for registration” was defined as patients who fulfilled the eligibility criteria and were registered with ATR in the patient record or in the DADB. The population was created by searching the patient registries from the hospitals for the International Classification of Diseases, Version 10, (ICD10) code DS860. Patient records were retrieved and patients who failed to meet the eligibility criteria were excluded. Next, we included patients registered in the DADB who were not found in the hospital patient register due to an incorrect ICD10 code.

“The number of patients correctly registered in the DADB” was found by extracting the patients registered in the DADB for the investigated period at the three included hospitals and excluding the patients who did not meet the eligibility criteria for registration. We considered a completeness of 80% to be satisfactory.

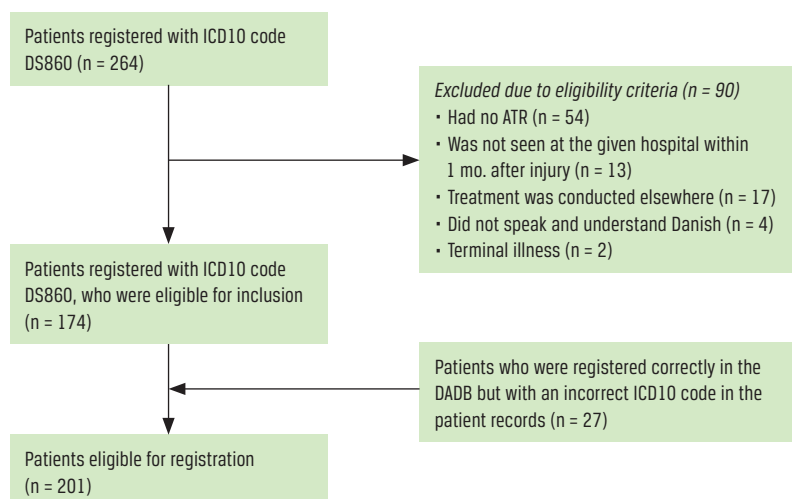
Validity

The validity was investigated based on the following seven data parameters entered at patient registration to the DADB: the date treatment was commenced (exact date), date of rupture (exact date), operative or non-operative treatment, activity leading to injury (badminton, football, handball, other sports or other activity), period of non-weight bearing (number of weeks), period of immobilisation of the ankle (number of weeks) and period of bracing (number of weeks).

The validity of each parameter was calculated as a measurement of whether the registered data was true. The calculation was performed as follows: “The number of patients with correctly registered data” divided by “the number of patients correctly registered in the DADB”. If a patient record or the DADB did not have information about a parameter, the patient was excluded in the validity calculation of the given parameter. To find “the number of patients with correctly registered data”, we compared the data entered in the DADB with data entered in the patient record. We considered the data in the patient record to be true. However, the validity of the data in the patient records has not been studied. A parameter was correctly registered for a given patient if there was total agreement between the DADB and the patient record. We considered a parameter valid if 80% of the patients’ data were in agree-

FIGURE 1

Flow chart illustrating the calculation of the number of patients eligible for registration in the Danish Achilles Tendon Database in the study period.



ATR = Acute Achilles tendon rupture; DADB = Danish Achilles Tendon Database; ICD10 = International Classification of Diseases, Version 10.

TABLE 1

Completeness of data in the Danish Achilles Tendon Database (DADB) in the study period at the three involved hospitals. The values are % (95% confidence interval) [patients correctly registered in the DADB/patients eligible for registration, n].

	Hvidovre Hospital	Zealand University Hospital, Køge	Nykøbing Falster Hospital	Total
Non-operated	73 (63-82) [67/92]	90 (80-96) [62/69]	88 (68-97) [21/24]	81 (75-86) [150/185]
Operated	25 (5-50) [3/12]	50 (1-98) [1/2]	50 (1-98) [1/2]	31 (11-59) [5/16]
Total	67 (57-76) [70/104]	89 (79-95) [63/71]	85 (65-96) [22/26]	77 (71-83) [155/201]

TABLE 2

Validity of the seven investigated parameters in the Danish Achilles Tendon Database (DADB). The values are % (95% confidence interval) [patients with correctly registered data/patients correctly registered in the DADB, n].

	Hvidovre Hospital	Zealand University Hospital, Køge	Nykøbing Falster Hospital	Total
Date of commenced treatment	93 (83-98) [62/67]	92 (82-97) [58/63]	90 (71-99) [20/22]	92 (87-96) [140/152]
Date of rupture	94 (85-98) [63/67]	93 (83-98) [54/58]	78 (52-94) [14/18]	92 (86-96) [131/143]
Operative or non-operative treatment	100 (95-100) [69/69]	100 (94-100) [63/63]	100 (85-100) [22/22]	100 (98-100) [154/154]
Activity leading to injury	75 (63-85) [48/64]	86 (75-94) [50/58]	100 (85-100) [22/22]	83 (76-89) [120/144]
Period of non-weight bearing	99 (92-100) [68/69]	87 (75-95) [47/54]	93 (66-100) [13/14]	93 (88-97) [128/137]
Period of immobilisation in ankle	91 (81-96) [63/69]	93 (84-98) [57/61]	100 (85-100) [22/22]	93 (88-97) [142/152]
Period of bracing	97 (90-100) [68/70]	100 (94-100) [63/63]	100 (85-100) [22/22]	99 (95-100) [153/155]

ment in the DADB and the patient record. This method was used by Gromov et al to investigate data validity in the Danish Fracture Database [8]. Confidence intervals were calculated by use of Fisher's exact test.

Trial registration: The study was approved by the Danish Data Protection Agency and the Danish Patient Safety Authority.

RESULTS

A total of 163 patients were registered in the DADB at the three involved hospitals in the study period. Hereof, eight did not meet the registration criteria (six partial ruptures and two patients seen more than one month after their rupture). Therefore, "the number of patients correctly registered in the DADB" was 155 (Hvidovre Hospital n = 70, Zealand University Hospital, Køge n = 63 and Nykøbing Falster Hospital n = 22) of whom five were operated and 150 were not operated.

Completeness

A total of 264 patients were registered with the ICD10 code DS860 at the three hospitals during the investigated period (**Figure 1**). In all, 90 patients failed to

meet the registration criteria, 54 hereof did not have an ATR but were in most cases partial rupture of the Achilles tendon or a muscle strain/rupture. In the investigated period, we found 27 patients who were correctly registered in the DADB but incorrectly registered in the hospital register due to an incorrect ICD10 code. These patients were added to "The number of patients eligible for registration", yielding a total of 201 patients. The total completeness for the three hospitals during the investigated period was 77% (155/201). The completeness of the non-operated patients was 81% (150/185), whereas for operated patients it was 31% (5/16) (**Table 1**).

Validity

The validity of the seven parameters entered at registration in the study period was 83-100% (**Table 2**). One patient had missing data in the DADB on the parameter "operative or non-operative treatment". Regarding the remaining six parameters, no missing data were recorded for any parameter.

In the study period, nine patients had a re-rupture according to the patient record. Of those, four patients had agreement between the patient record and the

DADB, one did not have agreement and four did not have data on re-rupture registered in the DADB. This produces a validity of 80% (4/5) of registered data. In total, 44% (4/9) of the patients with a re-rupture were correctly registered in the database.

DISCUSSION

This study documented a total completeness of 77% (155/201) for patients registered in the DADB in the study period at the three hospitals. Non-operated patients had a satisfactory completeness of 81% (150/185), but operated patients only recorded a completeness of 31% (5/16). The seven investigated parameters entered at the time of patient registration were valid with a validity ranging between 83 and 100%. These results suggest that for non-operated patients, data in the DADB may contribute to research within the field.

Due to a limited sample of operated patients, conclusions about these patients should be made with caution. However, the considerable difference in completeness between operated and non-operated patients might be explained by the primary treatment, which was non-operative at all three departments in the study period. Because of the limited number of operated patients, more attention was paid to ensuring correct registration procedure for the non-operated patients who, at all three departments, were followed by a small, dedicated team of physiotherapists. The operated patients were followed by a large group of surgeons of whom many had little interest in or knowledge of the DADB. Completeness for the operated patients might have been higher at hospitals where surgery was the primary treatment and emphasis was placed on a more complete registration of operated patients. Personal experience from the DADB indicates that a small, dedicated team allows for better registration of patients in the database than a larger group of people. To optimise inclusion of the operated patients, the setup at the involved hospitals has been changed to allow for all patients to be seen and registered by a designated team of physiotherapists at inclusion.

This study investigated the completeness in the DADB four years after implementation of the database at the three hospitals. Four years is considered sufficient time to fully implement the set-up at the departments [20]. The achieved completeness of the three included hospitals is considered a reliable estimate for the remaining hospitals in the DADB once they have reached a steady level of registration. This consideration is based on the present strategy aiming to have a uniform registration set-up at all the involved hospitals in the DADB. It is important to note that the measured completeness is a snapshot that may change if the registration set-up changes.

The total completeness at the Department of Orthopaedic Surgery at Zealand University Hospital, Køge was 89% and at Nykøbing Falster Hospital it was 85%. Hvidovre Hospital recorded a total completeness of 67%. At Zealand University Hospital, Køge and Nykøbing Falster Hospital, the majority of the patients followed the same treatment regime where they were seen by a designated physiotherapist, whereas the registration of patients at Hvidovre involved both doctors and physiotherapists. This might explain the lower completeness at Hvidovre Hospital.

The completeness of other Danish clinical databases has been reported to be slightly above 80%. Six years after its implementation, the Danish Knee Ligament Reconstruction Register recorded a high completeness of 86% [9], the Danish Fracture Database reported a total completeness of 83% shortly after its implementation [8] and the Danish Knee Arthroplasty Register presented a completeness of 88% 13 years after implementation [10].

The data from six of the investigated parameters entered at registration revealed a very high validity of 92-100%. The remaining parameter "Activity leading to injury" showed a slightly lower but satisfactory validity of 83%. This parameter contains a distinction between other sports and other activities, yet no clear definition was made of the difference between the two, which may explain the lower validity of the parameter. The data validity of the investigated parameters in the DADB (83-100%) was equal to those of the Danish Knee Ligament Reconstruction Register (85-100%) [9] and the Danish Fracture Database (82-100%) [8].

Data regarding re-rupture showed a satisfactory validity of 80% (4/5) when looking at data registered in the DADB. However, four out of nine patients with re-rupture had missing data in the DADB, resulting in only 44% of patients with re-rupture being registered correctly in the database. When extracting data concerning re-rupture, one should be careful only to include patients with available data regarding re-rupture in the analysis, because registrations will otherwise result in a lower registered re-rupture rate than is actually the case. Databases such as the DADB are useful for monitoring treatment and for generating research hypotheses, which can be addressed by prospective studies in the future.

For logistical reasons, the study was limited by the number of participating departments as completeness and data validity were examined only at three of the 11 reporting hospitals. Another limitation is the unknown completeness and validity of the DS860 code. Some eligible patients with ATR may have been registered with an incorrect ICD10 code and not captured in the DADB. In that case, the calculated completeness will have been overestimated slightly.

CONCLUSIONS

This study documents a satisfactory completeness of data for non-operated patients registered in the DADB and an unsatisfactory completeness of data for operated patients. All investigated parameters were valid. These results suggest that data in the DADB on non-operated patients may contribute to research within the field. Due to a limited sample size for operated patients, any conclusions should be made with caution. The logistics concerning data collection among operated patients warrants optimisation.

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